Therapeutic Goods (Medical Devices) Regulations 2002

Statutory Rules No. 236, 2002

made under the

Therapeutic Goods Act 1989

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About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Medical Devices) Regulations 2002* that shows the text of the law as amended and in force on 1 July 2022 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

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If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

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If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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Part 1—Preliminary

1.1 Name of Regulations

These Regulations are the *Therapeutic Goods (Medical Devices) Regulations 2002*.

1.3 Definitions—the dictionary etc

(1) The dictionary at the end of these Regulations defines certain words and expressions, and includes, for that purpose, references to certain words and expressions that are defined in the Act or elsewhere in these Regulations (***signpost definitions***).

Example: The signpost definition '***medical device***—see section 41BD of the Act' means that the expression ***medical device*** is defined in section 41BD of the *Therapeutic Goods Act 1989*.

Note: The dictionary only includes a signpost definition for a word or expression that is defined elsewhere in these Regulations if the word or expression is used in more than one regulation.

(2) The dictionary is part of these Regulations.

(3) A definition in these Regulations applies to each use of the word or expression in these Regulations, unless the contrary intention appears.

1.4 Medical devices with a measuring function

(1) For these Regulations, a medical device has a ***measuring function*** if the device is intended by the manufacturer to measure:

(a) quantitatively a physiological or anatomical parameter; or

(b) a quantity, or a qualifiable characteristic, of energy or substances delivered to or removed from the human body.

(2) This regulation does not apply to an IVD medical device.

1.5 Refurbishment (Act s 3(1))

(1) A ***refurbishment*** of a medical device is taken to have occurred if the medical device, or a part of the device, is substantially rebuilt from one or more used medical devices of that kind so as to create a medical device that is able to be used for the purpose originally intended by the manufacturer of the original device.

(2) Without limiting subregulation (1), a ***refurbishment*** of a medical device may involve the following actions:

(a) stripping the device into component parts or sub-assemblies;

(b) checking parts of the device for suitability for reuse;

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(c) replacing component parts or sub-assemblies of the device that are not suitable for reuse;

(d) assembling reclaimed or replacement component parts or sub-assemblies of the device or another used device;

(e) testing a reassembled device against the specifications of the original device or, if the manufacturer has revised those specifications, the revised specifications;

(f) identifying an assembled device as a refurbished device.

1.6 Kinds of medical devices—other common characteristics (Act s 41BE(1)(e))

For paragraph 41BE(1)(e) of the Act, in relation to any of the following medical devices, a characteristic is the unique product identifier of the device:

(a) a Class 4 IVD medical device, other than an immunohaematology reagent IVD medical device that is a Class 4 IVD medical device;

(c) a Class III medical device;

(d) an IVD companion diagnostic.

1.7 Device nomenclature system codes (Act s 41BE(3))

(1) In accordance with the Global Medical Device Nomenclature System Code, as set out in ISO 15225:2000(E), the device nomenclature system code specified for a medical device is:

(a) for a Class 4 IVD medical device—the relevant preferred term; and

(b) for a Class 4 IVD medical device that is an immunohaematology reagent IVD medical device—the relevant Level 2 collective term; and

(c) for a Class 3 IVD medical device—the relevant Level 3 collective term, or if no Level 3 collective term exists, the relevant Level 2 collective term; and

(d) for a Class 2 IVD medical device—the relevant Level 2 collective term; and

(e) for a Class 1 IVD medical device or an export only IVD medical device—the relevant Level 1 collective term; and

(f) for a Class III medical device, Class IIb medical device or Class IIa medical device—the relevant preferred term; and

(g) for any of the following—the relevant preferred term:

(i) a Class I medical device that the manufacturer intends to be supplied in a sterile state;

(ii) a Class I medical device that has a measuring function;

(iii) a Class I medical device for which there is no relevant template term; and

(h) for any other Class I medical device—the relevant template term.

(2) In this regulation:

collective term means a term that:

(a) is used for those medical devices that share common features; and

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(b) is identified in the Global Medical Device Nomenclature System Code; and

(c) is included in the document *Collective terms available as device nomenclature system codes for IVD medical devices for the purposes of section 41BE(3) of the Act*, published by the Therapeutic Goods Administration, as updated from time to time.

Examples:

Examples of the use of a collective term include the following:

(a) to illustrate the scope of certificates issued by conformity assessment bodies when assessing which groups, families or types of medical devices are covered within a manufacturer's quality system;

(b) to identify the range of skills and general technological abilities for which a conformity assessment body has been approved and is so appointed by the relevant regulatory authority;

(c) for the exchange of information between regulatory authorities when general information on individual manufacturers' capabilities is notified.

ISO 15225:2000(E) means International Standard ISO 15225:2000(E) (Nomenclature—Specification for a nomenclature system for medical devices for the purposes of regulatory data exchange).

relevant preferred term, for a medical device, means the preferred term for that device under ISO 15225:2000(E).

relevant template term, for a medical device, means the template term for that device under ISO 15225:2000(E).

1.8 Classes of persons that are not manufacturers of a medical device

For the purposes of subsection 41BG(4) of the Act, a class of persons is health professionals, or suitably qualified persons within a healthcare facility, who produce a medical device (the ***final device***) where the following are satisfied:

(a) a medical device production system is used to produce the final device;

(b) the medical device production system is included in the Register as a kind of medical device.

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Part 2—Essential principles

2.1 Essential principles (Act s 41CA)

For section 41CA of the Act, the essential principles for medical devices are set out in Schedule 1.

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Part 3—Conformity assessment procedures

Division 3.1—Medical device classifications

3.1 Medical device classifications (Act s 41DB)

(1) For section 41DB of the Act, the following table specifies the medical device classifications.

Medical device classifications

Item	Column 1 Medical device	Column 2 Class	Column 3 Class	Column 4 Class	Column 5 Class
1	Medical devices other than IVD medical devices	I	IIa	IIb	III
2	IVD medical devices and in-house IVD medical devices	1	2	3	4

(2) In the table:

(a) the lowest level of medical device classification is specified in column 2; and

(b) successively higher levels of classification are specified in columns 3 to 5; and

(d) a device specified in a column has the same level of classification as any other device specified in that column.

3.2 Classification of medical devices

(1) A medical device, other than an IVD medical device, has the medical device classification applying under the classification rules set out in Schedule 2.

(2) An IVD medical device has the medical device classification applying under the classification rules set out in Schedule 2A.

3.3 Principles for applying the classification rules

(1) For the purpose of classifying a medical device, the principles set out in this regulation apply.

(2) A medical device is classified as follows:

(a) if the medical device is a medical device other than an IVD medical device—having regard to the intended purpose of the device;

(b) if the medical device is an IVD medical device or an in-house IVD medical device—having regard to the intended purpose of the device in accordance with the following risk classes:

(i) Class 1 IVD medical device or Class 1 in-house IVD medical device—no public health risk or low personal risk;

(ii) Class 2 IVD medical device or Class 2 in-house IVD medical device—low public health risk or moderate personal risk;

(iii) Class 3 IVD medical device or Class 3 in-house IVD medical device—moderate public health risk or high personal risk;

(iv) Class 4 IVD medical device or Class 4 in-house IVD medical device—high public health risk.

(3) If a medical device is designed to be used in combination with another medical device, each of the devices is classified separately.

(4) An accessory to a medical device is classified separately from the medical device.

(5) If a medical device is driven, or influenced, by an item of software, the software has the same classification as the medical device.

(5A) A medical device production system has the same classification as the medical device the system is intended to produce.

(6) If a medical device is not designed to be used solely or principally in a specific part of a patient's body, the medical device is classified having regard to the most critical specified use of the medical device.

(7) If, based on the intended purpose of the device, 2 or more classification rules apply to the medical device, the device has the highest level of classification applying under the applicable classification rules.

(8) For classification of a medical device system or a medical device procedure pack, medicines are not considered to be integral to the system or the procedure pack.

(9) For a system or procedure pack that contains both the devices mentioned in subregulation (11), that have different levels of classification under the table in regulation 3.1, the classification level of the system or procedure pack is that of the highest class of device mentioned in subregulation (11).

(10) A system or procedure pack that contains both of the devices mentioned in subregulation (11), that have the same level of classification under the table in regulation 3.1, is classified according to its primary intended purpose.

(11) For subregulations (9) and (10), the devices are:

(a) an IVD medical device; and

(b) a medical device that is not an IVD medical device.

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Division 3.2—Conformity assessment procedures

3.4 Conformity assessment procedures (Act s 41DA)

(1) For section 41DA of the Act, the requirements relating to the obligations of manufacturers of medical devices (the ***conformity assessment procedures***) are set out in Schedule 3.

(2) The application of the conformity assessment procedures to a medical device, or a kind of medical device, is set out in this Division.

(3) Subregulation (4) applies to the following devices:
  (a) Class IIb medical devices;
  (b) Class 3 IVD medical devices;
  (c) Class IIa medical devices;
  (d) Class 2 IVD medical devices;
  (e) Class I medical devices;
  (f) Class 1 IVD medical devices.

(4) The manufacturer of a device mentioned in subregulation (3) must apply to the device appropriate conformity assessment procedures, being:
  (a) the minimum conformity assessment procedures that are applicable, under this Division, to the device; or
  (b) if the manufacturer prefers, conformity assessment procedures that are applicable, under this Division, to a medical device that is classified at a higher level than the device concerned.

3.5 Powers and functions of Secretary in relation to conformity assessment

(1) For the purpose of applying conformity assessment procedures to a kind of medical device, a power or function of the Secretary, in relation to an assessment to be conducted under the procedures, may be exercised or performed at the place where the manufacturer is located, and at the manufacturing site, by a body or authority that the Secretary is satisfied has the authority and expertise to exercise that power or perform that function.

(2) If, under the conformity assessment procedures, the manufacturer of the kind of medical device is required to give information of a kind mentioned in paragraph 41MP(2)(a) or (b) of the Act to the Secretary, the information must be given to the Secretary in addition to any such information that is given to the body or authority mentioned in subregulation (1).

3.6 Class III medical devices (other than medical devices used for a special purpose)

(1) Subject to subregulation (2), the conformity assessment procedures that must be applied to a Class III medical device (other than a medical device used for a special purpose) are, as the manufacturer prefers:

(a) the full quality assurance procedures; or
(b) the type examination procedures and:
(i) the verification procedures; or
(ii) the production quality assurance procedures.

(2) If the device is intended by the manufacturer to be supplied in a sterile state, the conformity assessment procedures that must be applied to the device are, as the manufacturer prefers:
(a) the full quality assurance procedures; or
(b) the type examination procedures and the production quality assurance procedures.

3.6A Class 4 IVD medical devices (other than medical devices to be used for a special purpose)

The conformity assessment procedures that must be applied to a Class 4 IVD medical device (other than a medical device to be used for a special purpose) are, as the manufacturer prefers:
(a) the full quality assurance procedures; or
(b) the type examination procedures and the production quality assurance procedures.

3.6B Class 4 in-house IVD medical devices (other than medical devices to be used for a special purpose)

The conformity assessment procedures that must be applied to a Class 4 in-house IVD medical device (other than a medical device to be used for a special purpose) are, as the manufacturer prefers:
(a) the full quality assurance procedures; or
(b) the conformity assessment procedures set out in Part 6B of Schedule 3.

3.7 Class IIb medical devices (other than medical devices used for a special purpose)

(1) Subject to subregulation (2), the minimum conformity assessment procedures that must be applied to a Class IIb medical device (other than a medical device used for a special purpose) are, as the manufacturer prefers:
(a) the full quality assurance procedures (other than clause 1.6); or
(b) the type examination procedures and:
(i) the verification procedures; or
(ii) the production quality assurance procedures; or
(iii) the product quality assurance procedures.

(2) If the device is intended by the manufacturer to be supplied in a sterile state, the minimum conformity assessment procedures that must be applied to the device are, as the manufacturer prefers:
(a) the full quality assurance procedures (other than clause 1.6); or

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(b) the type examination procedures and the production quality assurance procedures.

Note: The manufacturer of a Class IIb medical device (other than a medical device used for a special purpose) may prefer to apply to the device the conformity assessment procedures that must be applied to a medical device that is classified at a higher level—see subregulation 3.4(3).

3.7A Class 3 IVD medical devices (other than devices to be used for a special purpose)

The minimum conformity assessment procedures that must be applied to a Class 3 IVD medical device, other than a device to be used for a special purpose, are, as the manufacturer prefers:

(a) the full quality assurance procedures, other than clause 1.6 of Schedule 3; or

(b) the type examination procedures and the production quality assurance procedures.

Note: The manufacturer of a Class 3 IVD medical device may prefer to apply to the device the conformity assessment procedures that must be applied to an IVD medical device that is classified at a higher level—see subregulation 3.4(3).

3.7B Class 3 in-house IVD medical devices

The conformity assessment procedures that must be applied to a Class 3 in-house IVD medical device are the procedures mentioned in Part 6A of Schedule 3.

3.8 Class IIa medical devices (other than medical devices used for a special purpose)

(1) Subject to subregulation (2), the minimum conformity assessment procedures that must be applied to a Class IIa medical device (other than a medical device used for a special purpose) are, as the manufacturer prefers:

(a) the full quality assurance procedures (other than clause 1.6); or

(b) the declaration of conformity (not requiring assessment by Secretary) procedures and:

(i) the verification procedures (other than clause 3.5); or

(ii) the production quality assurance procedures (other than clause 4.7); or

(iii) the product quality assurance procedures (other than clause 5.7).

(2) If the device is intended by the manufacturer to be supplied in a sterile state, the minimum conformity assessment procedures that must be applied to the device are, as the manufacturer prefers:

(a) the full quality assurance procedures (other than clause 1.6); or

(b) the production quality assurance procedures (other than clause 4.7) and the declaration of conformity (not requiring assessment by Secretary) procedures.

Note: The manufacturer of a Class IIa medical device (other than a medical device used for a special purpose) may prefer to apply to the device the conformity assessment

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procedures that must or may be applied to a medical device that is classified at a higher level—see subregulation 3.4(3).

3.8A Class 2 IVD medical devices (other than devices to be used for a special purpose)

The minimum conformity assessment procedures that must be applied to a Class 2 IVD medical device, other than a device to be used for a special purpose, are, as the manufacturer prefers:

(a) the full quality assurance procedures, other than clause 1.6 of Schedule 3; or

(b) the declaration of conformity (not requiring assessment by Secretary) procedures and the production quality assurance procedures, other than clause 4.7 of Schedule 3.

Note: The manufacturer of a Class 2 IVD medical device may prefer to apply to the device the conformity assessment procedures that must be applied to an IVD medical device that is classified at a higher level—see subregulation 3.4(3).

3.8B Class 2 in-house IVD medical devices

The conformity assessment procedures that must be applied to a Class 2 in-house IVD medical device are the procedures mentioned in Part 6A of Schedule 3.

3.9 Class I medical devices (other than medical devices used for a special purpose)

(1) Subject to subregulations (2) and (3), the minimum conformity assessment procedures that must be applied to a Class I medical device (other than a medical device used for a special purpose) are the declaration of conformity (not requiring assessment by Secretary) procedures.

(2) If the device is intended by the manufacturer to be supplied in a sterile state, and the manufacturer applies the declaration of conformity (not requiring assessment by Secretary) procedures to the device, the production quality assurance procedures (other than clause 4.7) must also be applied to the device.

(3) If the device has a measuring function, and the manufacturer applies the declaration of conformity (not requiring assessment by Secretary) procedures, one of the following sets of procedures, as the manufacturer prefers, must also be applied to the device:

(a) the verification procedures (other than clause 3.5);

(b) the production quality assurance procedures (other than clause 4.7);

(c) the product quality assurance procedures (other than clause 5.7).

Note: The manufacturer of a Class I medical device (other than a medical device used for a special purpose) may prefer to apply to the device the conformity assessment procedures that must be applied to a medical device that is classified at a higher level—see subregulation 3.4(3).

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3.9A Class 1 IVD medical devices (other than devices to be used for a special purpose)

The minimum conformity assessment procedures that must be applied to a Class 1 IVD medical device, other than a device to be used for a special purpose, are the declaration of conformity (not requiring assessment by Secretary) procedures.

Note: The manufacturer of a Class 1 IVD medical device may prefer to apply to the device the conformity assessment procedures that must be applied to an IVD medical device that is classified at a higher level—see subregulation 3.4(3).

3.9B Class 1 in-house IVD medical devices

The conformity assessment procedures that must be applied to a Class 1 in-house IVD medical device are the procedures mentioned in Part 6A of Schedule 3.

3.10 Medical devices used for a special purpose

(1) This regulation applies to the following kinds of medical devices (***medical devices used for a special purpose***):

(a) an exempt device;

(b) a medical device that is the subject of an approval under section 41HB of the Act;

(c) a medical device that is the subject of an authority under section 41HC of the Act;

(d) a system or procedure pack to which subregulation (3) applies.

Note 1: An ***exempt device*** is a medical device of a kind that is exempted from the operation of Division 3 of Part 4-11 of the Act by the regulations (see subsection 3(1) of the Act). Division 7.1 and Schedule 4 to these Regulations deal with exempt devices.

Note 2: For a system or procedure pack to which paragraph (1)(d) applies and that contains an IVD medical device and a medical device that is not an IVD medical device:

(a) the system or procedure pack is classified in accordance with Division 3.1 and either Schedule 2 or Schedule 2A; and

(b) the conformity assessment procedures that must be applied to the system or procedure pack are the procedures for medical devices used for a special purpose in clause 7.5 of Schedule 3.

Note 3: For a system or procedure pack to which paragraph (1)(d) does not apply:

(a) the system or procedure pack is classified in accordance with Division 3.1 and either Schedule 2 or Schedule 2A; and

(b) the conformity assessment procedures that must be applied to the system or procedure pack are the procedures that apply to the relevant classification.

Exception

(1A) However, paragraphs (1)(a), (b) and (c) do not apply to a Class 1 in-house IVD medical device, a Class 2 in-house IVD medical device or a Class 3 in-house IVD medical device.

Note: The conformity assessment procedures that must be applied to Class 1 in-house IVD medical devices, Class 2 in-house IVD medical devices or Class 3 in-house IVD medical devices are the procedures mentioned in Part 6A of Schedule 3.

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(2) The conformity assessment procedures that must be applied to a medical device used for a special purpose are the procedures for medical devices used for a special purpose.

(3) This subregulation applies to a system or procedure pack:

(a) where each medical device included in the system or procedure pack is a medical device to which the relevant conformity assessment procedures have been applied; and

(aa) if one or more medicines, biologicals or other therapeutic goods are included in the system or procedure pack:

(i) if all of those medicines and biologicals are entered on the Register; and

(ii) if all of those other therapeutic goods are entered on the Register, or are covered by subregulation 12(1) of the *Therapeutic Goods Regulations 1990* to the extent that they are tampons, menstrual cups or disinfectants; and

(iii) if there has been no modification of the packaging of any of those medicines, biologicals or other therapeutic goods; and

(iv) if there has been no modification of any of those medicines, biologicals or other therapeutic goods; and

(b) that has been put together in accordance with the intended purpose of each medical device and the approved indications of each medicine, biological and other therapeutic goods; and

(c) the contents of which are compatible, having regard to the intended purpose of each medical device, the approved indications of each medicine, biological or other therapeutic goods, and the intended purpose of the system or procedure pack.

(4) If a system or procedure pack is intended by the manufacturer to be supplied in a sterile state:

(a) the full quality assurance procedures (other than clause 1.6); or

(b) the production quality assurance procedures (other than clause 4.7);

must also be applied to the system or procedure pack in relation to the aspects of the manufacturing process that relate to ensuring that the system or procedure pack is supplied and maintained in a sterile state.

Note: If a medicine is included in the system or procedure pack, the manufacturer of the system or procedure pack must ensure that the method to be used for sterilisation or resterilisation is appropriate or is in accordance with the approved indications of the medicine.

3.11 Medical devices to which the clinical evaluation procedures must be applied

(1) Subject to subregulation (2), in addition to the conformity assessment procedures that are applied to a medical device in accordance with another regulation in this Division, the clinical evaluation procedures must also be applied to the device, for the purpose of demonstrating that the device complies with the applicable provisions of the essential principles, in particular:

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(a) clause 1 of Schedule 1 (identification of the benefits and risks associated with the use of the device); and
(b) clause 3 of Schedule 1 (use of the device for its intended purpose); and
(c) clause 6 of Schedule 1 (acceptability of any side effects associated with the use of the device).

(2) This regulation does not apply to any of the following:
(a) an exempt device (other than an exempt device of a kind described in item 1.3 of Schedule 4);
(b) a medical device that is the subject of an approval under section 41HB of the Act;
(c) a medical device that is the subject of an authority under section 41HC of the Act.

(3) Despite subregulation (2), this regulation applies to a custom-made medical device.

3.12 Records to be provided in English

All records (including correspondence) provided by the manufacturer of a medical device in relation to the application of the conformity assessment procedures to the device must be in English.

3.13 Assessment or verification at intermediate stage of manufacture

(1) At the request of a person, and on payment of the prescribed fee, the Secretary may arrange for assessment or verification procedures to be carried out in relation to the application of the conformity assessment procedures to an article that is intended to be used in the manufacture of a medical device.

(2) A request may be made:
(a) at any stage of the manufacturing process; and
(b) whether or not an application has been made in relation to the article:
(i) for a conformity assessment certificate in respect of a medical device; or
(ii) for inclusion of a kind of medical device in the Register.

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Part 4—Conformity assessment certificates

Division 4.1—Issuing conformity assessment certificates

4.2 Considering applications for conformity assessment certificates (Act s 41EC)

For subsection 41EC(2) of the Act, the following other requirements of the conformity assessment procedures are specified:

(a) the applicable requirements in relation to the establishment and maintenance of a post-market monitoring, reporting and corrective action system;

(b) the applicable requirements in relation to the keeping of records.

4.3 Time for making decision on applications (Act s 41ED, s 63(2)(dc))

(1) This regulation applies to an application for the issue of a conformity assessment certificate in respect of a kind of medical device if, in considering the application, the Secretary is required to examine the design of the device.

(2) The Secretary must make a decision on the application within 255 working days after the application is received at an office of the Department specified by the Secretary.

(3) For subregulation (2), a working day that occurs in any of the following periods is to be disregarded:

(a) if the Secretary sends a query, or a request for information, to the applicant or sponsor—the period beginning on the day when the query or request is sent and ending at the end of the day when the Secretary receives from the applicant or sponsor a response that enables the Secretary to proceed with the assessment;

(b) if an appeal is lodged in relation to the application—the period beginning on the day when the appeal is lodged and ending at the end of the day when the appeal is finally determined;

(c) any other period in relation to which the applicant or sponsor agrees in writing for the purposes of this subregulation.

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Division 4.1A—Conformity assessment (priority applicant) determinations

4.3A Application of Division

For the purposes of subsection 41ECA(1) of the Act, this Subdivision makes provision for and in relation to the making of conformity assessment (priority applicant) determinations.

4.3B Application for conformity assessment (priority applicant) determination

(1) A person may apply to the Secretary for a conformity assessment (priority applicant) determination in relation to a medical device.

(2) An application under subregulation (1) must:
  (a) be in writing; and
  (b) be in a form approved, in writing, by the Secretary; and
  (c) have with it written information in such detail as is reasonably necessary to allow the application to be properly considered.

(3) An application under subregulation (1) is taken not to have been made unless:
  (a) the application meets the requirements in subregulation (2); and
  (b) the fee prescribed in item 1.1A of Part 1 of Schedule 5 for making the application has been paid.

4.3C Making of conformity assessment (priority applicant) determination

(1) On receiving an application under subregulation 4.3B(1) for a conformity assessment (priority applicant) determination in relation to a medical device, the Secretary must:
  (a) consider the application; and
  (b) decide either:
    (i) to make the determination; or
    (ii) to refuse to make the determination.

Criteria

(2) The Secretary may make the determination if the Secretary is satisfied, having regard to any matter that the Secretary considers relevant, that all of the following criteria are satisfied in relation to the medical device (the ***new device***):
  (a) the intended purpose of the new device is the monitoring, treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;
  (b) either:
    (i) no medical devices with that intended purpose are of a kind included in the Register; or

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(ii) if one or more medical devices with that intended purpose are of a kind included in the Register (the ***existing devices***)—there is substantial evidence demonstrating that the safety or performance of the new device when used for that intended purpose provides a significant improvement compared to the existing devices;

(c) at least one of the following applies to the new device:

(i) the new device is a breakthrough technology and there is evidence that it offers a major clinical advantage over existing technology;

(ii) there is evidence that the new device offers a major clinical advantage over existing alternatives included in the Register;

(iii) the new device is an IVD medical device and its early availability in Australia will result in a major public health benefit.

Information to be specified in determination

(3) The determination must specify:

(a) the person who, as a result of section 41ECA of the Act, is the priority applicant; and

(b) the medical device to which the determination relates; and

(c) the intended purpose of the medical device.

Notification of decision

(4) As soon as practicable after making the decision, the Secretary must notify the applicant, in writing, of the decision.

(5) If the Secretary decides to refuse to make the determination, the notification must include the reasons for the decision.

4.3D Period during which conformity assessment (priority applicant) determination is in force

(1) A conformity assessment (priority applicant) determination in relation to a medical device:

(a) comes into force on the day on which the Secretary notifies the priority applicant in accordance with subregulation 4.3C(4); and

(b) subject to subregulation (2) and regulation 4.3E, remains in force for 6 months.

(2) If the priority applicant specified in the determination makes an effective application under section 41EB of the Act for a conformity assessment certificate that covers the medical device before the end of the 6 month period beginning when the determination comes into force, the determination remains in force until:

(a) the priority applicant withdraws the application; or

(b) the application lapses in accordance with section 41EG of the Act; or

(c) the application is finally determined.

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Note: See subsection 41EB(2) of the Act for when an application under section 41EB of the Act is effective.

4.3E Revocation of conformity assessment (priority applicant) determination

(1) The Secretary may revoke a conformity assessment (priority applicant) determination in relation to a medical device if:

(a) either:

(i) the priority applicant specified in the determination has not made an application under section 41EB of the Act for a conformity assessment certificate that covers the medical device; or

(ii) the priority applicant has made such an application, but the application is not effective; and

(b) the Secretary is satisfied that the criteria specified in subregulation 4.3C(2) are no longer satisfied in relation to the medical device.

Note: See subsection 41EB(2) of the Act for when an application under section 41EB of the Act is effective.

(2) The revocation must be by written notice given by the Secretary to the priority applicant.

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Division 4.1B—Content of conformity assessment certificates

4.3F Content of conformity assessment certificates

For the purposes of subsection 41EE(3) of the Act, the information is all of the following:

(a) a unique identification number for the certificate;

(b) the day on which the certificate is issued;

(c) the name and address of the manufacturer of the medical devices;

(d) the conformity assessment procedures applied to the medical devices by the manufacturer;

(e) if the certificate covers a medical device to which paragraph 1.6(a), (b), (c) or (d) applies—the unique product identifier of the device;

(f) the conditions to which the certificate is subject under section 41EJ or 41EK of the Act;

(g) if one or more conformity assessment certificates have previously been issued in respect of the medical devices—the day on which each of those certificates was issued;

(h) the signature and name of the person issuing the certificate.

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Division 4.1C—Conditions

4.3G Conditions applying automatically—information about poisons

(1) This regulation applies to a conformity assessment certificate that covers a kind of medical device that contains a substance of a kind covered by an entry in a Schedule to the current Poisons Standard.

(2) However, this regulation does not apply to the certificate if, under Appendix A to the current Poisons Standard, the Standard does not apply to poisons in that kind of device.

(3) For the purposes of subsection 41EJ(5A) of the Act, the certificate is subject to the condition that the manufacturer in respect of whom the certificate is issued will not supply a medical device of that kind if the supply would contravene Part 2 of the current Poisons Standard.

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Division 4.2—Suspension of conformity assessment certificates

4.4 Period for revocation of suspension (Act s 41EP, s 63(2)(db))

(1) This regulation applies to an application to the Secretary under paragraph 41EP(2)(a) of the Act to revoke the suspension of a conformity assessment certificate.

(2) The Secretary must make a decision on the application within 40 working days after the application is received at an office of the Department specified by the Secretary.

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Division 4.3—Transfer of conformity assessment certificates

4.5 Application of Division 4.3

This Division applies in relation to a manufacturer of a medical device in respect of whom a conformity assessment certificate is issued.

4.6 Death, bankruptcy or winding up of manufacturer

(1) If the manufacturer dies, the manufacturer's legal personal representative:
  (a) is taken to be the person in respect of whom the conformity assessment certificate is issued; and
  (b) must notify the Secretary, in writing, of the death not later than 3 months after it occurred.

(2) If the manufacturer becomes bankrupt, the trustee in bankruptcy of the manufacturer's estate:
  (a) is taken to be the person in respect of whom the conformity assessment certificate is issued; and
  (b) must notify the Secretary, in writing, of the manufacturer's bankruptcy not later than 3 months after it occurred.

(3) If the manufacturer is a body corporate that is wound up, the liquidator of the body corporate:
  (a) is taken to be the person in respect of whom the conformity assessment certificate is issued; and
  (b) must notify the Secretary, in writing, of the winding up of the body corporate not later than 3 months after it occurred.

Note: See also regulations 4.10 and 4.11.

4.7 Disposal of business or amalgamation with another manufacturer

(1) This regulation applies if the name of the manufacturer is changed in any of the following circumstances:
  (a) the manufacturer agrees to dispose of a business concerned with the manufacture of the medical device, and it is agreed that the disposal is to include a transfer of the conformity assessment certificate issued in respect of the manufacturer and the medical device;
  (b) in the case of a manufacturer that is a body corporate—the manufacturer amalgamates with another body corporate under a name that is different from the name of the manufacturer on the conformity assessment certificate.

(2) The person to whom the business is disposed of, or the body corporate with whom the manufacturer amalgamates:
  (a) is taken to be the person in respect of whom the conformity assessment certificate is issued; and

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(b) must, not later than 3 months after the disposal or amalgamation, apply to the Secretary, in writing, for the name of the manufacturer to be changed on the conformity assessment certificate.

4.8 Change of name of manufacturer

If the name of the manufacturer is changed:

(a) the manufacturer, as renamed, is taken to be the person in respect of whom the conformity assessment certificate is issued; and

(b) the manufacturer must, not later than 3 months after the name is changed, notify the Secretary, in writing, of the new name and the circumstances in which the change occurred.

Note: See also regulations 4.10 and 4.11.

4.9 Effect of conformity assessment certificate after transfer, etc

If a conformity assessment certificate is taken to be issued in respect of a person because of the operation of regulation 4.6, 4.7 or 4.8:

(a) the certificate has effect as if it had actually been issued in respect of that person; and

(b) the medical devices to which the certificate relates may continue to be manufactured while the certificate is in effect.

4.10 Notification to Secretary of events

(1) If a person is required to notify the Secretary of an event under this Division, the person must send to the Secretary sufficient documentary evidence to establish the matter asserted in the notification.

(2) If, at any time, the Secretary becomes aware that he or she has not been notified of an event as required by this Division, the Secretary may suspend or revoke the conformity assessment certificate to which the event relates.

4.11 Notification of change of name or suspension or revocation of conformity assessment certificate

(1) If, under this Division, the Secretary:

(a) changes the name of a manufacturer on a conformity assessment certificate; or

(b) suspends or revokes a conformity assessment certificate issued in respect of a manufacturer;

the Secretary must, as soon as practicable after changing the name or suspending or revoking the conformity assessment certificate:

(c) notify the manufacturer that the name has been changed or the conformity assessment certificate has been suspended or revoked; and

(d) ask the manufacturer to return to the Secretary the conformity assessment certificate that was given before the change of name or suspension or revocation.

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(2) If a manufacturer receives a notice under subregulation (1), the manufacturer must return to the Secretary, as soon as practicable after receiving the notice, the conformity assessment certificate that was given before the change of name or suspension or revocation.

Penalty: 5 penalty units.

(3) An offence against subregulation (2) is an offence of strict liability.

Note: For ***strict liability***, see section 6.1 of the *Criminal Code*.

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Part 4A—Australian conformity assessment bodies

Division 4A.1—Preliminary

4A.1 Purposes of this Part

(1) This Part (other than Division 4A.7) is made for the purposes of section 41EWA of the Act (about Australian conformity assessment bodies).

(2) Division 4A.7 is made for the purposes of section 41EWB of the Act (about the content of Australian conformity assessment body certificates).

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Division 4A.2—Making conformity assessment body determinations

4A.2 Applications

(1) An Australian corporation may apply to the Secretary for a conformity assessment body determination in respect of the corporation.

(2) The application must:
  (a) be made:
    (i) in writing; and
    (ii) in a form (if any) approved under subregulation (4); and
    (iii) in a manner (if any) approved under subregulation (4); and
  (b) be delivered to an office of the Department specified under subregulation (6).

(3) The application is not effective if:
  (a) the application does not meet the requirements of subregulation (2) and regulation 4A.4; or
  (b) the application contains information that is false or misleading in a material particular; or
  (c) the application fee for the application has not been paid.

Note 1: For the application fee, see regulation 9.1 and Part 1 of Schedule 5.

Note 2: A conformity assessment body determination assessment fee is payable under Division 9.2 for assessment of the application.

Forms and manners

(4) For the purposes of subparagraph (2)(a)(ii) or (iii), the Secretary may, in writing, approve a form or manner for making an application for a conformity assessment body determination.

(5) The Secretary may approve different forms and manners for different classes of conformity assessment body determinations.

Offices

(6) For the purposes of paragraph (2)(b), the Secretary may, in writing, specify an office of the Department to which applications for conformity assessment bodies must be delivered.

(7) The Secretary may specify different offices for different classes of conformity assessment body determinations.

4A.3 Further information

(1) For the purposes of assessing an application for a conformity assessment body determination, the Secretary may, by written notice given to the applicant, require the applicant to deliver specified information or documents:

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(a) to the office of the Department to which the application was delivered; and
(b) within the period, of not less than 10 working days after the day the notice is given, specified in the notice; and
(c) in a manner (if any) specified in the notice; and
(d) in accordance with regulation 4A.4.

(2) For the purposes of assessing an application for a conformity assessment body determination, the Secretary may:
(a) by written notice given to the applicant, require the applicant to allow an authorised person, at any reasonable time specified in the notice, to inspect specified premises (including premises outside Australia) that are or will be used by the applicant to carry on certification-related activities; or
(b) by written notice given to a contractor of the applicant, require the contractor to allow an authorised person, at any reasonable time specified in the notice, to inspect specified premises (including premises outside Australia) that are or will be used by the contractor to carry on certification-related activities for the applicant.

Note: For ***authorised person***, see subsection 3(1) of the Act.

(3) If the Secretary gives a notice to a contractor under paragraph (2)(b), the Secretary must give a copy of the notice to the applicant.

4A.4 Documents to be provided in English

All documents (including correspondence) provided by an applicant in relation to an application for a conformity assessment body determination:
(a) must be provided in English; and
(b) may also be provided in any other language.

4A.5 Lapsing of applications

An application for a conformity assessment body determination lapses if:
(a) the applicant, or a contractor of the applicant, fails to comply with a notice under subregulation 4A.3(1) or (2) in relation to the application; or
(b) information given to the Secretary by, or on behalf of, the applicant in connection with the application, including information given for the purposes of a notice under subregulation 4A.3(1), is false or misleading in a material particular; or
(c) for the whole or a part of the conformity assessment body determination assessment fee for the application that is due and payable as mentioned in Division 9.2—the applicant fails to pay that whole or part in accordance with that Division.

4A.6 Assessing applications

(1) If an application is made in accordance with regulation 4A.2 for a conformity assessment body determination in respect of an Australian corporation, the

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Secretary must decide whether to make the conformity assessment body determination.

Conditions and criteria for making determinations

(2) The Secretary must not decide to make the determination unless he or she is satisfied that it is likely that the Australian corporation will be able to comply with the requirements of Schedule 3AA.

(3) In deciding whether to make the conformity assessment body determination, the Secretary must also consider:

(a) whether at least one of the following persons:

(i) the Australian corporation;

(ii) a person (a ***manager***) who makes, or participates in making, decisions that affect the whole, or a substantial part, of the Australian corporation's affairs;

(iii) a major interest holder of the Australian corporation;

has, within the 10 years immediately before the application:

(iv) been convicted of an offence against the Act or a corresponding State law; or

(v) been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(vi) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of the Act or a corresponding State law; or

(vii) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(viii) breached a condition of a conformity assessment body determination; or

(ix) had a conformity assessment body determination in respect of the person suspended or revoked; or

(x) been a manager, or a major interest holder, of a body corporate in respect of which subparagraph (iv), (v), (vi), (vii), (viii) or (ix) applies in that 10 years, if the conduct resulting in that subparagraph applying occurred when the person was a manager or major interest holder of the body corporate; and

(b) any other relevant matter.

(4) A reference in paragraph (3)(a) to a person convicted of an offence includes a reference to a person in respect of whom an order has been made relating to the offence under:

(a) section 19B of the *Crimes Act 1914*; or

(b) a corresponding provision of a law of a State or Territory.

Note: Section 19B of the *Crimes Act 1914* empowers a court that has found a person to have committed an offence to take action without proceeding to record a conviction.

(5) Nothing in this regulation affects the operation of Part VIIC of the *Crimes Act 1914* (which includes provisions that, in certain circumstances, relieve persons

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from the requirement to disclose spent convictions and require persons aware of such convictions to disregard them).

(6) Subregulation (2) and paragraph (3)(a) do not limit paragraph (3)(b).

4A.7 Procedure following decisions to make determinations

(1) This regulation applies if the Secretary decides under subregulation 4A.6(1) to make a conformity assessment body determination in respect of an Australian corporation.

(2) The Secretary must notify the Australian corporation within 20 working days.

(3) When all conformity assessment body determination assessment fees that are due and payable for the application have been paid, the Secretary must:
  (a) make the determination, including specifying:
    (i) the scope of the determination in accordance with subregulation (4); and
    (ii) the commencement and duration of the determination in accordance with regulation 4A.8; and
  (b) give it to the corporation.

(4) The conformity assessment body determination must specify whether it:
  (a) is of general application; or
  (b) is limited to either or both of the following:
    (i) one or more specified medical devices;
    (ii) one or more specified conformity assessment procedures.

(5) The conformity assessment body determination may specify conditions to which it is subject.

Note: See regulation 4A.19.

4A.8 Duration of determinations

(1) A conformity assessment body determination commences on the day specified for the purpose in the determination under subparagraph 4A.7(3)(a)(ii).

(2) A conformity assessment body determination has effect at all times:
  (a) unless the determination is suspended under Division 4A.4; or
  (b) until the end of the period specified in the determination under subparagraph 4A.7(3)(a)(ii); or
  (c) until the determination is revoked under Division 4A.5.

(3) The period specified in the determination as mentioned in paragraph (2)(b) must be 5 years or less, starting on the day the determination commences.

4A.9 Procedure following decisions not to make determinations

(1) This regulation applies if the Secretary decides under subregulation 4A.6(1) not to make a conformity assessment body determination in respect of an Australian corporation.

(2) The Secretary must notify the Australian corporation within 20 working days.

(3) The notice must state the reasons for the decision.

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Division 4A.3—Conditions on conformity assessment body determinations

Subdivision A—Automatic conditions on determinations

4A.10 Automatic conditions on determinations

A conformity assessment body determination is subject to the conditions set out in this Subdivision.

Note: See sections 41MN and 41MNA of the Act for offences and civil penalty provisions that apply to breaching a condition of a conformity assessment body determination.

4A.11 Conditions—requirements of Schedule 3AA

The Australian conformity assessment body will comply with the requirements of Schedule 3AA.

4A.12 Conditions—notifying Secretary and clients

(1) The Australian conformity assessment body will notify the Secretary within 10 working days if there are any substantial changes relating to the body's compliance with the requirements of Schedule 3AA.

(2) The Australian conformity assessment body will notify the Secretary and relevant clients of the body as soon as practicable if the body plans to cease carrying on one or more kinds of certification-related activities relating to conformity assessment procedures covered by the determination.

(3) The notice under subregulation (2) must specify the day on which the body plans to cease carrying on the activity.

4A.13 Conditions—entry and inspection

(1) The Australian conformity assessment body will allow an authorised person:
  (a) to enter, at any reasonable time, premises used by the body to carry on certification-related activities; and
  (b) while on those premises, to inspect those premises and anything on those premises that concerns certification-related activities carried on by the body; and
  (c) while on those premises, to make any still or moving image or any recording of those premises or anything on those premises that concerns certification-related activities carried on by the body; and
  (d) while on those premises, to inspect, and make copies of, any documents that concern certification-related activities carried on by the body.

(2) The Australian conformity assessment body will have procedures, including a written agreement, in place with each contractor of the body that carries on

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certification-related activities for the body that require the contractor to allow an authorised person:

(a) to enter, at any reasonable time, premises used by the contractor to carry on those certification-related activities; and

(b) while on those premises, to inspect those premises and anything on those premises that concerns those certification-related activities; and

(c) while on those premises, to make any still or moving image or any recording of those premises or anything on those premises that concerns those certification-related activities; and

(d) while on those premises, to inspect, and make copies of, any documents that concern those certification-related activities.

4A.14 Conditions—producing information and documents

(1) The Australian conformity assessment body will, if requested to do so by the Secretary, give the Secretary information, or produce to the Secretary documents, that concern certification-related activities carried on by the body.

(2) The information will be given, or the documents produced, within the period, of not less than 20 working days after the day the notice is given, specified in the notice.

(3) The Australian conformity assessment body will have procedures, including a written agreement, in place with each of:

(a) its clients; and

(b) the contractors of the body that carry on certification-related activities for the body;

that require the client or contractor to make available information or documents that the client or contractor has that is requested under subregulation (1).

4A.15 Conditions—reviews

The Australian conformity assessment body will cooperate in any review by the Secretary of:

(a) certification-related activities carried on by the body; or

(b) compliance with the conditions of the conformity assessment body determination.

4A.16 Conditions—record keeping

The Australian conformity assessment body will keep:

(a) the records required by Schedule 3AA; and

(b) any other records necessary to demonstrate the body's compliance, at all times while the determination is in effect, with the requirements of that Schedule.

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4A.17 Conditions—Australian conformity assessment body certificates

Conformity assessment procedures

(1) The Australian conformity assessment body will not issue an Australian conformity assessment body certificate unless the body is satisfied that an appropriate conformity assessment procedure has been applied to medical devices of the kind covered by the certificate.

Varying, suspending and revoking certificates

(2) If the Australian conformity assessment body:
  (a) issues an Australian conformity assessment body certificate to a manufacturer; and
  (b) ceases to be satisfied that an appropriate conformity assessment procedure has been applied to medical devices of the kind covered by the certificate;

the body will:
  (c) vary, suspend or revoke the certificate; or
  (d) give to the manufacturer a written notice stating that the body will vary, suspend or revoke the certificate if the manufacturer does not, within a specified period, take the action necessary to satisfy the body that an appropriate conformity assessment procedure has been applied to the devices.

(3) A period specified in a notice under paragraph (2)(d) must be appropriate.

(4) The Australian conformity assessment body will vary, suspend or revoke an Australian conformity assessment body certificate if:
  (a) the body gave a notice to a manufacturer under paragraph (2)(d) in relation to the certificate; and
  (b) at the end of the period specified in the notice, the body is not satisfied that an appropriate conformity assessment procedure has been applied to medical devices of the kind covered by the certificate.

Notifying Secretary of changes to certificates and other matters

(5) The Australian conformity assessment body will notify the Secretary within 10 working days if the body:
  (a) decides not to issue an Australian conformity assessment body certificate because the body is not satisfied as mentioned in subregulation (1); or
  (b) suspends or revokes an Australian conformity assessment body certificate; or
  (c) varies an Australian conformity assessment body certificate in the circumstances mentioned in subregulation (2) or (4); or
  (d) becomes aware of a matter of significant concern relating to the safety of a medical device to which an Australian conformity assessment body certificate issued by the body applies.

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4A.18 Conditions—clients

Notifying clients if determination varied or suspended

(1) The Australian conformity assessment body will notify its clients within 10 working days if the conformity assessment body determination is varied or suspended.

Agreements with successor Australian conformity assessment bodies

(2) If a client of the Australian conformity assessment body (the ***old body***) informs the old body that the client plans:

(a) to cease to be a client of the old body; and

(b) to become a client of another Australian conformity assessment body (the ***new body***);

the old body will enter into an agreement with the new body that deals appropriately with the transfer from the old body to the new body of responsibility for carrying on certification-related activities for the client.

Enquiries before accepting applications for certification

(3) Before the Australian conformity assessment body accepts an application from a manufacturer to issue an Australian conformity assessment body certificate in relation to a kind of medical device, the body will make reasonable enquiries as to whether the manufacturer has applied to another Australian conformity assessment body to issue an Australian conformity assessment body certificate in relation to that kind of device.

Subdivision B—Conditions specified in conformity assessment body determinations

4A.19 Conditions specified in determinations

(1) A conformity assessment body determination is subject to any conditions specified in the determination under subregulation 4A.7(5) or 4A.28(1).

Note: See sections 41MN and 41MNA of the Act for offences and civil penalty provisions that apply to breaching a condition of a conformity assessment body determination.

(2) A condition imposed under subregulation 4A.7(5) or 4A.28(1) is in addition to the conditions imposed under Subdivision A of this Division.

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Division 4A.4—Suspension of conformity assessment body determinations

4A.20 Suspension of determinations

(1) The Secretary may, by written notice given to an Australian conformity assessment body, suspend the body's conformity assessment body determination if the Secretary is satisfied that:

(a) it is likely that there are grounds for revoking the determination under regulation 4A.27; and

(b) it is likely that the body will, within the period of the suspension, be able to take action such that it will no longer be likely that there are grounds for revoking the determination.

(2) The notice must specify the period of the suspension. The period:

(a) must not exceed 12 months; and

(b) must not begin before the notice is given to the body.

Note: The period of the suspension may be extended once under regulation 4A.22.

4A.21 Notice of proposed suspension

(1) However, before suspending a conformity assessment body determination, the Secretary must:

(a) notify the Australian conformity assessment body in writing that the Secretary proposes the suspension and set out the reasons for it; and

(b) give the body a reasonable opportunity to make submissions to the Secretary in relation to the proposed suspension.

(2) The Secretary must not make a decision relating to the proposed suspension until the Secretary has had regard to any submissions the body makes under paragraph (1)(b).

4A.22 Duration of suspension

(1) The suspension takes effect on the day specified for the purpose in the notice, which must be at least 20 working days after the notice is given to the Australian conformity assessment body.

(2) The suspension has effect until:

(a) the Secretary revokes it under regulation 4A.23; or

(b) the end of:

(i) the period specified in the notice under subregulation 4A.20(2); or

(ii) if the period is extended under subregulation (3) of this regulation—the period as so extended.

Note 1: The conditions to which the determination is subject continue during the suspension: see subsection 41EWA(7A) of the Act.

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Note 2: Unless a suspension of a conformity assessment body determination has been revoked, the determination is automatically revoked at the end of the period of the suspension: see regulation 4A.25.

(3) The Secretary may, by written notice given to the body, extend the period specified in the notice under subregulation 4A.20(2) by a further specified period not exceeding 12 months if the Australian conformity assessment body shows that it has taken steps to address the grounds for revoking the determination under regulation 4A.27.

(4) Only one extension of the period of the suspension may be made.

4A.23 Revocation of suspension

(1) The Secretary must revoke the suspension if the Secretary is satisfied that:
  (a) the grounds on which the conformity assessment body determination was suspended no longer apply; and
  (b) there are no other grounds for suspending the determination.

(2) The Secretary's power to revoke the suspension may be exercised:
  (a) if the Australian conformity assessment body applies in writing to the Secretary; or
  (b) on the Secretary's own initiative.

(3) After revoking the suspension, the Secretary must, within 20 working days after the revocation, give written notice of the revocation to the Australian conformity assessment body.

(4) If the Secretary decides, after an application is made under paragraph (2)(a), not to revoke the suspension, the Secretary must:
  (a) notify the applicant in writing of his or her decision within 20 working days after the decision is made; and
  (b) state in the notice the reasons for the decision.

4A.24 Powers of revocation of determinations unaffected

(1) This Division does not affect the Secretary's powers to revoke a conformity assessment body determination under Division 4A.5.

(2) To the extent that a suspension under this Division relates to a conformity assessment body determination to which such a revocation relates, the suspension ceases to have effect.

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Division 4A.5—Revocation of conformity assessment body determinations

4A.25 Automatic revocation of determinations

(1) The Secretary must, by written notice given to an Australian conformity assessment body, revoke the body's conformity assessment body determination if:

(a) the determination has been suspended under Division 4A.4; and

(b) the period of the suspension under paragraph 4A.22(2)(b) ends before the suspension is revoked under regulation 4A.23.

(2) The revocation takes effect at the end of the period mentioned in paragraph (1)(b) of this regulation.

4A.26 Immediate revocation of determinations

(1) The Secretary may, by written notice given to an Australian conformity assessment body, revoke the body's conformity assessment body determination if:

(a) the body applies in writing to the Secretary; or

(b) the body notifies the Secretary, as mentioned in subregulation 4A.12(2), that the body plans to cease carrying on certification-related activities completely.

(2) The revocation takes effect on the day specified for the purpose in the notice given by the Secretary.

(3) If paragraph (1)(b) applies, the day specified in the notice given by the Secretary must be the day the Australian conformity assessment body notified the Secretary was the day the body planned to cease carrying on certification-related activities.

4A.27 Revocation of determinations after notice of proposed revocation

(1) The Secretary may, by written notice given to an Australian conformity assessment body, revoke the body's conformity assessment body determination if:

(a) the body refuses or fails to comply with a condition to which the determination is subject; or

(b) at least one of the following persons:

(i) the body;

(ii) a person (a ***manager)*** who makes, or participates in making, decisions that affect the whole, or a substantial part, of the body's affairs;

(iii) a major interest holder of the body;

has:

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(iv) been convicted of an offence against the Act or a corresponding State law; or

(v) been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(vi) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of the Act or a corresponding State law; or

(vii) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(viii) breached a condition of a conformity assessment body determination; or

(ix) had a conformity assessment body determination in respect of the person suspended or revoked; or

(x) been a manager, or a major interest holder, of a body corporate in respect of which subparagraph (iv), (v), (vi), (vii), (viii) or (ix) applies, if the conduct resulting in that subparagraph applying occurred when the person was a manager or major interest holder of the body corporate.

(2) A reference in paragraph (1)(b) to a person convicted of an offence includes a reference to a person in respect of whom an order has been made relating to the offence under:

(a) section 19B of the *Crimes Act 1914*; or

(b) a corresponding provision of a law of a State or Territory.

Note: Section 19B of the *Crimes Act 1914* empowers a court that has found a person to have committed an offence to take action without proceeding to record a conviction.

(3) Nothing in this regulation affects the operation of Part VIIC of the *Crimes Act 1914* (which includes provisions that, in certain circumstances, relieve persons from the requirement to disclose spent convictions and require persons aware of such convictions to disregard them).

Notice of proposed revocation

(4) Before revoking a conformity assessment body determination under this regulation, the Secretary must:

(a) notify the Australian conformity assessment body in writing that the Secretary proposes the revocation and set out the reasons for it; and

(b) give the body a reasonable opportunity to make submissions to the Secretary in relation to the proposed revocation.

(5) The Secretary must not make a decision relating to the proposed revocation until the Secretary has had regard to any submissions the body makes under paragraph (4)(b).

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When revocation takes effect

(6) A revocation under this regulation takes effect on the day specified for the purpose in the notice given to the Australian conformity assessment body under subregulation (1).

(7) The day specified must not be earlier than the day the notice is given to the body.

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Division 4A.6—Variation of conformity assessment body determinations

4A.28 Imposing, varying or removing conditions

(1) The Secretary may, by written notice given to an Australian conformity assessment body, vary the body's conformity assessment body determination to:
  (a) impose new conditions on the determination; or
  (b) vary or remove existing conditions imposed on the determination under subregulation 4A.7(5) or this regulation.

(2) The Secretary's power under subregulation (1) may be exercised:
  (a) if the Australian conformity assessment body applies in writing to the Secretary; or
  (b) on the Secretary's own initiative.

When imposition, variation or removal takes effect

(3) An imposition or variation of a condition under this regulation takes effect on the day specified for the purpose in the notice.

(4) The day specified in the notice under subregulation (3) must be at least 20 working days after the notice is given to the body, unless the body:
  (a) applied for the imposition or variation; and
  (b) has agreed to an earlier day.

(5) A removal of a condition under this regulation takes effect on the day specified in the notice.

(6) The day specified in the notice under subregulation (5) must be at least 20 working days after the notice is given to the body, unless the body has agreed to an earlier day.

(7) For the purposes of subregulations (4) and (6), the earlier day must not be earlier than the day the notice is given to the body.

4A.29 Limiting determinations

(1) The Secretary may, by written notice given to an Australian conformity assessment body, vary the body's conformity assessment body determination to limit, or further limit, the determination as mentioned in paragraph 4A.7(4)(b).

(2) The Secretary's power under subregulation (1) of this regulation may be exercised:
  (a) if the Australian conformity assessment body applies in writing to the Secretary; or
  (b) on the Secretary's own initiative.

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(3) A variation under this regulation takes effect on the day specified for the purpose in the notice.

(4) The day specified in the notice under subregulation (3) must be at least 20 working days after the notice is given to the body, unless the body:
  (a) applied for the variation; and
  (b) has agreed to an earlier day.

(5) For the purposes of subregulation (4), the earlier day must not be earlier than the day the notice is given to the body.

4A.30 Notice of proposed variation

(1) Before varying a conformity assessment body determination under this Division, the Secretary must:
  (a) notify the Australian conformity assessment body in writing that the Secretary proposes the variation and set out the reasons for it; and
  (b) give the body a reasonable opportunity to make submissions to the Secretary in relation to the proposed variation.

(2) The Secretary must not make a decision relating to the proposed variation until the Secretary has had regard to any submissions the body makes under paragraph (1)(b).

(3) This regulation does not apply if the body applied for the variation.

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Division 4A.7—Australian conformity assessment body certificates

4A.31 Content of Australian conformity assessment body certificates

For the purposes of subsection 41EWB(2) of the Act, the information is all of the following:

(a) the name and address of the body issuing the certificate;

(b) the body's ACN (within the meaning of the *Corporations Act 2001*);

(c) the unique identification number assigned to the body under subsection 41EWA(4A) of the Act;

(d) a unique identification number for the certificate;

(e) the day on which the certificate is issued;

(f) the name and address of the manufacturer of the medical devices;

(g) the conformity assessment procedures applied to the medical devices by the manufacturer;

(h) if the certificate covers a medical device to which paragraph 1.6(a), (b), (c) or (d) applies—the unique product identifier of the device;

(i) if the certificate is varied—the day and details of the variation;

(j) if one or more Australian conformity assessment body certificates have previously been issued in respect of the medical devices by the body—the information covered by paragraphs (a) to (i) in relation to each of those certificates.

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Part 5—Including medical devices in the Register

Division 5.1—Including medical devices in the Register

Note: Regulation 5.1 is intentionally not used.

Subdivision A—Applications

5.2 Matters to be certified—period for obtaining information from manufacturer (Act s 41FD)

For subparagraphs 41FD(e)(ii) and (g)(ii) of the Act, the period is 20 working days.

Subdivision C—Auditing of applications

5.3 Selecting applications for auditing (Act s 41FH)

(1) For paragraph 41FH(1)(a) of the Act and subject to this regulation, an application for any of the following kinds of medical devices to be included in the Register is prescribed:

(a) a medical device (other than a condom) that is a barrier indicated for contraception or prevention of the transmission of disease in the course of penile penetration during sexual intercourse;

(b) a medical device that is an implantable contraceptive device;

(c) a medical device that is a spinal fusion implantable device;

Note: Examples of spinal fusion implantable devices include screws, cages, plates, hooks or rods that are intended to be used during spinal fusion surgical procedures.

(d) a medical device of a kind described in subclause 5.3(2) of Schedule 2;

Note: Subclause 5.3(2) of Schedule 2 applies to a medical device that is specifically intended by the manufacturer to be used for disinfecting another medical device.

(g) a medical device that is an implantable intra-ocular lens;

(h) a medical device that is an intra-ocular visco-elastic fluid;

(i) a Class III medical device that has not been assessed under the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement;

(j) any of the following IVD medical devices:

(i) non assay-specific quality control material that is intended for monitoring a Class 4 IVD medical device;

(ii) an IVD medical device that is intended for self-testing;

(iii) an IVD medical device that is intended for point of care testing;

(iv) a Class 3 IVD medical device that is intended for detecting the presence of, or exposure to, a sexually transmitted agent;

(v) an IVD medical device for managing or monitoring the treatment of infections diagnosed using a Class 4 IVD medical device (for

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example, quantitative nucleic acid test (NAT) and genotyping assays for HIV and HCV);

(vi) an IVD medical device that is intended to be supplied for use under the pharmaceutical benefits scheme;

(vii) an IVD medical device that is intended to be supplied for use in a national screening program;

(viii) if the Secretary is not satisfied that a body or authority has the authority and expertise to exercise a power or perform a function of the Secretary mentioned in subregulation 3.5(1)—an IVD medical device that has been manufactured in a location and at a site where that body or authority has exercised such a power or performed such a function in relation to the device;

(viiia) a Class 4 IVD medical device;

(ix) a Class 4 in-house IVD medical device;

(x) an IVD companion diagnostic.

(2) Subregulation (1) does not apply to an application for a kind of medical device to be included in the Register if a conformity assessment certificate, or an Australian conformity assessment body certificate, has been issued, and has not been suspended or revoked, in respect of the kind of medical device.

(2AA) Subregulation (1) does not apply to an application for a kind of medical device to be included in the Register if:

(a) an overseas regulator conformity assessment document has been issued, in respect of the kind of medical device, by a notified body (within the meaning of the *Therapeutic Goods (Overseas Regulators) Determination 2018*) in accordance with:

(i) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, as in force from time to time; or

(ii) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, as in force from time to time; and

(b) the overseas regulator conformity assessment document has not been suspended or revoked.

(2A) Subregulation (1) does not apply to an application for a medical device that is covered by clause 5.8 of Schedule 2 or clause 1.8 of Schedule 2A.

Subdivision D—Miscellaneous—medical devices (priority applicant) determinations

5.4 Application of Subdivision

For the purposes of subsection 41FKA(1) of the Act, this Subdivision makes provision for and in relation to the making of medical devices (priority applicant) determinations.

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5.4A Application for medical devices (priority applicant) determination

(1) A person may apply to the Secretary for a medical devices (priority applicant) determination in relation to a medical device.

(2) An application under subregulation (1) must:
  (a) be in writing; and
  (b) be in a form approved, in writing, by the Secretary; and
  (c) have with it written information in such detail as is reasonably necessary to allow the application to be properly considered.

(3) An application under subregulation (1) is taken not to have been made unless:
  (a) the application meets the requirements in subregulation (2); and
  (b) the fee prescribed in item 1.5A of Part 1 of Schedule 5 for making the application has been paid.

5.4B Making of medical devices (priority applicant) determination

(1) On receiving an application under subregulation 5.4A(1) for a medical devices (priority applicant) determination in relation to a medical device, the Secretary must:
  (a) consider the application; and
  (b) decide either:
    (i) to make the determination; or
    (ii) to refuse to make the determination.

Criteria

(2) The Secretary may make the determination if the Secretary is satisfied, having regard to any matter that the Secretary considers relevant, that all of the following criteria are satisfied in relation to the medical device (the ***new device***):
  (a) the intended purpose of the new device is the monitoring, treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;
  (b) either:
    (i) no medical devices with that intended purpose are of a kind included in the Register; or
    (ii) if one or more medical devices with that intended purpose are of a kind included in the Register (the ***existing devices***)—there is substantial evidence demonstrating that the safety or performance of the new device when used for that intended purpose provides a significant improvement compared to the existing devices;
  (c) at least one of the following applies to the new device:
    (i) the new device is a breakthrough technology and there is evidence that it offers a major clinical advantage over existing technology;
    (ii) there is evidence that the new device offers a major clinical advantage over existing alternatives included in the Register;

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(iii) the new device is an IVD medical device and its early availability in Australia will result in a major public health benefit.

Information to be specified in determination

(3) The determination must specify:
(a) the person who, as a result of section 41FKA of the Act, is the priority applicant; and
(b) the medical device to which the determination relates; and
(c) the intended purpose of the medical device.

Notification of decision

(4) As soon as practicable after making the decision, the Secretary must notify the applicant, in writing, of the decision.

(5) If the Secretary decides to refuse to make the determination, the notification must include the reasons for the decision.

5.4C Period during which medical devices (priority applicant) determination is in force

(1) A medical devices (priority applicant) determination in relation to a medical device:
(a) comes into force on the day on which the Secretary notifies the priority applicant in accordance with subregulation 5.4B(4); and
(b) subject to subregulation (2) and regulation 5.4D, remains in force for 6 months.

(2) If the priority applicant specified in the determination makes an application under section 41FC of the Act for that kind of medical device to be included in the Register that passes preliminary assessment before the end of the 6 month period beginning when the determination comes into force, the determination remains in force until:
(a) the priority applicant withdraws the application; or
(b) the application lapses in accordance with section 41FK of the Act; or
(c) the application is finally determined.

Note: See subsection 41FDB(3) of the Act for when an application passes preliminary assessment.

5.4D Revocation of medical devices (priority applicant) determination

(1) The Secretary may revoke a medical devices (priority applicant) determination in relation to a medical device if:
(a) either:
(i) the priority applicant specified in the determination has not made an application under section 41FC of the Act for that kind of medical device to be included in the Register; or

(ii) the priority applicant has made such an application, but the application does not pass preliminary assessment; and

(b) the Secretary is satisfied that the criteria specified in subregulation 5.4B(2) are no longer satisfied in relation to the medical device.

Note: See subsection 41FDB(3) of the Act for when an application passes preliminary assessment.

(2) The revocation must be by written notice given by the Secretary to the priority applicant.

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Division 5.2—Conditions

Note: Regulation 5.5 is intentionally not used.

5.6 Conditions applying automatically—period for obtaining information from manufacturer (Act s 41FN)

For subparagraphs 41FN(3)(a)(ii) and (b)(iii) of the Act, the period is 20 working days.

5.7 Conditions applying automatically—period for giving information about adverse events etc (Act s 41FN)

(1) For paragraph 41FN(3)(d) of the Act, the period in which a person in relation to whom a kind of medical device is included in the Register must give information of a kind mentioned in subsection 41MP(2) or 41MPA(2) of the Act to the Secretary is:

(a) if the information relates to an event or other occurrence that represents a serious threat to public health—48 hours after the person becomes aware of the event or occurrence; and

(b) if the information relates to an event or other occurrence that led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—10 days after the person becomes aware of the event or occurrence; and

(c) if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—30 days after the person becomes aware of the event or occurrence; and

(d) in any other case—60 days after the person becomes aware of the information.

Note: See also regulation 5.8A (which deals with the giving of a report after information is given within a period covered by paragraph (1)(a), (b) or (c) of this regulation).

(2) For paragraph (1)(a), an event or other occurrence, in relation to a kind of medical device, ***represents a serious threat to public health*** if:

(a) the event or other occurrence is a hazard arising from a systematic failure of the device that becomes known to the person in relation to whom the device is included in the Register; and

(b) the event or other occurrence may lead to the death of, or a serious injury to, a patient, a user of the device or another person; and

(c) the existence of, probable rate of occurrence of, or degree of severity of harm caused by, the hazard was not previously known or anticipated by the manufacturer of the device; and

(d) the manufacturer will be required to take prompt action to eliminate, or reduce the risk of, the hazard.

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(3) For paragraphs (1)(b) and (c), an event or other occurrence leads to a ***serious deterioration*** in the state of health of a person if the event or other occurrence causes, or contributes to:

(a) a life-threatening illness or injury suffered by the person; or

(b) a permanent impairment of a bodily function of the person; or

(c) permanent damage to a body structure of the person; or

(d) a condition requiring medical or surgical intervention to prevent such permanent impairment or damage.

5.8 Conditions applying automatically—requirements in relation to information about kind of medical device (Act s 41FN)

For subsection 41FN(4) of the Act, the information required for the purposes of paragraph 41FN(3)(e) of the Act in relation to a kind of medical device that is included in the Register in relation to a person is:

(a) any information that the person is aware of relating to:

(i) any malfunction or deterioration in the characteristics or performance of the kind of device; or

(ii) any inadequacy in the design, manufacture, labelling, instructions for use or advertising materials of the kind of device; or

(iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that has led to any complaint or problem in relation to the kind of device, no matter how minor; and

(b) any information of the kind mentioned in subsection 41MP(2) of the Act that the person is aware of in relation to the kind of device.

5.8A Conditions applying automatically—giving of report about adverse events or occurrences (Act s 41FN)

(1) For the purposes of subsection 41FN(5A) of the Act, if the person in relation to whom a kind of medical device is included in the Register gives information of a kind mentioned in subsection 41MP(2) or 41MPA(2) of the Act to the Secretary within the period covered by paragraph 5.7(1)(a), (b) or (c) of these Regulations, the person must give a written report to the Secretary in accordance with this regulation.

(2) The person must give the report to the Secretary before the end of the period of 120 days beginning on the day the person gave that information to the Secretary.

(3) The report must:

(a) deal with any updates to that information since that information was given; and

(b) set out details of the action the person has taken, or the manufacturer of the kind of medical device has taken, to investigate the event or other occurrence concerned; and

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(c) set out details of the action the person has taken, or the manufacturer of the kind of medical device has taken, to alleviate the impact of the event or other occurrence concerned for patients or for users of the kind of medical device; and

(d) set out details of similar events or occurrences that have occurred in the last 3 years, in relation to the kind of medical device, of which the person is aware.

5.9 Conditions applying automatically—storage and transport of medical devices (Act s 41FN)

For the purposes of subsection 41FN(5A) of the Act, the person in relation to whom a kind of medical device is included in the Register must ensure that, while the person has control over a device of that kind, the device is stored and transported in accordance with the manufacturer's instructions for use of the device and any other information provided with the device by the manufacturer.

5.10 Conditions applying automatically—record-keeping (Act s 41FN)

(1) For the purposes of subsection 41FN(5A) of the Act, the person in relation to whom a kind of medical device is included in the Register must:

(a) create a record of information of a kind referred to in regulation 5.8 that relates to that kind of device as soon as practicable after the person becomes aware of the information; and

(b) create a record of information in relation to the distribution by the person of each device of that kind as soon as practicable after the distribution.

(2) A record created under subregulation (1) must be kept:

(a) for 10 years if the record relates to one of the following kinds of device:

(ii) a Class III medical device;

(iii) a Class IIb medical device that is an implantable medical device;

(iv) a Class 4 IVD medical device; or

(b) for 5 years if the record relates to any other kind of device.

5.11 Conditions applying automatically—reporting (Act s 41FN)

(1) This regulation applies in relation to the following kinds of medical devices:

(b) a Class III medical device;

(c) a Class IIb medical device that is an implantable medical device;

(d) a Class 4 IVD medical device.

(2) For the purposes of subsection 41FN(5A) of the Act, the person in relation to whom a medical device of that kind is included in the Register must, before 1 October after each reporting period for that kind of device, give the Secretary a report about that kind of device for the reporting period.

(3) The report must include the following:

(a) if no device of that kind was supplied in Australia or a foreign country during the reporting period—a statement to that effect;

(b) if the person became aware during the reporting period of information of a kind referred to in regulation 5.8 that relates to that kind of device—that information;

(c) if the person did not become aware during the reporting period of information of a kind referred to in regulation 5.8 that relates to that kind of device—a statement to that effect.

(4) For the purposes of this regulation, each of the following is a ***reporting period*** for a kind of medical device:

(a) the period:

(i) beginning on the day when that kind of device is included in the Register; and

(ii) ending at the end of the next 30 June;

(b) each of the next 2 financial years.

(5) If:

(a) on a day on or after 25 November 2021 medical devices of a kind (the ***current kind of medical device***) referred to in a particular paragraph of subregulation (1) are included in the Register because of the amendments made by the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*; and

(b) immediately before that day, those devices were of a kind (the ***previous kind of medical device***) referred to in a different paragraph of subregulation (1) and were included in the Register;

then subparagraph (4)(a)(i) applies in relation to the current kind of medical device as if the day when the current kind of medical device is included in the Register were the day when the previous kind of medical device was included in the Register.

5.12 Conditions applying automatically—notification of information (Act s 41FN)

(1) This regulation applies in relation to a kind of medical device specified in paragraph 5.3(1)(j) or a kind of medical device that is a spinal fusion implantable device.

Note: Examples of spinal fusion implantable devices include screws, cages, plates, hooks or rods that are intended to be used during spinal fusion surgical procedures.

(2) For the purposes of subsection 41FN(5A) of the Act, the person in relation to whom a medical device of that kind is included in the Register must give the Secretary a written notice if:

(a) the person intends to import, supply or export a medical device of that kind; and

(b) either of the following is not included in the Register:

(i) the product name of the device;

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(ii) information in relation to the manufacturer's intended purpose of the device.

(3) The notice must:

(a) specify the information mentioned in paragraph (2)(b) that is not included in the Register; and

(b) be given to the Secretary no later than 20 business days before the intended import, supply or export of the device.

5.13 Conditions applying automatically—information about poisons (Act s 41FN)

(1) This regulation applies in relation to a kind of medical device that contains a substance of a kind covered by an entry in a Schedule to the current Poisons Standard.

(2) However, this regulation does not apply in relation to that kind of medical device if, under Appendix A to the current Poisons Standard, the Standard does not apply to poisons in that kind of medical device.

(3) For the purposes of subsection 41FN(5A) of the Act, the person in relation to whom a medical device of that kind is included in the Register must not supply the device in Australia if the supply would contravene Part 2 of the current Poisons Standard.

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Part 6—Suspension and cancellation from the Register

6.1 Period for revocation of suspension (Act s 41GD, s 63(2)(dd))

(1) This regulation applies to an application to the Secretary under paragraph 41GD(2)(a) of the Act to revoke the suspension of a kind of medical device from the Register.

(2) The Secretary must make a decision on the application within 40 working days after the application is received at an office of the Department specified by the Secretary.

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Part 6A—Disposal of unused emergency medical devices

6A.1 Disposal of unused emergency medical devices

(1) For subsection 41GY(2) of the Act, the arrangements for disposal of unused emergency medical devices are set out in Schedule 3A.

(2) Nothing in this regulation or in Schedule 3A is taken to prevent a disposal of unused emergency medical devices if:

(a) the devices have become:

(i) devices of a kind included in the Register under Part 4-5 of the Act; or

(ii) exempt devices under section 41HA of the Act; or

(iii) devices that are the subject of an approval under section 41HB of the Act; or

(iv) devices that are the subject of an authority under section 41HC of the Act; and

(b) the disposal is in accordance with other provisions of the Act and these Regulations relevant to the devices.

Part 7—Exempting medical devices from inclusion in the Register

Division 7.1—Exempt devices

7.1 Exempt devices—general (Act s 41HA)

(1) For paragraph 41HA(1)(b) of the Act, a kind of medical device mentioned in Part 1 of Schedule 4 is exempt from the operation of Division 3 of Part 4-11 of the Act.

(2) For paragraph 41HA(1)(b) and subsection 41HA(2) of the Act, a kind of medical device mentioned in column 2 of an item in Part 2 of Schedule 4 is exempt from the operation of Division 3 of Part 4-11 of the Act, subject to compliance with the conditions mentioned in column 3 of that item.

(3) If:

(a) a kind of medical device that is exempt from the operation of Division 3 of Part 4-11 of the Act ceases to be so exempt; and

(b) an application was made for the kind of device to be included in the Register before the device ceased to be exempt;

the kind of device is taken to be exempt from the operation of Division 3 of Part 4-11 of the Act until the application is determined.

Limited exemptions

(4) For a kind of medical device that is exempt under paragraph (a) of item 1.6 of the table in Part 1 of Schedule 4, the exemption is subject to the condition that the exemption only has effect in relation to the importation.

(5) For a kind of medical device that is exempt under paragraph (b) of item 1.6 of the table in Part 1 of Schedule 4, the exemption is subject to the condition that the exemption only has effect in relation to the manufacture.

(6) For a kind of medical device that is exempt under paragraph (c) of item 1.6 of the table in Part 1 of Schedule 4, the exemption is subject to the condition that the exemption only has effect in relation to the supply by the intermediate supplier.

(7) For a kind of medical device that is exempt under paragraph (d) of item 1.6 of the table in Part 1 of Schedule 4, the exemption is subject to the condition that the exemption only has effect in relation to the supply covered by that paragraph.

(8) For a kind of medical device that is exempt under item 1.7 of the table in Part 1 of Schedule 4, the exemption, to the extent that it relates to a particular manufacturer of a patient-matched medical device, is subject to the condition that the exemption only has effect in relation to the first 5 patient-matched medical devices manufactured by the manufacturer in a financial year.

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7.2 Exempt devices—use in life-threatening cases (Act s 41HA)

(1) For paragraph 41HA(1)(b) of the Act, and without limiting regulation 7.1, a kind of medical device is exempt from the operation of Division 3 of Part 4-11 of the Act if:

(a) the kind of device is to be used in or on a person who is a Category A patient; and

(b) the following conditions are satisfied in relation to the use of the device:

(i) the person in or on whom the kind of device is to be used, or the person's guardian, has given informed consent to the use of the device in or on the person;

(ii) a statement in relation to the person is completed in accordance with subregulation (1A);

(iii) the device is used in accordance with the direction of the medical practitioner who requested its use.

(1A) For the purposes of subparagraph (1)(b)(ii), a statement in relation to the use of an exempt device in or on a person who is a Category A patient must:

(a) be completed by:

(i) the medical practitioner by whom, or at whose direction, the device is used; or

(ii) by a health practitioner acting on behalf of that medical practitioner; and

(b) be in the form approved by the Secretary for the purposes of this paragraph; and

(c) include the following:

(i) the initial letters of the person's given name and surname, and the person's date of birth and sex;

(ii) the diagnosis of the person's condition;

(iii) the expected duration of the treatment;

(iv) a description of the exempt device;

(v) the supplier of the exempt device;

(vi) the number of units of the exempt device to be supplied;

(vii) the treating medical practitioner's name, practising address and other contact details; and

(d) include a statement to the effect that:

(i) the person is a Category A patient; and

(ii) the person, or the person's guardian, has given informed consent to the use of the device in or on the person.

(1C) A person commits an offence of strict liability if the person:

(a) completes a statement referred to in subparagraph (1)(b)(ii); and

(b) does not send a copy of the statement to the Secretary within 28 days after the use of the exempt device to which the statement relates.

Penalty: 10 penalty units.

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Regulation 7.2

(2) In this regulation:

Category A patient means a person who is seriously ill with a condition that is reasonably likely to lead to the person's death within less than a year or, without early treatment, to the person's premature death.

informed consent, in relation to treatment or proposed treatment of a person, means consent to the treatment of the person that is freely given on the basis of information concerning the potential risks and benefits of the treatment that is sufficient to allow the person, or the person's guardian, to make an informed decision about whether to consent to the treatment.

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Division 7.2—Exemptions for experimental uses

7.3 Conditions of approval—use of device by person to whom approval is given (Act s 41HB)

(1) For subsection 41HB(3) of the Act, the conditions mentioned in this regulation apply to an approval granted to a person to use a kind of medical device solely for experimental purposes in humans.

(2) Before the commencement of any clinical trial proposed to be undertaken in relation to the device, the person to whom the approval is granted and the principal investigator of the clinical trial must give to the Secretary:

(a) a written assurance that each clinical trial will be conducted in accordance with the 'National Statement on Ethical Conduct in Research Involving Humans', published by the National Health and Medical Research Council, as in force from time to time; and

(b) a written undertaking:

(i) that the person will comply with any request by an authorised person, whether made before or after the commencement of a clinical trial, to give to the authorised person information about the conduct of the trial; and

(ii) that the person will allow an authorised person to do any of the things mentioned in regulation 7.4 in relation to a clinical trial.

7.4 Powers of authorised persons in relation to medical devices being used in clinical trials

(1) For subparagraph 7.3(2)(b)(ii) and subject to subregulation (2), an authorised person may do any of the following things in relation to a clinical trial of a kind of medical device that has been approved for use solely for experimental purposes in humans:

(a) enter the site of the trial;

(b) search the site and anything on the site;

(c) inspect, examine, take measurements of, or conduct tests on (including by the taking of samples), anything on the site that relates to the trial;

(d) take photographs, make video recordings or make sketches of the site or anything on the site;

(e) inspect any book, record or other document on the site that relates to the trial;

(f) request the principal investigator of the trial to:

(i) answer any question asked by the authorised person; or

(ii) produce any book, record or other document requested by the authorised person.

(2) An authorised person is not entitled to do a thing mentioned in subregulation (1) if:

(a) the principal investigator, or any other person present at the site concerned and in apparent control, requests the authorised person to produce his or her identity card for inspection; and
(b) the authorised person fails to comply with the request.

Note: See section 52 of the Act in relation to identity cards.

(3) The principal investigator, or any other person present at the site and in apparent control, is entitled to observe a search conducted under paragraph (1)(b), but must not obstruct the search.

(4) Subregulation (3) does not prevent 2 or more areas of the site being searched at the same time.

7.5 Conditions of approval—use of device by another person (Act s 41HB)

(1) For subsection 41HB(7) of the Act, the conditions mentioned in this regulation apply to the use by a person, for experimental purposes in humans, of a kind of medical device that is the subject of an approval granted to someone else under paragraph 41HB(1)(e) of the Act.

(2) The use of the device must comply with a procedural protocol approved by the ethics committee that is to be responsible for monitoring the conduct of the trial at each trial site (the ***responsible ethics committee***).

(3) The use of the device must be in accordance with the ethical standards set out in the 'National Statement on Ethical Conduct in Research Involving Humans', published by the National Health and Medical Research Council, as in force from time to time.

(4) The person must cease using the device if the responsible ethics committee informs the principal investigator of the clinical trial that the use is inconsistent with:
(a) the protocol mentioned in subregulation (2); or
(b) any condition subject to which approval for the use was given.

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Division 7.3—Exemptions for medical practitioners

7.6 Classes of medical practitioners and recipients (Act s 41HC)

(1) A class of medical practitioners prescribed for the purposes of paragraph 41HC(4)(a) of the Act is the class of medical practitioners each of whom is:

(a) a specialist medical practitioner who is engaged in clinical practice in a hospital and is endorsed by the ethics committee of the hospital; or

(b) a specialist medical practitioner who is engaged in treating patients outside a hospital and is endorsed by an ethics committee that:

(i) has expertise relating to the principal activities of the practitioner; or

(ii) conducts its activities within the geographic area where the medical practitioner is engaged in treating patients.

(2) A class of recipients prescribed for the purposes of paragraph 41HC(4)(c) of the Act is the class of recipients each of whom is a person who is suffering from a life-threatening or otherwise serious illness or condition.

(3) For subsection 41HC(4) of the Act, each of the following is an exceptional circumstance in which paragraph 41HC(4)(b) of the Act does not apply:

(a) the Secretary is satisfied that the medical practitioner has no access to an ethics committee;

(b) the medical practitioner has an endorsement from a specialist college that does not have an ethics committee, but has expertise relevant to the treatment of the condition for which the authority is sought.

7.7 Circumstances for supply of device under authority (Act s 41HC)

For subsection 41HC(5) of the Act, a kind of medical device may be supplied under an authority under subsection 41HC(1) of the Act if the supplier of the device complies with the directions relating to the therapeutic intervention, or class of therapeutic intervention, mentioned in the authority.

7.8 Information to be notified in relation to supply of certain medical devices

For the purposes of paragraph 41HC(6C)(b) of the Act, the information that must be contained in a notification under subsection 41HC(6B) of the Act in relation to the supply by a health practitioner of a medical device to a person is as follows:

(a) the person's initials, date of birth and gender;

(b) each medical condition in relation to which the device was supplied;

(c) each intended use of the device in relation to which the device was supplied;

(d) the product name of the device;

(e) the name of the manufacturer of the device;

(f) a brief description of the device including whether the device is a variant;

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(g) the practitioner's name, AHPRA number and contact details;
(h) the health profession in which the practitioner is registered or licensed to practise;
(i) the address of the practitioner's principal place of practice.

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Part 8—Obtaining information

8.1A Matters for which information and documents can be requested

For paragraph 41JA(1)(j) of the Act, the following matters are prescribed:

(a) whether the devices are medical devices;

(b) whether the devices are intended for a specified purpose, as ascertained under subsection 41BD(2) of the Act;

(c) whether the devices are correctly classified under Division 3.1 of Part 3;

(d) whether procedures are in place, including a written agreement with the manufacturer of the devices, that require the manufacturer to make available information mentioned in paragraph 41FD(e) or (g) of the Act;

(e) whether the devices contain substances that are prohibited imports under the *Customs Act 1901*;

(f) whether the devices are to be used exclusively for one or more of the purposes specified under section 41BEA of the Act;

(g) the accuracy and completeness of information included in or with the application;

(h) matters relating to the scheme provided in Subdivision 2 of Division 1 of Part 7 of the *Therapeutic Goods Regulations 1990* for exempting a person from liability to pay an annual charge for inclusion of the devices in the Register for a financial year, based on low value turnover of the devices;

(i) matters relating to an application to the Secretary under regulation 43AAH of the *Therapeutic Goods Regulations 1990* to waive the annual charge for inclusion of the devices in the Register for a financial year;

(j) matters relating to:

(i) any malfunction or deterioration in the characteristics or performance of the devices; or

(ii) any inadequacy in the design, manufacture, labelling, instructions for use or advertising materials of the devices; or

(iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the devices;

that has led to any complaint or problem in relation to the devices, no matter how minor;

(k) matters of the kind mentioned in subsection 41MP(2) of the Act;

(l) whether the devices comply with conditions to which the inclusion of the devices in the Register is subject;

(m) matters relating to the formulation of ingredients that constitute the devices.

8.1 Notice period (Act s 41JA)

For paragraph 41JA(2)(a) of the Act, the notice period for a kind of medical device in relation to which a person is required, by written notice given by the

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Secretary under subsection 41JA(1) of the Act, to give information to the Secretary is:

(a) if the information relates to manufacturing records—5 years; and

(b) if the information relates to distribution records:

(i) in the case of records relating to a Class III medical device, or Class IIb medical device that is an implantable medical device—10 years; and

(ii) in the case of records relating to any other device—5 years.

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Part 9—Fees

Division 9.1—Fees

9.1 Fees

The following fees are prescribed:

(a) the fee mentioned in column 4 of an item in Part 1 of Schedule 5 in relation to the matter mentioned in column 2 of that item;

(b) the additional fees mentioned in Part 2 of Schedule 5.

Division 9.1A—Reduced fee for consent to import, supply or export implantable medical devices—patient implant cards and patient information leaflets

9.1AA Working out the reduced fee

(1) If:

(a) an application is covered by paragraph (a) of item 1.15 of the table in Part 1 of Schedule 5; and

(b) the application is made solely in relation to the application of either or both of clauses 13A.2 and 13A.3 of Schedule 1;

the amount of the fee is not worked out in accordance with Part 1 of Schedule 5. Instead, the amount of the fee is $30.

(2) If:

(a) an application is covered by paragraph (b) of item 1.15 of the table in Part 1 of Schedule 5; and

(b) the application is made solely in relation to the application of either or both of clauses 13A.2 and 13A.3 of Schedule 1;

the amount of the fee is not worked out in accordance with Part 1 of Schedule 5. Instead, the amount of the fee is worked out in accordance with the following method statement:

Method statement	
Step 1.	Work out the number of separate entries in the Register in relation to the devices concerned.
Step 2.	The amount of the fee is the number at step 1 multiplied by $30.

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Division 9.2—Conformity assessment body determination assessment fees

9.1A Purposes of this Division

This Division is made for the purposes of paragraph 41EWA(3)(g) of the Act.

9.1B Conformity assessment body determination assessment fees

(1) A fee is payable in relation to the assessment of an application for a conformity assessment body determination mentioned in column 2 of item 1.4D, 1.4E or 1.4F in Part 1 of Schedule 5.

(2) Subject to regulation 9.1C, the amount of the fee is the amount mentioned in column 4 of that item.

(3) The fee is payable by the applicant.

(4) Subject to regulation 9.1D, the fee is due and payable in full on the day specified under subregulation (5) of this regulation.

(5) For the purposes of subregulation (4), the Secretary may give the applicant a written notice specifying when the fee is due and payable in full.

9.1C Conformity assessment body determination assessment fees—abridged assessment

If the Secretary considers that he or she has sufficient information to allow assessment of an application for a conformity assessment body determination to be abridged:

(a) the Secretary may decide to conduct an abridged assessment of the application; and

(b) if the Secretary so decides—the Secretary may reduce the amount of the conformity assessment body determination assessment fee for assessment of the application.

9.1D Payment of conformity assessment body determination assessment fees by instalments

(1) The Secretary may approve, in relation to an application (the ***relevant application***) for a conformity assessment body determination, the payment of a conformity assessment body determination assessment fee by instalments if:

(a) the applicant for the determination has applied in writing to pay the amount by instalments; and

(b) the amount payable exceeds $10,000; and

(c) the Secretary is reasonably satisfied that the applicant will experience financial hardship if the amount is paid before the commencement of the assessment of the relevant application; and

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(d) any information or material required under subregulation (3) has been given to the Secretary.

(2) An application under subregulation (1) must:
(a) state the reasons why paying the full amount of the fee before the assessment of the relevant application commences would cause financial hardship to the applicant; and
(b) have with it documents or other material in support of the application.

(3) The Secretary may reasonably require information or material in addition to the documents or material mentioned in paragraph (2)(b).

(4) If the Secretary approves an application for payment by instalments:
(a) half of the fee is due for payment before the commencement of the assessment of the relevant application; and
(b) one-quarter of the fee is due for payment at the end of one month after the last day when the amount referred to in paragraph (a) may be paid; and
(c) the remaining one-quarter of the fee is due for payment:
(i) if the relevant application is withdrawn—when the relevant application is withdrawn; and
(ii) in any other case—when the applicant is notified of the Secretary's decision in respect of the relevant application under regulation 4A.7 or 4A.9.

(5) If the Secretary receives an application for payment by instalments, the Secretary must:
(a) within 30 days of receiving the application and any information or material required under subregulation (3), give notice, in writing, to the applicant stating whether the application has been approved; and
(b) if the application is approved—include with the notice information about the amount of each instalment and when it is due for payment.

(6) If:
(a) the Secretary approves an application for payment by instalments; and
(b) any amount of the instalment payable by the applicant is not paid when it becomes due for payment;
the balance of the fee becomes due for payment.

9.1E Recovery of conformity assessment body determination assessment fees

A conformity assessment body determination assessment fee may be recovered by the Commonwealth as a debt due to the Commonwealth.

9.1F Refund of conformity assessment body determination assessment fees if applications withdrawn

(1) The applicant for a conformity assessment body determination may apply to the Secretary, in writing, for a refund of the conformity assessment body

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determination assessment fee for the application if the applicant withdraws the application:

(a) after all or part of the fee becomes due and payable; and

(b) before the Secretary makes a decision on the application under subregulation 4A.6(1).

(2) Within 20 working days after receiving the application, the Secretary must:

(a) decide whether to refund any of the fee; and

(b) if so—the amount of the fee to be refunded.

(3) To avoid doubt, the applicant is not entitled to a refund of the application fee for the application.

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Division 9.3—Assessment fees and reductions or refunds of fees connected with applications for conformity assessment certificates

9.2 Application audit assessment fee (Act ss 41LA, 41LB)

For section 41LB of the Act, an application audit assessment fee is due and payable 28 days after the day that the applicant is notified of the amount of the fee.

9.3 Conformity assessment fee (Act ss 41LA, 41LB)

(1) For section 41LB of the Act, and subject to subregulation (2), a conformity assessment fee for consideration of an application for a conformity assessment certificate is due and payable in full:

(a) on the day specified in a notice given to the applicant by the Secretary; or

(b) if the application is withdrawn before a decision is made in relation to the application and within the period mentioned in subregulation 4.3(2)—on the day when the application is withdrawn.

Note: See section 41LE of the Act in relation to the requirement to pay three-quarters only of the conformity assessment fee in relation to certain kinds of applications.

(2) If:

(a) in accordance with section 41LE of the Act, an applicant has paid three-quarters of the conformity assessment fee in relation to an application for a conformity assessment certificate; and

(b) the application is withdrawn before a decision is made in relation to the application and within the period mentioned in subregulation 4.3(2);

the part of the fee that is unpaid is due and payable on the day when the application is withdrawn.

(3) If the Secretary considers that additional assessment work is required in relation to an application for a conformity assessment certificate, the additional amount is due and payable on the day specified in a notice given to the applicant by the Secretary.

Note: The fee for any additional work is prescribed in item 1.12 of Schedule 5.

9.5 Payment of assessment fee by instalments (Act s 41LC)

(1) For section 41LC of the Act, the Secretary may, subject to subregulation (7), approve, in relation to a kind of medical device, the payment of an assessment fee by instalments if:

(a) the person who is liable to pay the fee (the ***applicant***) has applied in writing to pay the amount by instalments; and

(b) the amount payable exceeds $10 000; and

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(c) the Secretary is reasonably satisfied that the applicant will experience financial hardship if the amount is paid before the commencement of the consideration or audit of the application to which the fee relates (the ***relevant application***); and

(d) any information or material required under subregulation (3) has been given to the Secretary.

(2) An application under subregulation (1) must:

(a) state the reasons why paying the full amount of the fee before the consideration or audit of the relevant application commences would cause financial hardship to the applicant; and

(b) have with it documents or other material in support of the application.

(3) The Secretary may reasonably require information or material in addition to the documents or material mentioned in paragraph (2)(b).

(4) If the Secretary approves an application for payment by instalments:

(a) half of the fee is due for payment before the commencement of the consideration or audit of the relevant application; and

(b) one-quarter of the fee is due for payment at the end of one month after the last day when the amount referred to in paragraph (a) may be paid; and

(c) the remaining one-quarter of the fee is due for payment:

(i) if the relevant application is withdrawn—when the application is withdrawn; and

(ii) in any other case—when the applicant is notified of the Secretary's decision in respect of the relevant application under section 41EE or 41FJ of the Act.

(5) If the Secretary receives an application for payment by instalments, the Secretary must:

(a) within 30 days of receiving the application and any information or material required under subregulation (3), give notice, in writing, to the applicant stating whether the application has been approved; and

(b) if the application is approved, include with the notice information about the amount of each instalment and when it is due for payment.

(6) If:

(a) the Secretary approves an application for payment by instalments; and

(b) any amount of the instalment payable by the applicant is not paid when it becomes due for payment;

the balance of the fee becomes due for payment.

(7) This regulation does not apply if another assessment fee, or an evaluation fee under section 24 of the Act, (or part of either of those kinds of fee) that is due for payment by the applicant is unpaid.

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9.6 Reduction of assessment fees

The Secretary may reduce by 70% the amount of an assessment fee specified in Schedule 5 in relation to a medical device if the supply of the medical device:

(a) is in the interest of public health; and

(b) would not be commercially viable for the manufacturer or sponsor of the medical device if the full amount of the fee were paid.

9.7 Reduction of assessment fees—abridged assessment

(1) This regulation applies to an assessment fee specified in Part 1 of Schedule 5 in relation to any of the following:

(a) items 1.2, 1.3 and 1.3A (review of conformity assessment certificate);

(b) items 1.9 and 1.9A (initial assessment under conformity assessment procedures);

(c) item 1.10 (assessment consequent on a change to:

(i) a medical device; or

(ii) the quality management system applying to a medical device);

(ca) item 1.10A (assessment because of changes or proposed changes to:

(i) an IVD medical device; or

(ii) the quality management system applying to an IVD medical device);

(d) items 1.13, 1.14, 1.14A, 1.14B and 1.14C (application subject to audit assessment);

(e) item 1.16 (intermediate stage assessment or verification procedures).

(2) The Secretary may reduce the amount of the assessment fee if the Secretary has information that allows the assessment to be abridged, being information about:

(a) the medical device to which the fee relates; or

(b) some or all aspects of whether the conformity assessment procedures have been applied to the medical device.

9.8 Refund of fees—kinds of medical devices covered by former regulation 4.1

(1) If:

(a) on or after 1 January 2019 and before the commencement of this regulation, a person made an application under section 41EB of the Act for a conformity assessment certificate in respect of a kind of medical device covered by regulation 4.1 (as in force immediately before 28 July 2021); and

(b) on or after 1 January 2019 and before 1 December 2021, the person paid all or part of one or more of the following:

(i) the fee covered by item 1.1 of the table in Part 1 of Schedule 5 in connection with the application;

(ii) the fee covered by item 1.9, 1.9A, 1.10 or 1.10A of the table in Part 1 of Schedule 5 (to the extent that fee is in connection with the application);

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(iii) the fee covered by item 1.11 or 1.12 of the table in Part 1 of Schedule 5 (to the extent that fee is in connection with the application);

(iv) the fee covered by clause 2.1 or 2.2 in Part 2 of Schedule 5 (to the extent that fee is in connection with the application); and

(c) on or after 28 July 2021 and before 1 March 2022, the person, by notice in writing given to the Secretary, withdrew the application; and

(d) the person withdrew the application before the Secretary had made a decision on the application; and

(e) on or after 28 July 2021 and before 1 March 2022, the person requested the Secretary, in writing, for a refund of that fee; and

(f) the request is accompanied by information that satisfies the requirements of subparagraphs 41FDB(2)(d)(i) and (ii) of the Act for that classification of medical device;

then, before the end of the applicable period, the Secretary must:

(g) decide whether or not to refund any of that fee; and

(h) if the Secretary decides to make a refund on behalf of the Commonwealth—decide the amount of that fee to be refunded.

(2) In making a decision under paragraph (1)(g) or (h), the Secretary must take into account the extent of completion of the assessment or assessments, or of the testing, in connection with the application for the conformity assessment certificate, at the time the person withdrew the application.

(3) Subregulation (2) does not limit the matters the Secretary may take into account.

(4) For the purposes of this regulation, the ***applicable period*** is:

(a) if the person requested the refund on or after 28 July 2021 and before the commencement of this regulation—the period of 20 working days beginning on the day this regulation commences; or

(b) if the person requested the refund on or after the commencement of this regulation—the period of 20 working days beginning on the day the Secretary received the request.

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Division 9.4—Other refunds or waivers of fees

9.9 Other refunds or waivers of fees

Refunds

(1) For the purposes of paragraph 63(3)(b) of the Act, the Secretary must, on behalf of the Commonwealth, refund the fee covered by item 1.6A of the table in Part 1 of Schedule 5 if:

(a) the request referred to in that item was made on or after 21 August 2021 and before the commencement of this regulation; and

(b) that request was for revocation of the cancellation of an entry of a kind of medical device covered by item 3A, 3B, 3C, 3D or 3E of the table in Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*, as that instrument was in force before that commencement.

Waivers

(2) For the purposes of paragraph 63(3)(b) of the Act, the Secretary must, on behalf of the Commonwealth, waive the fee covered by item 1.6A of the table in Part 1 of Schedule 5 if:

(a) the request referred to in that item is made on or after the commencement of this regulation and before the end of 31 December 2022; and

(b) that request is for revocation of the cancellation of an entry of a kind of medical device covered by item 3A, 3B, 3C, 3D or 3E of the table in Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*, as that instrument is in force from time to time.

(3) For the purposes of paragraph 63(3)(b) of the Act, the Secretary must, on behalf of the Commonwealth, waive the fee covered by item 1.5 of the table in Part 1 of Schedule 5 if:

(a) the application referred to in that item is made on or after the commencement of this regulation and before the end of 31 December 2022; and

(b) that application is for inclusion in the Register of a kind of medical device covered by item 3A, 3B, 3C, 3D or 3E of the table in Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*, as that instrument is in force from time to time; and

(c) the person making that application had made a request before the commencement of this regulation under paragraph 41GL(d) of the Act for cancellation of the entry of the kind of device that is the subject of that application.

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Part 10—Miscellaneous

10.1 Authorised persons

The Secretary may, in writing, authorise any of the following persons to exercise powers under a specified provision of these Regulations:

(a) an officer of the Department, of another Department or of an authority of the Commonwealth;

(b) an officer of:

(i) a Department of State of a State; or

(ii) a Department or administrative unit of the Public Service of a Territory; or

(iii) an authority of a State or of a Territory;

being a Department, unit or authority that has functions relating to health matters.

10.2 Information about sponsor

(1) The sponsor of a medical device must ensure that the sponsor's name and address are:

(a) provided with the device in such a way that a user of the device can readily identify the sponsor; and

(b) located in accordance with clause 13.2 in Schedule 1.

Penalty: 10 penalty units.

(2) If the sponsor of a medical device arranges for a label to be attached or affixed to the device for the purpose of complying with subregulation (1) or for any other purpose (for example, to comply with a labelling requirement under the law of a State or Territory), the label must not in any way adulterate the device or obscure the information provided with the device by the manufacturer.

Penalty: 10 penalty units.

10.3 Custom-made medical devices—information about manufacturer

(1) The manufacturer of a custom-made medical device that is manufactured in Australia must, within 2 months after the medical device is first manufactured in Australia, give the following information about the device to the Secretary:

(a) the manufacturer's name and business address;

(b) a description of the kinds of medical devices being custom-made by the manufacturer (including the device nomenclature system code for any such devices).

Penalty: 10 penalty units.

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(2) The sponsor of a custom-made medical device that is imported into Australia must, within 2 months after the medical device is first imported into Australia, give the following information about the device to the Secretary:

(a) the sponsor's name and address;

(b) the manufacturer's name and business address;

(c) a description of the kinds of medical devices being custom-made by the manufacturer (including the device nomenclature system code for any such devices).

Penalty: 10 penalty units.

10.3A Custom-made medical devices—information about supplies

(1) A person commits an offence if:

(a) the person is the manufacturer of a custom-made medical device that is manufactured in Australia in a financial year (the ***relevant financial year***); and

(b) the person does not, before 1 October in the next financial year, give the Secretary a written report that relates to all the custom-made medical devices the person manufactured in the relevant financial year and that complies with subregulation (3).

Penalty: 10 penalty units.

(2) A person commits an offence if:

(a) the person is the sponsor of a custom-made medical device that the person imported into Australia in a financial year (the ***relevant financial year***); and

(b) the person does not, before 1 October in the next financial year, give the Secretary a written report that relates to all the custom-made medical devices the person imported in the relevant financial year and that complies with subregulation (3).

Penalty: 10 penalty units.

(3) A report under this regulation must:

(a) be made in accordance with a form approved, in writing, by the Secretary; and

(b) contain the information that the form requires.

(4) Without limiting subregulation (3), the form may require details in relation to supplies of custom-made medical devices covered by paragraph (1)(b) or (2)(b).

(5) The Secretary must make the form available on the Therapeutic Goods Administration's website.

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10.4 Offences—period for notifying adverse events (Act s 41MP)

For paragraph 41MP(1)(c) of the Act, the period for giving information of a kind mentioned in subsection 41MP(2) of the Act is the relevant period specified in regulation 5.7.

10.4AA Civil penalty—period for notifying adverse events

For the purposes of paragraph 41MPA(1)(c) of the Act, the period for giving information of a kind mentioned in subsection 41MPA(2) of the Act is the relevant period specified in regulation 5.7.

10.4A Secretary may maintain a system to enhance safe and effective use of particular medical devices

(1) The Secretary may, for the purpose of performing his or her functions, or exercising his or her powers, in relation to therapeutic goods (including under the Act or under another law), maintain either or both of the following:

(a) a system that is designed to enhance the safe and effective use of implantable breast medical devices (an ***implantable breast medical devices registry***);

(b) a system that is designed to enhance the safe and effective use of implantable cardiac medical devices (an ***implantable cardiac medical devices registry***).

(2) An implantable breast medical devices registry, or an implantable cardiac medical devices registry, may involve any of the following:

(a) collecting and analysing data and information in relation to the relevant medical devices;

(b) monitoring the safety and performance of the relevant medical devices;

(c) identifying particular medical devices (if any) in relation to which there are safety or performance risks or concerns;

(d) providing information about the safety and performance of the relevant medical devices to:

(i) authorities or bodies of the Commonwealth, a State or a Territory that have functions relating to therapeutic goods or health; or

(ii) health professionals; or

(iii) persons or bodies involved in the manufacture, importation or supply of the relevant medical devices in Australia; or

(iv) patients; or

(v) the general public.

(3) For paragraph (2)(a), the following are examples of data and information that may be collected and analysed in relation to the relevant medical devices:

(a) data and information relating to the safety and performance of the relevant medical devices;

(b) data and information about any revision procedures relating to the relevant medical devices and the reasons for those procedures;

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(c) in relation to each particular medical device that has been implanted in a patient:

(i) information identifying the medical device, including the brand and batch or serial number; and

(ii) the date on which the medical device was implanted; and

(iii) the name of the hospital or surgery where the medical device was implanted; and

(iv) data or information that tracks the performance of the medical device and the patient outcomes following implant of the medical device.

(4) The Secretary may enter into a written agreement with a person or body for the purpose of maintaining an implantable breast medical devices registry or an implantable cardiac medical devices registry.

(5) An implantable breast medical devices registry or an implantable cardiac medical devices registry:

(a) may be maintained at a place and in a form that is acceptable to the Secretary; and

(b) may involve keeping records, or carrying out other actions, by electronic means.

10.5 Delegation—powers and functions under these Regulations

The Secretary may, by signed instrument, delegate a power or function of the Secretary under these Regulations to an officer of the Department.

10.6 Delegation—powers under paragraph 41HB(1)(d) of the Act

(1) In this regulation:

delegation means a delegation, under subsection 57(3) of the Act, of powers of the Secretary, under paragraph 41HB(1)(d) of the Act, to approve the use of a specified medical device or kind of medical device in the treatment of a person.

(2) A delegate may only be a person who:

(a) is a medical practitioner registered in a State or internal Territory and employed by an institution that has an ethics committee; and

(b) is proposed by the medical superintendent or, if there is no medical superintendent, the person occupying a position comparable to that of medical superintendent, of the institution, as a person to be a delegate under subsection 57(3) of the Act.

(3) If:

(a) a person proposes another person under paragraph (2)(b) as a person to be a delegate; and

(b) that other person becomes a delegate;

the first-mentioned person must supervise each approval that the delegate grants under the delegation.

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(4) An instrument of delegation must describe the person or class of persons to be treated with the medical device or kind of medical device to which the delegation relates.

(5) A delegation may be made for the purpose of allowing the delegate to grant an approval in relation to:

(a) a particular medical device or kind of medical device; or

(b) a particular class of medical devices;

for treating a specific illness or condition.

(6) A delegate may grant an approval under a delegation only if:

(a) a medical practitioner, other than the delegate, has stated in writing that the person who is to be treated with the medical device of a kind to which the approval relates has an illness or condition that requires treatment with that kind of medical device; and

(b) an ethics committee has agreed to the granting of an approval under paragraph 41HB(1)(d) of the Act for the use, in the circumstances in which the delegate grants the approval, of the kind of medical device to which the delegation relates.

10.6A Delegation of Secretary's powers under section 41HD of the Act

The following positions are prescribed for the purposes of subsection 57(9) of the Act:

(a) First Assistant Secretary, Medicines Regulation Division;

(b) First Assistant Secretary, Medical Devices and Product Quality Division;

(c) Chief Medical Adviser, Health Products Regulation Group;

(d) each position classified as Medical Officer Class 5, Health Products Regulation Group.

10.6B Forms or manners—software requirements

If a provision of these Regulations provides for the approval or specification of a form or manner of giving an application, notice or other document, the approval or specification may require or permit the application, notice or other document to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

10.7 Review of decisions

(1) In this regulation:

decision has the same meaning as in the *Administrative Appeals Tribunal Act 1975*.

initial decision means a decision of the Secretary under any of the following provisions:

(a) subparagraph 4.3C(1)(b)(ii);

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(aa) subregulation 4.3E(1);
(ab) subregulation 4.10(2);
(aba) the following provisions (about conformity assessment body determinations):
(i) subregulation 4A.6(1);
(ii) subparagraph 4A.7(3)(a)(i) or (ii);
(iii) subregulation 4A.7(5);
(iv) regulation 4A.20;
(v) subregulation 4A.22(3);
(vi) subregulation 4A.23(1);
(vii) subregulation 4A.26(1);
(viii) subregulation 4A.27(1);
(ix) subregulation 4A.28(1);
(x) subregulation 4A.29(1);
(ac) subparagraph 5.4B(1)(b)(ii);
(ad) subregulation 5.4D(1);
(ae) the following provisions (about conformity assessment body determination assessment fees):
(i) regulation 9.1C;
(ii) subregulation 9.1D(1);
(iii) subregulation 9.1F(2);
(b) paragraph 9.4(2)(a);
(c) subregulation 9.5(1);
(d) paragraph 9.8(1)(g) or (h).

reviewable decision means a decision of the Minister under subregulation (4).

(2) The Minister may, by signed instrument, delegate a power or function of the Minister under this regulation to an officer of the Department.

(3) A person whose interests are affected by an initial decision may request the Minister to reconsider the decision by notice in writing given to the Minister within 90 days after the decision first comes to the person's notice.

(3A) Despite subregulation (3), only the following persons may make a request under that subregulation in relation to a conformity assessment (priority applicant) determination:
(a) if the initial decision was to refuse to make the determination—the person who applied for the determination;
(b) if the initial decision was to revoke the determination—the priority applicant specified in the determination.

(3B) Despite subregulation (3), only the following persons may make a request under that subregulation in relation to a medical devices (priority applicant) determination:
(a) if the initial decision was to refuse to make the determination—the person who applied for the determination;

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(b) if the initial decision was to revoke the determination—the priority applicant specified in the determination.

(4) The Minister must reconsider the initial decision as soon as practicable after receiving a request under subregulation (3), and may:
   (a) confirm the initial decision; or
   (b) revoke the initial decision; or
   (c) revoke the initial decision and make a decision in substitution for the initial decision.

(5) After reconsidering an initial decision, the Minister must give to the applicant a notice in writing stating:
   (a) the result of the reconsideration; and
   (b) that the applicant may, unless subsection 28(4) of the *Administrative Appeals Tribunal Act 1975* applies:
      (i) apply for a statement setting out the reasons for the decision on reconsideration; and
      (ii) subject to that Act, make an application to the Administrative Appeals Tribunal for review of that decision.

(6) If a person who makes a request under subregulation (3) does not receive notice of the decision of the Minister on reconsideration within 60 days after making the request, the Minister is taken to have confirmed the initial decision.

(7) If written notice of the making of an initial decision is given to a person whose interests are affected by the decision, the notice must include a statement to the effect that a person whose interests are affected by the decision may:
   (a) seek a reconsideration of the decision under this regulation; and
   (b) subject to the *Administrative Appeals Tribunal Act 1975*, if the person is dissatisfied with the decision upon reconsideration, make an application to the Administrative Appeals Tribunal for review of that decision.

(8) Any failure to comply with the requirements of subregulation (6) or (7) in relation to a decision does not affect the validity of the decision.

(9) Application may be made to the Administrative Appeals Tribunal for review of a reviewable decision.

Note: Under section 27A of the *Administrative Appeals Tribunal Act 1975*, the decision-maker must give to any person whose interests are affected by the decision notice, in writing or otherwise, of the making of the decision and of the person's right to have the decision reviewed. In giving that notice, the decision-maker must have regard to the Code of Practice determined under section 27B of that Act (*Gazette* No. S 342, 7 December 1994), accessible on the Internet at: http://scaleplus.law.gov.au/html/instruments/0/14/0/IN000020.htm

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Part 11—Transitional provisions

Division 11.1—Transitional provisions relating to the Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 1)

Subdivision A—Preliminary

11.1 Interpretation

(1) In this Division:

2010 Amendment Regulations means the *Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 1)* as in force immediately before 1 July 2014.

approved transitional device means an IVD medical device (other than an in-house IVD medical device) that, immediately before 1 July 2010:

(a) was a diagnostic good for in vitro use; and

(b) was declared not to be a medical device under subsection 41BD(3) of the Act; and

(c) was:

(i) exempt from listing or registration under Part 3-2 of the Act because item 3 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applied to the device; or

(ii) covered by an approval under paragraph 19(1)(b) of the Act; or

(iii) a device for which an application for approval under paragraph 19(1)(b) of the Act had been made but not finally determined.

diagnostic good for in vitro use has the same meaning as in the *Therapeutic Goods Regulations 1990* as in force on 30 June 2010.

exempt transitional device means an IVD medical device (other than an in-house IVD medical device) that, immediately before 1 July 2010:

(a) was a diagnostic good for in vitro use; and

(b) was declared not to be a medical device under subsection 41BD(3) of the Act; and

(c) was exempt from listing or registration under Part 3-2 of the Act; and

(d) was not a device to which item 3 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applied.

listed or registered transitional device means an IVD medical device (other than an in-house IVD medical device) that, immediately before 1 July 2010:

(a) was a diagnostic good for in vitro use; and

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(b) was declared not to be a medical device under subsection 41BD(3) of the Act; and

(c) was:

(i) listed or registered under Part 3-2 of the Act; or

(ii) a device for which an effective application for listing or registration under Part 3-2 of the Act had been made but not finally determined.

transitional device means:

(a) a Class 1 in-house IVD medical device that is in existence before 1 July 2017; or

(b) a Class 2 in-house IVD medical device that is in existence before 1 July 2017; or

(c) a Class 3 in-house IVD medical device that is in existence before 1 July 2017; or

(d) a Class 4 in-house IVD medical device that is in existence before 1 July 2016; or

(e) a listed or registered transitional device; or

(f) an approved transitional device; or

(g) an exempt transitional device.

transitional period means:

(a) for a transitional device that is not an in-house IVD medical device—the period starting on 1 July 2014 and ending immediately before the transition day for the device; and

(b) for a transitional device that is an in-house IVD medical device—the period starting on the later of:

(i) 1 July 2014; and

(ii) the day the device comes into existence;

and ending immediately before the transition day for the device.

transition day, for a transitional device, means the day on which Schedule 1 to the 2010 Amendment Regulations starts to apply, for all purposes, in relation to the device.

*Meaning of **finally determined***

(2) For this Division, an application is ***finally determined*** at the first time both the following conditions are met:

(a) a decision has been made not to grant the application;

(b) there is no longer any possibility of a change in the outcome of the decision.

(3) For paragraph (2)(b), the possibility of a discretion being exercised after the period has ended, to extend the period for seeking review by a court or tribunal of the decision or for starting other proceedings (including appeals) arising out of the application, decision or review, is not to be considered.

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References to including a device in the Register

(4) In this Division, a reference to including a device in the Register is a reference to including the device in the Register under Chapter 4 of the Act.

11.2 Application of 2010 Amendment Regulations

(1) The amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to a transitional device as set out in Subdivisions C to F of this Division unless:
  (a) the device was included in the Register before 1 July 2014; or
  (b) an effective application for including the device in the Register was made before 1 July 2014 and the application was finally determined before that date.

(2) To avoid doubt, the amendments made by Schedule 1 to the 2010 Amendment Regulations apply, for all purposes, on and after 1 July 2014 in relation to:
  (a) a transitional device covered by paragraph (1)(a); and
  (b) a transitional device covered by paragraph (1)(b); and
  (c) an IVD medical device that is not a transitional device.

Subdivision B—General provisions relating to transitional devices

11.3 Application of this Subdivision

This Subdivision applies in relation to a transitional device unless:
  (a) the device was included in the Register before 1 July 2014; or
  (b) an effective application for including the device in the Register was made before 1 July 2014 and the application was finally determined before that date.

11.4 Transitional devices exempted from requirement to be included in the Register

(1) For paragraph 41HA(1)(b) of the Act, a transitional device is exempt from the operation of Division 3 of Part 4-11 of the Act during the transitional period for the device.

(2) Subregulation 7.1(3) does not apply in relation to a transitional device during the transitional period for the device.

(3) Regulation 3.10 does not apply in relation to a transitional device, during the transitional period for the device, for a purpose connected with:
  (a) an application for a conformity assessment certificate in respect of the device; or
  (b) issuing a conformity assessment certificate in respect of the device; or
  (c) an application for including the device in the Register; or
  (d) including the device in the Register.

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11.5 Essential principles for transitional devices

(1) For section 41CA of the Act, the essential principles set out in clauses 3 and 6 of Schedule 1 to these Regulations, as in force immediately before 1 July 2010, are prescribed for a transitional device during the transitional period for the device, for a purpose other than a purpose mentioned in subregulation (2).

(2) Regulation 2.1 and Schedule 1 to these Regulations as in force on and after 1 July 2010 apply in relation to a transitional device for a purpose connected with:

(a) an application for a conformity assessment certificate in respect of the device; or

(b) issuing a conformity assessment certificate in respect of the device; or

(c) an application for including the device in the Register; or

(d) including the device in the Register;

and not for any other purpose, during the transitional period for the device.

Subdivision C—Listed or registered transitional devices and exempt transitional devices

11.6 Application of this Subdivision

This Subdivision applies in relation to the following devices:

(a) a listed or registered transitional device;

(b) an exempt transitional device.

11.7 Application of 2010 Amendment Regulations—certain purposes

The amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, on and after 1 July 2014, for purposes connected with:

(a) an application for a conformity assessment certificate in respect of the device; or

(b) issuing a conformity assessment certificate in respect of the device; or

(c) an application for including the device in the Register; or

(d) including the device in the Register.

11.8 Application of 2010 Amendment Regulations—conformity assessment certificate required and applied for before 1 September 2014

(1) This regulation applies in relation to the device if:

(a) a conformity assessment certificate is required under section 41EA of the Act before an effective application for including the device in the Register may be made; and

(b) an effective application for a conformity assessment certificate in respect of the device is made before 1 September 2014.

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Certificate issued and inclusion application made before 1 July 2015—device included in Register

(2) If:

(a) a conformity assessment certificate in respect of the device is issued before 1 June 2015; and

(b) an effective application for including the device in the Register is made before 1 July 2015; and

(c) the device is included in the Register;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the device is included in the Register.

Certificate issued and inclusion application made before 1 July 2015—device not included in Register

(3) If:

(a) a conformity assessment certificate in respect of the device is issued before 1 June 2015; and

(b) an effective application for including the device in the Register is made before 1 July 2015; and

(c) the application for including the device in the Register is finally determined;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the application for including the device in the Register is finally determined.

Certificate issued but inclusion application not made before 1 July 2015

(4) If:

(a) a conformity assessment certificate in respect of the device is issued before 1 June 2015; and

(b) an effective application for including the device in the Register is not made before 1 July 2015;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after 1 July 2015.

Certificate issued on or after 1 June 2015 and inclusion application made within 30 days—device included in Register

(5) If:

(a) a conformity assessment certificate in respect of the device is issued on or after 1 June 2015; and

(b) an effective application for including the device in the Register is made no later than 30 days after the day the certificate is issued; and

(c) the device is included in the Register;

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the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the device is included in the Register.

Certificate issued on or after 1 June 2015 and inclusion application made within 30 days—device not included in Register

(6) If:

(a) a conformity assessment certificate in respect of the device is issued on or after 1 June 2015; and

(b) an effective application for including the device in the Register is made no later than 30 days after the day the certificate is issued; and

(c) the application for including the device in the Register is finally determined;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on the day the application for including the device in the Register is finally determined.

Certificate issued on or after 1 June 2015 but inclusion application not made within 30 days

(7) If:

(a) a conformity assessment certificate in respect of the device is issued on or after 1 June 2015; and

(b) an effective application for including the device in the Register is not made within 30 days after the day the certificate is issued;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, 30 days after the day the certificate is issued.

Certificate application finally determined and certificate not issued

(8) If the application for the conformity assessment certificate is finally determined, the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the application for the certificate is finally determined.

11.9 Application of 2010 Amendment Regulations—conformity assessment certificate required but not applied for before 1 September 2014

If:

(a) a conformity assessment certificate is required under section 41EA of the Act before an effective application for including the device in the Register may be made; and

(b) an effective application for a conformity assessment certificate in respect of the device is not made before 1 September 2014;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after 1 September 2014.

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Regulation 11.10

11.10 Application of 2010 Amendment Regulations—conformity assessment certificate not required

(1) This regulation applies in relation to the device if a conformity assessment certificate is not required under section 41EA of the Act before an effective application for including the device in the Register may be made.

Inclusion application made before 1 July 2015—device included in Register

(2) If:

(a) an effective application for including the device in the Register is made before 1 July 2015; and

(b) the device is included in the Register;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the device is included in the Register.

Inclusion application made before 1 July 2015—device not included in Register

(3) If:

(a) an effective application for including the device in the Register is made before 1 July 2015; and

(b) the application for including the device in the Register is finally determined;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the application for including the device in the Register is finally determined.

Inclusion application not made before 1 July 2015

(4) If an effective application for including the device in the Register is not made before 1 July 2015, the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after 1 July 2015.

11.11 Cancellation of listing or registration

If a listed or registered transitional device is listed or registered under Part 3-2 of the Act immediately before 1 July 2014, the listing or registration is taken to be cancelled on the transition day for the device.

Subdivision D—Approved transitional devices

11.12 Application of this Subdivision

This Subdivision applies in relation to an approved transitional device.

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11.13 Application of 2010 Amendment Regulations—certain purposes

The amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to an approved transitional device, on and after 1 July 2014, for purposes connected with:

(a) an application for a conformity assessment certificate in respect of the device; or

(b) issuing a conformity assessment certificate in respect of the device; or

(c) an application for including the device in the Register; or

(d) including the device in the Register.

11.14 Application of 2010 Amendment Regulations—all purposes

The amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to an approved transitional device, for all purposes, on and after:

(a) if the device is covered by subparagraph (c)(i) of the definition of ***approved transitional device*** in subregulation 11.1(1)—the day the device ceases to be a device to which item 3 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applies; and

(b) if the device is covered by subparagraph (c)(ii) of the definition of ***approved transitional device*** in subregulation 11.1(1)—the day the approval for the device ceases to have effect; and

(c) if the device is covered by subparagraph (c)(iii) of the definition of ***approved transitional device*** in subregulation 11.1(1):

(i) if approval is given for the device under paragraph 19(1)(b) of the Act—the day the approval ceases to have effect; and

(ii) in any other case—the day the application for approval is finally determined.

Subdivision E—Class 4 in-house IVD medical devices

11.15 Application of this Subdivision

This Subdivision applies in relation to a transitional device that is a Class 4 in-house IVD medical device.

11.16 Application of 2010 Amendment Regulations—certain purposes

The amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device on and after the later of the following days:

(a) 1 July 2014;

(b) the day on which the device comes into existence;

for purposes connected with:

(c) an application for a conformity assessment certificate in respect of the device; or

(d) issuing a conformity assessment certificate in respect of the device; or

(e) an application for including the device in the Register; or

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(f) including the device in the Register.

11.17 Application of 2010 Amendment Regulations—conformity assessment certificate applied for before 1 July 2016

(1) This regulation applies in relation to the device if an application for a conformity assessment certificate in respect of the device is made before 1 July 2016.

Certificate issued and inclusion application made before 1 July 2017—device included in Register

(2) If:

(a) a conformity assessment certificate in respect of the device is issued before 1 June 2017; and

(b) an effective application for including the device in the Register is made before 1 July 2017; and

(c) the device is included in the Register;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the device is included in the Register.

Certificate issued and inclusion application made before 1 July 2017—device not included in Register

(3) If:

(a) a conformity assessment certificate in respect of the device is issued before 1 June 2017; and

(b) an effective application for including the device in the Register is made before 1 July 2017; and

(c) the application for including the device in the Register is finally determined;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the application for including the device in the Register is finally determined.

Certificate issued but inclusion application not made before 1 July 2017

(4) If:

(a) a conformity assessment certificate in respect of the device is issued before 1 June 2017; and

(b) an effective application for including the device in the Register is not made before 1 July 2017;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after 1 July 2017.

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Certificate issued on or after 1 June 2017 and inclusion application made within 30 days—device included in Register

(5) If:

(a) a conformity assessment certificate in respect of the device is issued on or after 1 June 2017; and

(b) an effective application for including the device in the Register is made no later than 30 days after the day the certificate is issued; and

(c) the device is included in the Register;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the device is included in the Register.

Certificate issued on or after 1 June 2017 and inclusion application made within 30 days—device not included in Register

(6) If:

(a) a conformity assessment certificate in respect of the device is issued on or after 1 June 2017; and

(b) an effective application for including the device in the Register is made no later than 30 days after the day the certificate is issued; and

(c) the application for including the device in the Register is finally determined;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on the day the application for including the device in the Register is finally determined.

Certificate issued on or after 1 June 2017 and inclusion application not made within 30 days

(7) If:

(a) a conformity assessment certificate in respect of the device is issued on or after 1 June 2017; and

(b) an effective application for including the device in the Register is not made within 30 days after the day the certificate is issued;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, 30 days after the day the certificate is issued.

(8) If the amendments made by Schedule 1 to the 2010 Amendment Regulations do not apply in relation to the device, for all purposes, under any of subregulations (2) to (7) of this regulation, then the amendments apply in relation to the device under regulation 11.18.

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Regulation 11.18

11.18 Application of 2010 Amendment Regulations—devices not covered by regulation 11.17

(1) This regulation applies in relation to the device if the amendments made by Schedule 1 to the 2010 Amendment Regulations do not apply in relation to the device, for all purposes, under any of subregulations 11.17(2) to (7).

Note 1: This regulation will apply, for example, in relation to a device if an application for a conformity assessment certificate is not made in respect of the device before 1 July 2016.

Note 2: The amendments made by Schedule 1 to the 2010 Amendment Regulations are affected by amendments made by Part 1 of Schedule 1 to the *Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015*. Regulation 11.25 deals with the application of those 2015 amendments.

Inclusion application made before 1 July 2017—device included in Register

(2) If:
(a) an effective application for including the device in the Register is made before 1 July 2017; and
(b) the device is included in the Register;
the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the device is included in the Register.

Inclusion application made before 1 July 2017—application withdrawn or finally determined

(3) If:
(a) an effective application for including the device in the Register is made before 1 July 2017; and
(b) the application is withdrawn or is finally determined;
the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the application is withdrawn or is finally determined (as the case may be).

Inclusion application not made before 1 July 2017

(4) If an effective application for including the device in the Register is not made before 1 July 2017, the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after 1 July 2017.

Subdivision F—Class 1, 2 and 3 in-house IVD medical devices

11.20 Application of this Subdivision

This Subdivision applies in relation to a transitional device that is any of the following:
(a) a Class 1 in-house IVD medical device;

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(b) a Class 2 in-house IVD medical device;

(c) a Class 3 in-house IVD medical device.

11.21 Application of 2010 Amendment Regulations for all purposes

The amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after 1 July 2017.

Note: The amendments made by Schedule 1 to the 2010 Amendment Regulations are affected by amendments made by Part 2 of Schedule 1 to the *Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015*. Regulation 11.26 deals with the application of those 2015 amendments.

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Division 11.2—Transitional provisions relating to joint replacements

11.22A Purpose of this Division

This Division includes transitional provisions relating to:

(a) the *Therapeutic Goods (Medical Devices) Amendment Regulation 2012 (No. 1)*; and

(b) the *Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) Regulation 2015*.

11.22 Certain Class IIb medical devices

(1) This regulation applies to a joint replacement medical device.

Note: ***Joint replacement medical device*** is defined in the Dictionary.

(2) If an application is made before 1 July 2012 to include a medical device mentioned in subregulation (1) in the Register, but is not finally determined on 1 July 2012, the medical device must be included in the Register as a Class IIb medical device if the application is successful.

(3) If:

(a) a medical device mentioned in subregulation (1) is included in the Register as a Class IIb medical device on or after 1 July 2012; and

(b) an application is made to include the medical device in the Register as a Class III medical device;

no annual charge is payable for inclusion of the medical device in the Register as a Class III medical device until after 30 June 2015.

(4) Subregulation 5.3(1) does not apply to an application mentioned in subregulation (3).

(5) No application fee is payable for an application mentioned in subregulation (3) if the application is made before 1 July 2013.

(6) If a medical device mentioned in subregulation (1) is included in the Register as a Class IIb medical device on 1 July 2015, the inclusion of the medical device in the Register is cancelled on that day, unless:

(a) an application was made before 1 July 2015 for the medical device to be included in the Register as a Class III medical device; and

(b) the Secretary has not decided whether or not to include the medical device in the Register.

(7) If the application mentioned in paragraph (6)(a) is unsuccessful, the inclusion of the Class IIb medical device in the Register is cancelled on the later of 1 July 2015 and the day that notification is given to the applicant that the application was not successful.

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(8) In this regulation, an application is finally determined at the first time that both the following conditions are met:

(a) a decision has been made whether or not to grant the application;

(b) there is no longer any possibility of a change in the outcome of the decision.

(9) For paragraph 8(b), the exercise of a discretion, after the period has ended, to extend a period for seeking review by a court or tribunal of the decision or for starting other proceedings (including appeals) arising out of the application, decision or review is not to be considered.

11.23 Refund of fees in relation to inclusion of certain devices in the Register as Class III medical devices

(1) This regulation applies in relation to an implantable medical device if:

(a) the device is of the kind referred to in subregulation 11.22(1) of the old Regulations; and

(b) the device is not a joint replacement medical device; and

(c) an application to include the device in the Register as a Class III medical device was made on or after 1 July 2012 and before the commencement of the amending Regulation.

Note: Subregulation 11.22(1) of the old Regulations referred to an implantable medical device that is intended by the manufacturer to be any of the following:

(a) a total or partial shoulder joint replacement;

(b) a total or partial hip joint replacement;

(c) a total or partial knee joint replacement.

(2) The Secretary may refund any fee paid in relation to the application.

(3) If any annual charge has been paid in respect of the inclusion of the device in the Register as a Class III medical device, the Secretary may refund the difference between the annual charge paid and the annual charge that would have been payable in respect of the inclusion of the device in the Register as a Class IIb medical device.

(4) In this regulation:

amending Regulation means the *Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) Regulation 2015*.

old Regulations means these Regulations as in force immediately before the commencement of the amending Regulation.

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Division 11.3—Transitional provisions relating to the Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015

11.24 Definitions

In this Division:

2010 Amendment Regulations has the meaning given by regulation 11.1.

2015 Amendment Regulations means the *Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015*.

commencement day means the day this Division commences.

transitional device has the meaning given by regulation 11.1.

transition day has the meaning given by regulation 11.1.

11.25 Application of 2015 Amendment Regulations—transitional Class 4 in-house IVD medical devices

(1) This regulation applies in relation to a transitional device that is a Class 4 in-house IVD medical device.

(2) The amendments made by Part 1 of Schedule 1 to the 2015 Amendment Regulations apply in relation to the device, for a purpose connected with a matter mentioned in any of paragraphs 11.16(c) to (f), on and after the later of the following days:
  (a) the commencement day;
  (b) the day on which the device comes into existence.

(3) The amendments made by Part 1 of Schedule 1 to the 2015 Amendment Regulations apply in relation to the device, for all purposes, on and after the later of the following days:
  (a) the commencement day;
  (b) the transition day for the device.

11.26 Application of 2015 Amendment Regulations etc.—transitional Class 1, 2 and 3 in-house IVD medical devices

(1) This regulation applies in relation to a transitional device that is a Class 1 in-house IVD medical device, Class 2 in-house IVD medical device or Class 3 in-house IVD medical device.

(2) Subject to subregulations (3) and (4), the amendments made by Part 2 of Schedule 1 to the 2015 Amendment Regulations apply in relation to the device for all purposes, on and after 1 July 2017.

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(3) If, before the commencement day, the manufacturer of the device has notified the Secretary of the matters referred to in subclause 1.2(1) of Part 6A of Schedule 3 (as inserted by Schedule 1 to the 2010 Amendment Regulations), the manufacturer is taken to have complied with the notification requirements in subclauses 6A.2(1) and (2) and paragraph (3)(a) of Part 6A of Schedule 3 in relation to the devices covered by the notification.

(4) If:

(a) on or after the commencement day and before 1 July 2017, the manufacturer of the device notifies the Secretary of the Class 1, 2 or 3 in-house IVD medical devices being manufactured; and

(b) the notification is in accordance with subclauses 6A.2(2) and (3) of Part 6A of Schedule 3;

the manufacturer is taken to have complied with the notification requirements in subclauses 6A.2(1) and (2) and paragraph (3)(a) of Part 6A of Schedule 3 in relation to the devices covered by the notification.

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Division 11.4—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (Charges Exemptions and Other Measures) Regulation 2016

11.27 Application

(1) The amendments made by items 1, 12 and 13 of Schedule 3 to the *Therapeutic Goods Legislation Amendment (Charges Exemptions and Other Measures) Regulation 2016* apply in relation to medical devices included in the Register on or after the day that Schedule commences if the application for inclusion in the Register was made on or after that day.

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Division 11.5—Transitional provisions relating to the Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017

11.28 Definitions

In this Division:

amending regulations means the *Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017*.

finally determined has the meaning given by subregulation 11.29(5).

inclusion day for an entry of a kind of medical device in the Register means the day on which the inclusion of that kind of device in the Register commences.

pre-commencement entry: an entry of a kind of medical device in the Register is a ***pre-commencement entry*** if that kind of medical device is included in the Register because of an application made before 1 December 2018 (whether the inclusion day for the entry occurred before, on or after 1 December 2018).

unique product identifier, in relation to a medical device, means the unique product identifier given to the device by its manufacturer to identify the device and any variants.

11.29 Surgical mesh—application of amendments

Applications and entries other than pre-commencement entries

(1) The amendment made by Part 1 of Schedule 1 to the amending regulations applies on and after 1 December 2018 in relation to the following:
  (a) an application for a kind of medical device to be included in the Register, if the application is made on or after 1 December 2018;
  (b) an entry of a kind of medical device in the Register that is not a pre-commencement entry.

Pre-commencement entries

(2) Subject to subregulations (3) and (4A), the amendment made by Part 1 of Schedule 1 to the amending regulations applies in relation to a pre-commencement entry of a kind of medical device on and after:
  (a) if medical devices of that kind are urogynaecological mesh—1 December 2020; or
  (b) otherwise—1 December 2021.

(3) The amendment does not apply in relation to the pre-commencement entry before the day mentioned in subregulation (4) if:
  (a) the person applies under the Act:

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(i) on or after the inclusion day for the pre-commencement entry; and
(ii) on or after the commencement of Part 11 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*; and
(iii) before 1 December 2021;

to have a kind of medical device included in the Register; and

(b) that kind of medical device is surgical mesh (other than urogynaecological mesh).

(4) For the purposes of subregulation (3), the day is the day after the day on which:
(a) the person withdraws the application mentioned in paragraph (3)(a); or
(b) that application lapses under section 41FK of the Act; or
(c) that application is finally determined.

(4A) The amendment referred to in subregulation (2) does not apply in relation to the pre-commencement entry before the day applicable under subregulation (4B) if:
(a) the kind of medical device covered by that entry is surgical mesh (other than urogynaecological mesh); and
(b) the person has not made an application of the kind covered by subregulation (3) (as in force before or after the commencement of this subregulation) before 1 December 2021; and
(c) on or after 1 July 2020 and before 1 December 2021, the person made an application under section 41EB of the Act for a conformity assessment certificate in respect of a kind of medical device that is surgical mesh (other than urogynaecological mesh); and
(d) the person has not withdrawn that application before 1 December 2021; and
(e) that application has not lapsed under section 41EG of the Act before 1 December 2021; and
(f) if the conformity assessment certificate was issued before 1 December 2021—the period of 6 months beginning on the day of the issue of the certificate has not ended before 1 December 2021.

(4B) For the purposes of subregulation (4A), the day applicable under this subregulation is the later of 1 December 2021 and the day after the earliest of the following days:
(a) the day the person withdraws the application mentioned in paragraph (4A)(c);
(b) the day that application lapses under section 41EG of the Act;
(c) in the case of a decision to refuse to issue the conformity assessment certificate and where there is no longer any possibility of a change in the outcome of that decision—the first day on which there is no longer that possibility;
(d) if the conformity assessment certificate was issued:
(i) if, at the end of the period of 6 months beginning on the day of the issue of the certificate, the person has not made an application under the Act to have the kind of medical device referred to in

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paragraph (4A)(c) included in the Register—the last day of that 6-month period; or

(ii) if, before the end of the period of 6 months beginning on the day of the issue of the certificate, the person has made an application under the Act to have the kind of medical device referred to in paragraph (4A)(c) included in the Register—the relevant day under subregulation (4C).

(4C) For the purposes of subparagraph (4B)(d)(ii), the ***relevant day*** is:

(a) the day the person withdraws the application mentioned in that subparagraph; or

(b) the day that application lapses under section 41FK of the Act; or

(c) the day on which that application is finally determined;

whichever occurs first.

(5) For the purposes of this regulation, an application is ***finally determined*** at the first time both the following conditions are met:

(a) a decision has been made whether or not to grant the application;

(b) there is no longer any possibility of a change in the outcome of the decision.

11.31 Patient information—application of amendments

Devices other than urogynaecological mesh

(1) The amendments made by Part 2 of Schedule 1 to the amending regulations apply on and after the day mentioned in column 1 of an item of the following table:

(a) to the extent that the amendments relate to a patient implant card or patient information leaflet mentioned in column 2 of the item; and

(b) in relation to:

(i) an application for a kind of medical device to be included in the Register; or

(ii) an entry of a kind of medical device in the Register;

mentioned in column 3 of the item;

if devices of that kind are not urogynaecological mesh.

Entries and applications relating to medical devices other than urogynaecological mesh

Item	Column 1 Day amendments start applying	Column 2 Card or leaflet	Column 3 Application or entry
1	1 December 2018	patient information leaflet	(a) an application made on or after 1 December 2018; or (b) an entry that is not a pre-commencement entry
2	1 December 2020	patient implant card	(a) an application made on or after

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Regulation 11.31

Entries and applications relating to medical devices other than urogynaecological mesh

Item	Column 1 Day amendments start applying	Column 2 Card or leaflet	Column 3 Application or entry
			1 December 2020; or (b) an entry that is not a pre-commencement entry
3	1 December 2021	(a) patient implant card; or (b) patient information leaflet	a pre-commencement entry

Urogynaecological mesh

(2) The amendments made by Part 2 of Schedule 1 to the amending regulations apply on and after the day mentioned in column 1 of an item of the following table in relation to:

(a) an application for a kind of medical device to be included in the Register; or

(b) an entry of a kind of medical device in the Register;

mentioned in column 2 of the item, if devices of that kind are urogynaecological mesh.

Entries and application relating to urogynaecological mesh

Item	Column 1 Day amendments start applying	Column 2 Application or entry
1	1 December 2018	(a) an application made on or after 1 December 2018; or (b) an entry that is not a pre-commencement entry
2	1 December 2019	a pre-commencement entry

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Division 11.6—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (2017 Measures No. 2) Regulations 2017

11.32 Definitions

In this Division:

Amendment Regulations means the *Therapeutic Goods Legislation Amendment (2017 Measures No. 2) Regulations 2017*.

commencement day means the day on which Part 3 of Schedule 4 to the Amendment Regulations commences.

11.33 Application—statements in relation to exempt devices

The amendments of regulations 7.2 and 8.2 of these Regulations made by Part 3 of Schedule 4 to the Amendment Regulations apply in relation to the use of a medical device in or on a person on or after the commencement day.

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Division 11.7—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (Exempt Devices and Goods) Regulations 2018

11.34 Application of amendments

The amendments of these Regulations made by the *Therapeutic Goods Legislation Amendment (Exempt Devices and Goods) Regulations 2018* apply to a medical device imported into Australia:

(a) on or after the commencement of this regulation; or

(b) during the 12 months ending immediately before that commencement, if the device was held under the direct control of the sponsor immediately before that commencement.

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Division 11.8—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018

11.35 Application—regulation 4.3G (conditions applying automatically to conformity assessment certificates)

Regulation 4.3G applies to a conformity assessment certificate issued before, on or after 1 July 2018.

11.36 Application—regulation 5.13 (conditions applying automatically to medical devices included in the Register)

Regulation 5.13 applies to a kind of medical device included in the Register before, on or after 1 July 2018.

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Division 11.9—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (2018 Measures No. 3) Regulations 2018

11.37 Application of table item 1.5 in Part 1 of Schedule 5

(1) Table item 1.5 in Part 1 of Schedule 5, as amended by the *Therapeutic Goods Legislation Amendment (2018 Measures No. 3) Regulations 2018*, applies in relation to applications made on or after 1 July 2018.

(2) If, on or after 1 July 2018 and before the commencement of Part 1 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2018 Measures No. 3) Regulations 2018*, a person:

(a) applied for the inclusion in the Register of a Class I medical device intended by the manufacturer to be for export only; and

(b) paid the fee prescribed in relation to that application by table item 1.5 in Part 1 of Schedule 5 to these Regulations as in force before that commencement;

the Secretary must refund to the person the difference between the fee paid and the fee prescribed in relation to the application by that table item as in force after that commencement.

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Division 11.10—Application and transitional provisions relating to the Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019

Subdivision A—Definitions

11.38 Definitions

In this Division:

amending regulations means the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*.

finally determined: an application is finally determined at the first time both the following conditions are met:

(a) a decision has been made whether or not to grant the application;

(b) there is no longer any possibility of a change in the outcome of the decision.

unique product identifier, in relation to a medical device, means the unique product identifier given to the device by its manufacturer to identify the device and any variants.

Subdivision B—Reclassification of medical devices

11.39 Definitions

In this Subdivision:

inclusion day for an entry of a kind of transitional medical device in the Register means the day on which the inclusion of that kind of device in the Register commences.

pre-commencement entry: an entry of a kind of transitional medical device in the Register is a ***pre-commencement entry*** if that kind of medical device is included in the Register because of an application made before 25 November 2021 (whether the inclusion day for the entry occurred before, on or after 25 November 2021).

transitional AIMD device means a transitional medical device of a kind mentioned in column 1 of item 2 of the table in the definition of ***transitional medical device***.

transitional medical device means a medical device of a kind mentioned in column 1 of an item in the following table if:

(a) the medical device is, immediately before 25 November 2021, included in the Register and classified as a class of medical device mentioned in column 2 of the item; or

(b) on 25 November 2021:

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(i) the medical device was the subject of a class of application mentioned in column 2 of the item for inclusion in the Register; and

(ii) the application had not been finally determined.

Transitional medical device		
Item	**Column 1** **Kind of medical device**	**Column 2** **Class of medical device or application**
1	a medical device of a kind described in subclause 3.4(4B) of Schedule 2	Class IIb
2	an active implantable medical device	Class AIMD
3	a medical device of a kind described in clause 5.10 of Schedule 2	Class I or Class IIa
4	a medical device of a kind described in clause 5.11 of Schedule 2	Class I, Class IIa or Class IIb
5	a medical device of a kind described in subclause 4.2(4) of Schedule 2	Class IIa or Class IIb
6	a medical device of a kind described in subclause 3.2(3A) of Schedule 2	Class IIa or Class IIb

11.40 Transitional medical devices—application of amendments

Applications and entries other than for transitional medical devices

(1) The amendments made by Parts 1 to 6 of Schedule 1 to the amending regulations, and the amendments made by Part 4 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, apply on and after 25 November 2021 in relation to the following:

(a) an application for a kind of medical device to be included in the Register that is made on or after 25 November 2021;

(b) a kind of medical device that is included in the Register as a result of such an application.

Applications and entries for transitional medical devices

(2) Subject to subregulations (3) and (5), the amendments made by Parts 1 to 6 of Schedule 1 to the amending regulations, and the amendments made by Part 4 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, apply in relation to a transitional medical device on and after 1 November 2024.

(3) The amendments made by Parts 1 to 6 of Schedule 1 to the amending regulations, and the amendments made by Part 4 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, do not apply in relation to a transitional medical device before the day applicable under subregulation (4) if:

(a) a person applies under the Act:
  (i) on or after the inclusion day for the entry of the transitional medical device; and
  (ii) on or after 25 November 2021; and
  (iii) before 1 November 2024;
  to have a kind (the ***new kind***) of medical device included in the Register; and
(b) the person gives to the Secretary a notice under regulation 11.41 in relation to the transitional medical device; and
(c) the unique product identifier of the device of the new kind is the unique product identifier, or one of the unique product identifiers, stated in the notice.

(4) For the purposes of subregulation (3), the day is the day after the day on which:
(a) the person withdraws the application mentioned in paragraph (3)(a); or
(b) that application lapses under section 41FK of the Act; or
(c) that application is finally determined.

(5) If:
(a) a person is required under regulation 11.41 to give a notice to the Secretary in relation to a transitional medical device; and
(b) the person fails to give the notice in accordance with that regulation before the later of:
  (i) 25 May 2022; and
  (ii) the day occurring 2 months after the inclusion day for the entry of the transitional medical device;

then the amendments made by Parts 1 to 6 of Schedule 1 to the amending regulations, and the amendments made by Part 4 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, apply in relation to the transitional medical device on and after the later of those days.

11.41 Transitional medical devices—Secretary must be notified of unique product identifiers of devices supplied under pre-commencement entries

(1) For the purposes of subsection 41FN(5A) of the Act, a person must give to the Secretary a notice in accordance with subregulation (2) if:
(a) a kind of medical device is included in the Register in relation to the person; and
(b) the entry of that kind of medical device is a pre-commencement entry; and
(c) a medical device of that kind is a transitional medical device.

(2) The notice must:
(a) be in writing; and
(b) state:

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(i) the unique device number assigned to that kind of device under section 41FL of the Act; and

(ii) the unique product identifier given to each medical device (if any) of that kind that the person supplies in Australia; and

(c) be given to the Secretary before the later of:

(i) 25 May 2022; and

(ii) the day occurring 2 months after the inclusion day for the entry of the transitional medical device.

11.42 Transitional medical devices—selecting applications for auditing

Subregulation 5.3(1) does not apply to an application for inclusion of a kind of medical device in the Register as a Class III medical device if the application is for a transitional AIMD device.

11.43 Waiver of certain application fees

(1) This regulation applies in relation to an application to include in the Register a transitional AIMD device as a Class III medical device.

(2) The Secretary must waive the fee set out in paragraph (b) of column 2 in item 1.5 of the table in Part 1 of Schedule 5 in relation to the application.

(3) This regulation ceases to have effect at the end of 24 November 2022.

Subdivision C—Programmed or programmable medical device or software that is a medical device

11.44 Definitions

In this Subdivision:

inclusion day for an entry of a kind of medical device in the Register means the day on which the inclusion of that kind of device in the Register commences.

transitional kind of medical device means a kind of medical device included in the Register because of an application made before 25 February 2021 (whether the inclusion day for the entry of that kind of medical device occurred before, on or after that day).

11.45 Programmed or programmable medical device or software that is a medical device—classification rules

Applications and entries other than a transitional kind of medical device

(1) Clauses 4.5 to 4.8 of Schedule 2, as added by Schedule 2 to the amending regulations, apply on and after 25 February 2021 in relation to the following:

(a) an application for a kind of medical device to be included in the Register that is made on or after 25 February 2021;

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(b) a kind of medical device that is included in the Register as a result of such an application.

Transitional kind of medical device

(2) Subject to subregulations (3) and (5), clauses 4.5 to 4.8 of Schedule 2, as added by Schedule 2 to the amending regulations, apply in relation to a transitional kind of medical device on and after 1 November 2024.

(3) Clauses 4.5 to 4.8 of Schedule 2, as added by Schedule 2 to the amending regulations, do not apply in relation to a transitional kind of medical device before the day applicable under subregulation (4) if:

(a) the person applies under the Act:

(i) on or after the inclusion day for the entry of the transitional kind of medical device; and

(ii) on or after 25 February 2021; and

(iii) before 1 November 2024;

to have a kind (the ***new kind***) of medical device included in the Register; and

(b) the person gives to the Secretary a notice under regulation 11.46 in relation to the transitional kind of medical device; and

(c) the unique product identifier of the devices of the new kind is the unique product identifier, or one of the unique product identifiers, stated in the notice.

(4) For the purposes of subregulation (3), the day is the day after the day on whichever of the following events occurs first:

(a) the person withdraws the application mentioned in paragraph (3)(a);

(b) that application lapses under section 41FK of the Act;

(c) that application is finally determined.

(5) If:

(a) a person is required under regulation 11.46 to give a notice to the Secretary in relation to a transitional kind of medical device; and

(b) the person fails to give the notice in accordance with that regulation before the later of:

(i) 25 August 2021; and

(ii) the day occurring 2 months after the inclusion day for the entry of the transitional kind of medical device;

then clauses 4.5 to 4.8 of Schedule 2, as added by Schedule 2 to the amending regulations, apply in relation to the transitional kind of medical device on and after the later of those days.

11.46 Secretary must be notified in relation to a transitional kind of medical device

(1) For the purposes of subsection 41FN(5A) of the Act, a person must give to the Secretary a notice in accordance with subregulation (2) if:

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(a) a kind of medical device is included in the Register in relation to the person; and

(b) the kind of medical device so included is a transitional kind of medical device; and

(c) medical devices of that kind are programmed or programmable medical devices or software.

(2) The notice must:

(a) be in writing; and

(b) state:

(i) the unique device number assigned to that kind of device under section 41FL of the Act; and

(ii) the unique product identifier given to each medical device (if any) of that kind that the person supplies in Australia; and

(c) be given to the Secretary before the later of:

(i) 25 August 2021; and

(ii) the day occurring 2 months after the inclusion day for the entry of the transitional kind of medical device.

11.47 Programmed or programmable medical device or software that is a medical device—essential principles

(1) Clause 13B of Schedule 1, as inserted by Schedule 2 to the amending regulations, applies on and after 25 February 2021 in relation to the following:

(a) an application for a kind of medical device to be included in the Register that is made on or after 25 February 2021;

(b) a kind of medical device that is included in the Register as a result of such an application.

(2) Clause 13B of Schedule 1, as inserted by Schedule 2 to the amending regulations, applies in relation to a transitional kind of medical device on and after 1 November 2024.

Subdivision D—Personalised medical devices

11.48 Definitions

In this Subdivision:

inclusion day for an entry of a kind of medical device in the Register means the day on which the inclusion of that kind of device in the Register commences.

transitional kind of medical device means a kind of medical device included in the Register because of an application made before 25 February 2021 (whether the inclusion day for the entry of that kind of medical device occurred before, on or after that day).

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11.49 Personalised medical devices—reports

(1) Subregulation 10.3A(1), as inserted by Schedule 3 to the amending regulations, applies in relation to a custom-made medical device that is manufactured on or after 25 February 2021.

(2) Subregulation 10.3A(2), as inserted by Schedule 3 to the amending regulations, applies in relation to a custom-made medical device that is imported into Australia on or after 25 February 2021.

11.50 Personalised medical devices—conformity assessment procedures

(1) The amendments of clause 7.2 of Schedule 3 made by Schedule 3 to the amending regulations apply in relation to a custom-made medical device that is manufactured on or after 25 February 2021.

(2) The repeal and substitution of subclause 7.6(2) of Schedule 3 made by Schedule 3 to the amending regulations applies in relation to a medical device that is manufactured on or after 25 February 2021.

11.51 Personalised medical devices—exemptions

(1) Item 1.5 of the table in Part 1 of Schedule 4, as in force immediately before 25 February 2021, continues to apply on and after that day in relation to the following:

(a) a custom-made medical device (within the meaning of these Regulations as in force immediately before that day) that is manufactured before that day;

(b) a custom-made medical device (within the meaning of these Regulations as in force immediately before that day) that is manufactured on or after that day, where the request from the health professional was made before that day.

(2) Items 2.12 and 2.13 of the table in Part 2 of Schedule 4, as added by Schedule 3 to the amending regulations, apply in relation to a custom-made medical device that is manufactured on or after 25 February 2021, where the request from the health professional is made on or after that day.

(3) Item 2.14 of the table in Part 2 of Schedule 4, as added by Schedule 3 to the amending regulations, applies in relation to a patient-matched medical device if it is manufactured on or after 25 February 2021 and before 1 November 2024.

11.52 Personalised medical devices—classification rules

Applications and entries other than a transitional kind of medical device

(1) Clause 5.4 of Schedule 2, as substituted by Schedule 3 to the amending regulations, applies on and after 25 February 2021 in relation to the following:

(a) an application for a kind of medical device to be included in the Register that is made on or after 25 February 2021;

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(b) a kind of medical device that is included in the Register as a result of such an application.

Transitional kind of medical device

(2) Subject to subregulations (3) and (5), clause 5.4 of Schedule 2, as substituted by Schedule 3 to the amending regulations, applies in relation to a transitional kind of medical device on and after 1 November 2024.

(3) Clause 5.4 of Schedule 2, as substituted by Schedule 3 to the amending regulations, does not apply in relation to a transitional kind of medical device before the day applicable under subregulation (4) if:

(a) the person applies under the Act:

(i) on or after the inclusion day for the entry of the transitional kind of medical device; and

(ii) on or after 25 February 2021; and

(iii) before 1 November 2024;

to have a kind (the ***new kind***) of medical device included in the Register; and

(b) the person gives to the Secretary a notice under regulation 11.53 in relation to the transitional kind of medical device; and

(c) the unique product identifier of the devices of the new kind is the unique product identifier, or one of the unique product identifiers, stated in the notice.

(4) For the purposes of subregulation (3), the day is the day after the day on whichever of the following events occurs first:

(a) the person withdraws the application mentioned in paragraph (3)(a);

(b) that application lapses under section 41FK of the Act;

(c) that application is finally determined.

(5) If:

(a) a person is required under regulation 11.53 to give a notice to the Secretary in relation to a transitional kind of medical device; and

(b) the person fails to give the notice in accordance with that regulation before the later of:

(i) 25 August 2021; and

(ii) the day occurring 2 months after the inclusion day for the entry of the transitional kind of medical device;

then clause 5.4 of Schedule 2, as substituted by Schedule 3 to the amending regulations, applies in relation to the transitional kind of medical device on and after the later of those days.

11.53 Secretary must be notified in relation to a transitional kind of medical device

(1) For the purposes of subsection 41FN(5A) of the Act, a person must give to the Secretary a notice in accordance with subregulation (5) if:

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(a) a kind of medical device is included in the Register in relation to the person; and
(b) the kind of medical device so included is a transitional kind of medical device; and
(c) medical devices of that kind are medical devices that are covered by subregulation (2), (3) or (4).

(2) This subregulation covers a medical device that is intended by the manufacturer to be used to record patient images that are to be used for either or both of the following:
(a) the diagnosis or monitoring of a disease, injury or disability;
(b) the investigation of the anatomy or of a physiological process;
where the images are to be acquired through a method that relies on energy outside the visible spectrum.

(3) This subregulation covers a medical device that is an anatomical model (whether physical or virtual) that is intended by the manufacturer to be used for either or both of the following:
(a) the diagnosis or monitoring of a disease, injury or disability;
(b) the investigation of the anatomy or of a physiological process.

(4) This subregulation covers a programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to generate a virtual anatomical model that is to be used for either or both of the following:
(a) the diagnosis or monitoring of a disease, injury or disability;
(b) the investigation of the anatomy or of a physiological process.

(5) The notice must:
(a) be in writing; and
(b) state:
(i) the unique device number assigned to that kind of device under section 41FL of the Act; and
(ii) the unique product identifier given to each medical device (if any) of that kind that the person supplies in Australia; and
(c) be given to the Secretary before the later of:
(i) 25 August 2021; and
(ii) the day occurring 2 months after the inclusion day for the entry of the transitional kind of medical device.

Subdivision E—IVD companion diagnostics

11.54 IVD companion diagnostics

Applications required to be audited

(1) The amendment of paragraph 5.3(1)(j) by Schedule 4 to the amending regulations applies to applications made on or after 1 February 2020.

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Regulation 11.54

Classification and kind of medical device

(2) Despite the amendments made by Schedule 4 to the amending regulations on 1 February 2020, until 1 July 2022 those amendments:
  (a) do not affect the classification of a device covered by subregulation (3), (4) or (5); and
  (b) do not affect whether such a device is of the same kind as another device.

(3) This subregulation covers an IVD companion diagnostic that, immediately before 1 February 2020, was either a Class 4 in-house IVD medical device or an IVD medical device other than an in-house IVD medical device, and:
  (a) was included in the Register; or
  (b) was the subject of an application for inclusion in the Register that had not been finally determined.

(4) This subregulation covers an IVD companion diagnostic that, immediately before 1 February 2020, was either a Class 4 in-house IVD medical device or an IVD medical device other than an in-house IVD medical device, that:
  (a) was not included in the Register but was covered by a conformity assessment certificate having effect; or
  (b) was proposed to be covered by a conformity assessment certificate for which an application had been made but not finally determined.

(5) This subregulation covers an IVD companion diagnostic that, immediately before 1 February 2020, was:
  (a) a Class 1 in-house IVD medical device; or
  (b) a Class 2 in-house IVD medical device; or
  (c) a Class 3 in-house IVD medical device.

(6) Subregulation (2) does not prevent the making and determination on or after 1 February 2020 and before 1 July 2022 of an application for inclusion in the Register of a device covered by subregulation (3), (4) or (5) in accordance with these Regulations as amended by Schedule 4 to the amending regulations.

(7) Paragraph (h) of item 1.5 of the table in Part 1 of Schedule 5 does not apply to an application described in subregulation (6) of this regulation (made within the period described in that subregulation).

Note: This means that an application described in subregulation (6) can pass the preliminary assessment without payment of any fee.

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Division 11.11—Application provisions relating to the Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020

11.55 System or procedure packs

The amendments made by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020* apply in relation to a system or procedure pack that is manufactured on or after the commencement of that Part.

11.56 Period for notifying adverse events

Paragraph 5.7(1)(d), as inserted by Schedule 3 to the *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020*, applies in relation to information that a person becomes aware of on or after the commencement of that Schedule.

11.57 Class 4 in-house IVD medical devices

Item 2.10A of the table in Part 2 of Schedule 4, as inserted by Schedule 7 to the *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020*, applies in relation to the following:

(a) a Class 4 in-house IVD medical device that is manufactured on or after the commencement of this regulation;

(b) a Class 4 in-house IVD medical device that is manufactured before that commencement and is intended by its manufacturer to be used on or after that commencement.

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Division 11.12—Application provisions relating to the Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021

11.58 Application provisions

Nicotine vaping products

(1) Item 1.5 of the table in Part 1 of Schedule 4, as added by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to the following:

(a) a medical device imported or manufactured on or after the commencement of that item;

(b) a medical device supplied on or after the commencement of that item, where that device was imported or manufactured on or after that commencement.

System or procedure packs

(2) Paragraph (a) of item 1.6 of the table in Part 1 of Schedule 4, as added by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to a system or procedure pack imported on or after the commencement of that item.

(3) Paragraph (b) of item 1.6 of the table in Part 1 of Schedule 4, as added by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to a system or procedure pack manufactured on or after the commencement of that item.

(4) Paragraph (c) of item 1.6 of the table in Part 1 of Schedule 4, as added by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to a system or procedure pack supplied on or after the commencement of that item, where that system or procedure pack was imported or manufactured on or after that commencement.

(5) Paragraph (d) of item 1.6 of the table in Part 1 of Schedule 4, as added by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to a system or procedure pack supplied on or after the commencement of that item, where that system or procedure pack was imported or manufactured on or after that commencement.

Conformity assessment

(6) The amendments made by Part 3 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021* apply in relation to an application for a kind of medical device to be included in the Register that is made on or after the commencement of that Part.

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Division 11.13—Application, saving and transitional provisions relating to the Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021

11.59 System or procedure packs

Applications and entries other than a transitional kind of medical device

(1) The amendments made by Part 1 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* apply in relation to the following:

(a) an application for a kind of medical device to be included in the Register that is made on or after 25 November 2021;

(b) a kind of medical device that is included in the Register as a result of such an application.

Transitional kind of medical device

(2) The amendments made by Part 1 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* apply in relation to a transitional kind of medical device on and after 25 November 2025.

Exempt devices

(3) The amendments made by Part 1 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, to the extent the amendments relate to a system or procedure pack covered by an item in Part 1 of Schedule 4, or by column 2 of an item in Part 2 of Schedule 4, to these Regulations, apply in relation to a system or procedure pack that is manufactured on or after 25 November 2025.

Definitions

(4) In this regulation:

inclusion day for an entry of a kind of medical device in the Register means the day on which the inclusion of that kind of device in the Register commences.

transitional kind of medical device means a kind of medical device included in the Register because of an application that was made before 25 November 2021 (whether the inclusion day for the entry of that kind of medical device occurred before, on or after that day).

11.60 Reports about adverse events or occurrences for medical devices

Subregulation 5.8A(1), as inserted by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, applies in relation to information of a kind mentioned in subsection 41MP(2) or

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41MPA(2) of the Act that is given to the Secretary on or after the commencement of that Part.

11.61 Patient implant cards and patient information leaflets

(1) The amendments of Part 9 and of item 1.15 of the table in Part 1 of Schedule 5 made by Part 3 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* apply in relation to an application for consent that is made on or after the commencement of those amendments.

(2) The amendments of clauses 13A.1 to 13A.4 of Schedule 1 made by Part 3 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* apply in relation to an implantable medical device, or an active implantable medical device, that is imported, supplied or exported on or after the commencement of that Part.

(3) If:

(a) on or after 1 January 2021 and before the commencement of this regulation, a person made an application of a kind covered by paragraph (a) or (b) of item 1.15 of the table in Part 1 of Schedule 5 (as that item was in force before that commencement); and

(b) the application was made solely in relation to the application of either or both of clauses 13A.2 and 13A.3 of Schedule 1 (as those clauses were in force before that commencement); and

(c) on or after 1 January 2021 and before the commencement of this regulation, the person paid the fee applicable in relation to the application under item 1.15 of the table in Part 1 of Schedule 5 (as that item was in force before that commencement);

the Secretary must, on behalf of the Commonwealth, refund to the person the difference between the fee paid and the fee that would have been applicable in relation to the application under regulation 9.1AA if the application had been made on the day on which this regulation commences.

11.62 Medical devices assembled or adapted at point of care

Item 1.3B of the table in Part 1 of Schedule 4, as inserted by Part 5 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, applies in relation to a medical device that is manufactured on or after the commencement of that item.

11.63 Patient-matched medical devices

Subregulation 7.1(8) and item 1.7 of Part 1 of Schedule 4, as added by Part 6 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, apply in relation to patient-matched medical devices manufactured on or after the commencement of that item in the following:

(a) the financial year in which that item commences;

(b) each later financial year.

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11.64 Surgical loan kits

The amendment made by Part 7 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* applies on and after the commencement of that Part in relation to a surgical loan kit manufactured before, on or after that commencement.

11.65 Nicotine vaping products

(1) The amendment of subparagraph (a)(iii) of item 1.6 of the table in Part 1 of Schedule 4 made by Part 8 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* applies in relation to a system or procedure pack imported into Australia on or after the commencement of that amendment.

(2) The amendment of subparagraph (b)(iii) of item 1.6 of the table in Part 1 of Schedule 4 made by Part 8 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* applies in relation to a system or procedure pack manufactured on or after the commencement of that amendment.

(3) The amendment of subparagraph (c)(iii) of item 1.6 of the table in Part 1 of Schedule 4 made by Part 8 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* applies in relation to a system or procedure pack supplied on or after the commencement of that amendment, where that system or procedure pack was imported or manufactured on or after that commencement.

(4) The amendment of subparagraph (d)(iii) of item 1.6 of the table in Part 1 of Schedule 4 made by Part 8 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* applies in relation to a system or procedure pack supplied on or after the commencement of that amendment, where that system or procedure pack was imported or manufactured on or after that commencement.

11.66 Surgical mesh

Regulations 11.29 and 11.30, as in force immediately before the commencement of Part 11 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, continue to apply on and after that commencement in relation to an application referred to in paragraph 11.29(3)(a) (as so in force) that was made before that commencement.

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Regulation 11.67

Division 11.14—Application provisions relating to the Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021

11.67 Patient implant cards and patient information leaflets

The amendments of clause 13A.1 of Schedule 1 made by Part 1 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021* apply in relation to a medical device that is imported, supplied or exported on or after the commencement of that Part.

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Schedule 1—Essential principles

(regulation 2.1)

Part 1—General principles

1 Use of medical devices not to compromise health and safety

A medical device is to be designed and produced in a way that ensures that:

(a) the device will not compromise the clinical condition or safety of a patient, or the safety and health of the user or any other person, when the device is used on a patient under the conditions and for the purposes for which the device was intended and, if applicable, by a user with appropriate technical knowledge, experience, education or training; and

(b) any risks associated with the use of the device are:

(i) acceptable risks when weighed against the intended benefit to the patient; and

(ii) compatible with a high level of protection of health and safety.

2 Design and construction of medical devices to conform with safety principles

(1) The solutions adopted by the manufacturer for the design and construction of a medical device must conform with safety principles, having regard to the generally acknowledged state of the art.

(2) Without limiting subclause (1), in selecting appropriate solutions for the design and construction of a medical device so as to minimise any risks associated with the use of the device, the manufacturer must:

(a) first, identify hazards and associated risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device; and

(b) second, eliminate, or reduce, these risks as far as possible by adopting a policy of inherently safe design and construction; and

(c) third, if appropriate, ensure that adequate protection measures are taken, including alarms if necessary, in relation to any risks that cannot be eliminated; and

(d) fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted.

(3) In paragraph (2)(d):

residual risk, for a medical device, means the risk remaining after the measures described in paragraphs (2)(a), (b) and (c) have been applied.

3 Medical devices to be suitable for intended purpose

A medical device must:

(a) perform in the way intended by the manufacturer; and

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(b) be designed, produced and packaged in a way that ensures that it is suitable for one or more of the purposes mentioned in the definition of ***medical device*** in subsection 41BD(1) of the Act.

4 Long-term safety

A medical device must be designed and produced in a way that ensures that if:

(a) the device is used within the period, indicated by the manufacturer, in which the device can be safely used; and

(b) the device is not subjected to stresses that are outside the stresses that can occur during normal conditions of use; and

(c) the device is regularly maintained and calibrated in accordance with the manufacturer's instructions;

the characteristics and performances mentioned in clauses 1, 2 and 3 are not adversely affected.

5 Medical devices not to be adversely affected by transport or storage

A medical device must be designed, produced and packed in a way that ensures that the characteristics and performance of the device when it is being used for its intended purpose will not be adversely affected during transport and storage that is carried out taking account of the instructions and information provided by the manufacturer.

6 Benefits of medical devices to outweigh any undesirable effects

The benefits to be gained from the use of a medical device for the performance intended by the manufacturer must outweigh any undesirable effects arising from its use.

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Part 2—Principles about design and construction

7 Chemical, physical and biological properties

7.1 Choice of materials

In ensuring that the requirements of Part 1 are met in relation to a medical device, particular attention must be given to:

(a) the chemical and physical properties of the materials used in the device; and

(b) the compatibility between the materials used and biological tissues, cells, body fluids and specimens;

having regard to the intended purpose of the device.

7.2 Minimisation of risks associated with contaminants and residues

(1) A medical device must be designed, produced and packed in a way that ensures that any risks associated with contaminants and residues that may affect a person who is involved in transporting, storing or using the device, or a patient, are minimised, having regard to the intended purpose of the device.

(2) In minimising risks, particular consideration must be given to the likely duration and frequency of any tissue exposure associated with the transportation, storage or use of the device.

7.3 Ability to be used safely with materials etc

(1) A medical device must be designed and produced in a way that ensures that the device can be used safely with any material, substance or gas with which the device may come into contact during normal use or use in routine procedures.

(2) If the device is intended to be used to administer medicine, it must be designed and produced in a way that ensures that the device:

(a) is compatible with the provisions and restrictions applying to the medicine to be administered; and

(b) allows the medicine to perform as intended.

7.4 Verification of incorporated substance

(1) If a medical device incorporates, or is intended to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device:

(a) the safety and quality of the substance must be verified in accordance with the requirements for medicines; and

(b) the ancillary action of the substance must be verified having regard to the intended purpose of the device.

(2) For the purposes of this clause, any stable derivative of human blood or human plasma is considered to be a medicine.

7.5 Minimisation of risks associated with leaching substances

A medical device must be designed and produced in a way that ensures that any risks associated with substances that may leach from the device are minimised.

7.6 Minimisation of risks associated with ingress or egress of substances

A medical device must be designed and produced in a way that ensures that any risks associated with unintentional ingress of substances into, or unintentional egress of substances out of, the device are minimised, having regard to the nature of the environment in which the device is intended to be used.

8 Infection and microbial contamination

8.1 Minimisation of risk of infection and contamination

(1) A medical device must be designed and produced in a way that ensures that the risk of infection to a patient, a user, or any other person, is eliminated or minimised.

(2) The device must be designed in a way that:
  (a) allows it to be easily handled; and
  (b) if appropriate, minimises contamination of the device or specimen by the patient, user or other person; and
  (c) if appropriate, minimises contamination of the patient, user or other person by the device or specimen.

8.2 Control of animal, microbial or recombinant tissues, tissue derivatives, cells and other substances

(1) This clause applies in relation to a medical device that contains:
  (a) tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable; and
  (b) tissues, tissue derivatives, cells or substances of microbial or recombinant origin.

(2) If the tissues, tissue derivatives, cells or substances originated from animals, the animals must have been subjected to appropriate veterinary controls and supervision, having regard to the intended use of the tissues, tissue derivatives, cells or substances.

(3) If the medical device contains tissues, tissue derivatives, cells or substances of animal origin, a record must be kept of the country of origin of each animal from which the tissues, tissue derivatives, cells or substances originated.

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(4) The processing, preservation, testing and handling of tissues, tissue derivatives, cells or substances of animal, microbial or recombinant origin must be carried out in a way that ensures the highest standards of safety for a patient, the user of the device, and any other person.

(5) In particular, the production process must implement validated methods of elimination, or inactivation, in relation to viruses and other transmissible agents.

Note: This may not apply to certain IVD medical devices if the characteristics mentioned in subclause 8.2(5) are integral to the intended purpose of the IVD medical device.

8.3 Medical devices to be supplied in a sterile state

(1) This clause applies in relation to a medical device that is intended by the manufacturer to be supplied in a sterile state.

(2) The device must be designed, produced and packed in a way that ensures that the device is sterile when it is supplied, and will remain sterile, if stored and transported in accordance with the directions of the manufacturer, until the protective packaging is opened or damaged.

(3) The device must be produced and sterilised using an appropriate validated method.

(4) The device must be produced in appropriately controlled conditions.

8.4 Medical devices to be supplied in a non-sterile state

(1) A medical device that is intended by the manufacturer to be supplied in a non-sterile state must be packed in a way that ensures that the device maintains the level of cleanliness stipulated by the manufacturer.

(2) If the device is intended to be sterilised before it is used, the device must be packed in a way that:

(a) ensures that the risk of microbial contamination is minimised; and

(b) is suitable, having regard to the method of sterilisation that the manufacturer indicates is to be used for the device.

(3) The device must be produced in appropriately controlled conditions.

8.5 Distinction between medical devices supplied in sterile and non-sterile state

If a medical device is supplied in both a sterile state and a non-sterile state, the information provided with the device must clearly indicate whether the device is in a sterile state or a non-sterile state.

Clause 9

9 Construction and environmental properties

9.1 Medical devices intended to be used in combination with other devices or equipment

A medical device that is intended by the manufacturer to be used in combination with another medical device or other equipment (including a connection system) must be designed and produced in a way that ensures that:

(a) the medical device, and any other device or equipment with which it is used, operate in a safe way; and

(b) the intended performance of the device, and any other device or equipment with which it is used, is not impaired.

9.2 Minimisation of risks associated with use of medical devices

A medical device must be designed and produced in a way that ensures that, as far as practicable, the following risks are removed or minimised:

(a) the risk of injury arising from the physical features of the device;

(b) any risks associated with reasonably foreseeable environmental conditions;

(c) the risk of reciprocal interference involving other devices that are normally used in an investigation or treatment of the kind for which the device is intended to be used;

(d) any risks arising if maintenance or calibration of the device is not possible;

(e) any risks associated with the ageing of materials used in the device;

(f) any risks associated with loss of accuracy of any measuring or control mechanism of the device;

(g) the risk of fire or explosion occurring during normal use of the device, and in the event of a single fault condition, especially if the device is intended to be exposed to flammable substances or substances that can cause combustion;

(h) the risks associated with disposal of any waste substances.

10 Medical devices with a measuring function

(1) A medical device that has a measuring function must be designed and produced in a way that ensures that the device provides accurate, precise and stable measurements within the limits indicated by the manufacturer and having regard to the intended purpose of the device.

(2) The measurement, monitoring and display scale of the device must be designed and produced in accordance with ergonomic principles, having regard to the intended purpose of the device.

(3) The measurements made by the device must be expressed:

(a) in Australian legal units of measurement or be compared to at least one point of reference indicated in Australian legal units of measurement; or

(b) if the device measures a physical quantity for which no Australian legal unit of measurement has been prescribed under the *National Measurement*

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Act 1960, in units approved in writing by the Secretary for the particular device.

11 Protection against radiation

11.1 Minimisation of exposure to radiation

A medical device must be designed and produced in a way that ensures that the exposure of a patient, the user, or any other person, to radiation is minimised, having regard to the levels of radiation required to enable the device to perform its therapeutic and diagnostic functions and the intended purpose of the device.

11.2 Medical devices intended to emit radiation

(1) This clause applies in relation to a medical device that is intended by the manufacturer to emit hazardous levels of visible or invisible radiation because the emission is necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks inherent in the emission.

(2) The device must be designed and produced in a way that ensures that the user can control the level of the emission.

(3) The device must be designed and produced in a way that ensures the reproducibility and tolerance of relevant variable parameters.

(4) If practicable, the device must be fitted with a visual indicator or an audible warning, or both, that operates if potentially hazardous levels of radiation are emitted.

11.3 Minimisation of exposure to unintended radiation

A medical device must be designed and produced in a way that ensures that the exposure of a patient, the user, or any other person, to the emission of unintended, stray or scattered radiation is minimised.

11.4 Operating instructions

The operating instructions for a medical device that emits radiation must include detailed information about the following matters:

(a) the nature of the radiation emitted;
(b) the means by which patients and users can be protected from the radiation;
(c) ways to avoid misusing the device;
(d) ways to eliminate any risks inherent in the installation of the device.

11.5 Medical devices intended to emit ionising radiation—additional requirements

(1) This clause applies, in addition to clauses 11.1 to 11.4, in relation to a medical device that is intended by the manufacturer to emit ionising radiation.

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(2) The device must be designed and produced in a way that ensures that, if practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be controlled and varied, having regard to the intended purpose of the device.

(3) If the device is intended to be used for diagnostic radiology, the device must be designed and produced in a way that ensures that, when used in relation to a patient for a purpose intended by the manufacturer:
  (a) the device achieves an appropriate image or output quality for that purpose; and
  (b) the exposure of the patient, or the user, to radiation is minimised.

(4) If the device is intended to be used for therapeutic radiology, the device must be designed and produced in a way that ensures that the delivered dose of radiation, the type and energy of the radiation beam and, if appropriate, the energy distribution of the radiation beam, can be reliably controlled and monitored.

12 Medical devices connected to or equipped with an energy source

12.1 Programmed or programmable medical device or software that is a medical device

(1) A programmed or programmable medical device, or software that is a medical device, that is intended to make use of either or both of data and information must be designed and produced in a way that ensures that:
  (a) the safety, performance, reliability, accuracy, precision, useability, security and repeatability of the device are appropriate for the intended purpose of the device; and
  (b) any consequent risks, or impairment of performance, associated with one or more fault conditions is eliminated or appropriately reduced; and
  (c) the device is resilient with respect to interactions that could occur during the use of the device and that could result in unsafe performance of the device; and
  (d) if relevant to the safety of a patient, or the safety and health of the user or any other person, the device provides suitable warnings in a timely manner:
    (i) following the disruption to services upon which the device is dependent for the device's operation; and
    (ii) following the performance of the device being adversely affected; and
  (e) if relevant to the safety of a patient, or the safety and health of the user or any other person, the device provides a means by which the user can verify correct operation of the device; and
  (f) if relevant to the safety of a patient, or the safety and health of the user or any other person, the integrity and quality of the data or information is maintained; and
  (g) if relevant, the privacy of the data or information is maintained.

(2) A programmed or programmable medical device, or software that is a medical device, must be developed, produced and maintained having regard to the

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generally acknowledged state of the art (including for design, development life cycle, development environment, version control, quality and risk management, security, verification and validation, change and configuration management and problem resolution).

(3) A programmed or programmable medical device, or software that is a medical device, that is intended to be used in combination with computing platforms must be designed and developed taking into account the capability, resources and configuration of the platforms and the external factors (including information technology environments) related to the use of the platforms.

(4) The manufacturer of a programmed or programmable medical device, or software that is a medical device, must provide instructions or information with the device that sets out requirements (including requirements about hardware, software, information technology environments and security measures) necessary to operate the device as intended.

(5) A programmed or programmable medical device, or software that is a medical device, must be designed, produced and maintained with regard to best practice in relation to software, security and engineering to provide cybersecurity of the device, including where appropriate the following:
  (a) protection against unauthorised access, unauthorised influence or unauthorised manipulation;
  (b) minimisation of risks associated with known cybersecurity vulnerabilities (including either or both of remediation of known vulnerabilities and application of compensating controls);
  (c) facilitation of the application of updates, patches, compensating controls and other improvements;
  (d) disclosure of known vulnerabilities in the device or its components and associated mitigations;
  (e) making available sufficient information for a user to make decisions with respect to the safety of applying, or not applying, updates, patches, compensating controls and other improvements.

(6) The manufacturer of a programmed or programmable medical device, or software that is a medical device, having regard to the intended purpose of the device, the generally acknowledged state of the art and best practice, must ensure that the data that influences the performance of the device is:
  (a) representative; and
  (b) of sufficient quality; and
  (c) maintained to ensure integrity; and
  (d) managed to reduce bias.

12.2 Safety dependent on internal power supply

(1) This clause applies in relation to a medical device if the safety of a patient on whom the device is to be used will depend on an internal power supply for the device.

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(2) The device must be fitted with a means of determining the state of the power supply.

12.3 Safety dependent on external power supply

(1) This clause applies in relation to a medical device if the safety of a patient on whom the device is to be used will depend on an external power supply for the device.

(2) The device must be fitted with an alarm system that indicates whether a power failure has occurred.

12.4 Medical devices intended to monitor clinical parameters

A medical device that is intended by the manufacturer to be used to monitor one or more clinical parameters of a patient must be fitted with an appropriate alarm system to warn the user if a situation has developed that could lead to the death of the patient or a severe deterioration in the state of the patient's health.

12.5 Minimisation of risk of electromagnetic fields

A medical device must be designed and produced in a way that ensures that the risk of an electromagnetic field being created that could impair the operation of other devices or equipment being used in the vicinity of the medical device is minimised.

12.6 Protection against electrical risks

A medical device must be designed and produced in a way that ensures that, as far as possible, when the device is installed correctly, and the device is being used for an intended purpose under normal conditions of use and in the event of a single fault condition, patients, users, and any other persons, are protected against the risk of accidental electric shock.

12.7 Protection against mechanical risks

A medical device must be designed and produced in a way that ensures that a patient, the user, and any other person, is protected against any mechanical risks associated with the use of the device.

12.8 Protection against risks associated with vibration

(1) A medical device must be designed and produced in a way that ensures that any risks associated with vibrations generated by the device are minimised.

(2) If vibrations are not part of the intended performance of the device, particular attention must be given to relevant technical progress, and the available means, for limiting vibrations, particularly at source.

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12.9 Protection against risks associated with noise

(1) A medical device must be designed and produced in a way that ensures that any risks associated with noise emitted by the device are minimised.

(2) If noise is not part of the intended performance of the device, particular attention must be given to relevant technical progress, and the available means, for reducing the emission of noise, particularly at source.

12.10 Protection against risks associated with terminals and connectors

A medical device that is intended by the manufacturer to be connected to an electric, gas, hydraulic, pneumatic or other energy supply must be designed and produced in a way that ensures that any risks to the user associated with the handling of a terminal or connector on the device, in relation to the energy supply, are minimised.

12.11 Protection against risks associated with heat

A medical device must be designed and produced in a way that ensures that, during normal use, any accessible part of the device (other than any part intended by the manufacturer to supply heat or reach a given temperature), and any area surrounding an accessible part of the device, does not reach a potentially dangerous temperature.

12.12 Protection against risks associated with administration of energy or substances

(1) This clause applies in relation to a medical device that is intended by the manufacturer to be used to administer energy or a substance to a patient.

(2) The device must be designed and produced in a way that ensures that:
  (a) the delivered rate and amount of energy, or of the substance, can be set and maintained accurately to ensure the safety of the patient and the user; and
  (b) as far as possible, the accidental release of dangerous levels of energy or of the substance is prevented.

(3) The device must be fitted with a means of indicating or, if appropriate, preventing inadequacies in the rate and amount of energy, or of the substance, administered that might cause danger to the patient, the user or any other person.

(4) The functions of each control and indicator on the device must be clearly specified on the device.

(5) If the instructions for the operation of the device, or the operating or adjustment parameters for the device, are displayed by means of a visual system incorporated into the device, the instructions or parameters must be able to be understood by the user and, if appropriate, the patient.

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Clause 12.13

12.13 Active implantable medical devices

(1) An active implantable medical device must incorporate, display, emit or exhibit a code or unique characteristic that can be used to identify:
  (a) the type of device; and
  (b) the manufacturer of the device; and
  (c) the year of manufacture of the device.

(2) The code or unique characteristic must be able to be read without the need for surgery to the person in whom the device is implanted.

13 Information to be provided with medical devices

13.1 Information to be provided with medical devices—general

(1) The following information must be provided with a medical device:
  (a) information identifying the device;
  (b) information identifying the manufacturer of the device;
  (c) information explaining how to use the device safely;
having regard to the training and knowledge of potential users of the device.

(2) In particular:
  (a) the information required by clause 13.3 must be provided with a medical device; and
  (b) if instructions for use of the device are required under subclause 13.4, the information mentioned in subclause 13.4(3) must be provided in those instructions.

(3) The information:
  (a) must be provided in English; and
  (b) may also be provided in any other language.

Note: The information may also include diagrams or drawings.

(4) The format, content and location of the information must be appropriate for the device and its intended purpose.

(5) Any number, letter, symbol, or letter or number in a symbol, used in the information must be legible and at least 1 millimetre high.

(6) If a symbol or identification colour that is not included in a medical device standard is used in the information provided with the device, or in the instructions for use of the device, the meaning of the symbol or identification colour must be explained in the information provided with the device or the instructions for use of the device.

13.2 Information to be provided with medical devices—location

(1) Unless it is impracticable or inappropriate to do so, the information required to be provided with a medical device must be provided on the device itself.

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(2) If it is not practicable to comply with subclause (1) in relation to the provision of the information, the information must be provided:

(a) on the packaging used for the device; or

(b) in the case of devices that are packaged together because individual packaging of the devices for supply is not practicable—on the outer packaging used for the devices.

(3) If it is not practicable to comply with subclause (1) or (2) in relation to the provision of the information required under subregulation 10.2(1) or clause 13.3:

(a) for a medical device that is not software—the information must be provided on a leaflet supplied with the device; or

(b) for a medical device that is software—the information must be provided on a leaflet supplied with the device or the information must be provided electronically.

(4) If it is not practicable to comply with subclause (1) or (2) in relation to the provision of the information required under clause 13.4, the information must be provided in a printed document or using other appropriate media.

13.3 Information to be provided with medical devices—particular requirements

The information mentioned in the following table must be provided with a medical device.

Item	Information to be provided
1	The manufacturer's name, or trading name, and address
2	The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used (if this information is not obvious)
3	Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging
4	Any particular handling or storage requirements applying to the device
5	Any warnings, restrictions, or precautions that should be taken, in relation to use of the device
6	Any special operating instructions for the use of the device
7	If applicable, an indication that the device is intended for a single use only
8	If applicable, an indication that the device has been custom-made for a particular individual or health professional and is intended for use only by that individual or health professional
9	If applicable, an indication that: (a) if the device is a medical device other than an IVD medical device—the device is intended for pre-market clinical investigation; or (b) if the device is an IVD medical device—the device is intended for performance evaluation only
10	For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device
11	The batch code, lot number or serial number of the device

Clause 13.4

Item	Information to be provided
12	If applicable, a statement of the date (expressed in a way that clearly identifies the month and year) up to when the device can be safely used
13	If the information provided with the device does not include the information mentioned in item 12—a statement of the date of manufacture of the device (this may be included in the batch code, lot number or serial number of the device, provided the date is clearly identifiable)
14	If applicable, the words 'for export only'

Note: In addition to the information mentioned in the above table, regulation 10.2 requires certain information to be provided with a medical device.

13.4 Instructions for use

(1) Instructions for the use of a medical device must be provided with the device.

(2) However, instructions for the use of a medical device need not be provided with the device, or may be abbreviated, if:
  (a) the device is a Class I medical device, a Class IIa medical device or a Class 1 IVD medical device; and
  (b) the device can be used safely for its intended purpose without instructions.

(3) Instructions for the use of a medical device must include information mentioned in the following table that is applicable to the device.

Item	Information to be provided
1	The manufacturer's name, or trading name, and address
2	The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used
3	Information about any risk arising because of other equipment likely to be present when the device is being used for its intended purpose (for example, electrical interference from electro-surgical devices or magnetic field interference from magnetic resonance imaging devices)
4	Information about the intended performance of the device and any undesirable side effects caused by use of the device
5	Any contra-indications, warnings, restrictions, or precautions that may apply in relation to use of the device
6	Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging
7	Any particular handling or storage requirements applying to the device
8	If applicable, an indication that the device is intended for a single use only
9	If applicable, an indication that the device has been custom-made for a particular individual or health professional and is intended for use only by that individual or health professional
10	If applicable, an indication that: (a) if the device is a medical device other than an IVD medical device—the device is intended for pre-market clinical investigation; or

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Item	Information to be provided
	(b) if the device is an IVD medical device—the device is intended for performance evaluation only
11	For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device
12	For a device that is intended by the manufacturer to be supplied in a sterile state: (a) an indication that the device is sterile; and (b) information about what to do if sterile packaging is damaged; and (c) if appropriate, instructions for resterilisation of the device
13	For a medical device that is intended by the manufacturer to be sterilised before use—instructions for cleaning and sterilising the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles
14	Any special operating instructions for the use of the device
15	Information to enable the user to verify whether the device is properly installed and whether it can be operated safely and correctly, including details of calibration (if any) needed to ensure that the device operates properly and safely during its intended life
16	Information about the nature and frequency of regular and preventative maintenance of the device, including information about the replacement of consumable components of the device during its intended life
17	Information about any treatment or handling needed before the device can be used
18	For a device that is intended by the manufacturer to be installed with, or connected to, another medical device or other equipment so that the device can operate as required for its intended purpose—sufficient information about the device to enable the user to identify the appropriate other medical device or equipment that will ensure a safe combination
19	For an implantable medical device—information about any risks associated with its implantation
20	For a reusable device: (a) information about the appropriate processes to allow reuse of the device (including information about cleaning, disinfection, packaging and, if appropriate, resterilisation of the device); and (b) an indication of the number of times the device may be safely reused
21	For a medical device that is intended by the manufacturer to emit radiation for medical purposes—details of the nature, type, intensity and distribution of the radiation emitted
22	Information about precautions that should be taken by a patient and the user if the performance of the device changes
23	Information about precautions that should be taken by a patient and the user if it is reasonably foreseeable that use of the device will result in the patient or user being exposed to adverse environmental conditions
24	Adequate information about any medicinal product that the device is designed to administer, including any limitations on the substances that may be administered using the device
25	Information about any medicine (including any stable derivative of human blood or blood plasma) that is incorporated, or is intended to be incorporated, into the device as an integral part of the device

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Clause 13A

Item	Information to be provided
25A	For a medical device, other than an IVD medical device, information about any tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin that are included in the device
26	Information about precautions that should be taken by a patient and the user if there are special or unusual risks associated with the disposal of the device
27	Information about the degree of accuracy claimed if the device has a measuring function
28	Information about any particular facilities required for use of the device or any particular training or qualifications required by the user of the device
29	For an IVD medical device, information (including, to the extent practicable, drawings and diagrams) about the following: (a) the scientific principle (the 'test principle') on which the performance of the IVD medical device relies; (b) specimen type, collection, handling and preparation; (c) reagent description and any limitations (for example, use with a dedicated instrument only); (d) assay procedure including calculations and interpretation of results; (e) interfering substances and their effect on the performance of the assay; (f) analytical performance characteristics, such as sensitivity, specificity, accuracy and precision; (g) clinical performance characteristics, such as sensitivity and specificity; (h) reference intervals, if appropriate; (i) any precautions to be taken in relation to substances or materials that present a risk of infection
30	For an adaptable medical device, instructions for assembling or adapting the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles
31	For a medical device production system, instructions for the process to be followed in producing the medical device the system is intended to produce which, if followed, will ensure that the device so produced will comply with the applicable provisions of the essential principles

13A Patient information about implantable medical devices or active implantable medical devices to be made available

13A.1 Scope of clauses 13A.2 to 13A.4

(1) Clauses 13A.2 to 13A.4 apply to a medical device that is:
  (a) an implantable medical device or an active implantable medical device; and
  (b) not a suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip, connector or similar article; and
  (c) not a medical device to which subclause (2) applies.

(2) This subclause applies to a medical device if:

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(a) the medical device is intended by the manufacturer to be wholly, or mostly, absorbed by a patient's body within 6 months of being implanted; and

(b) the medical device is:

(i) for use as a filler; or

(ii) for haemostasis; or

(iii) for tissue approximation; or

(iv) for the fixation of other medical devices within tissue; or

(v) a similar medical device to a medical device covered by subparagraph (i), (ii), (iii) or (iv).

13A.2 Patient implant cards etc. for implantable devices

(1) Either:

(a) a card (a ***patient implant card***) that includes the information covered by subclause (2) and that satisfies clause 13A.4 must be made available for provision to the patient concerned; or

(b) information covered by subclause (2) that is in electronic form and that satisfies clause 13A.4 must be made available in a way that is readily accessible by the patient concerned.

(2) The information covered by this subclause is the information in the following table.

Information to be made available for provision to patient

Item	Information
1	(a) the name of the device; and (b) the model of the device; and (c) the batch code, lot number or serial number of the device
2	The manufacturer's name, address and website

13A.3 Patient information leaflets etc. for implantable devices

(1) Either:

(a) a leaflet (a ***patient information leaflet***) that includes the information covered by subclauses (2) and (3) and that satisfies subclause (4) and clause 13A.4 must be made available for provision to the patient concerned; or

(b) information covered by subclauses (2) and (3) that is in electronic form and that satisfies subclause (4) and clause 13A.4 must be made available in a way that is readily accessible by the patient concerned.

(2) The information covered by this subclause is the following information:

(a) information identifying the device, or the kind of device;

(b) the intended purpose of the device;

(c) information explaining how to use the device safely;

(d) other information about the device that the manufacturer considers would be useful for patients.

(3) The information covered by this subclause is the information in the following table.

Information to be made available for provision to patient

Item	Information
1	(a) the name of the device; and (b) the model of the device
2	(a) the intended purpose of the device; and (b) the kind of patient on whom the device is intended to be used
3	Any special operating instructions for the use of the device
4	(a) the intended performance of the device; and (b) any undesirable side effects that could be caused by use of the device
5	Any residual risks that could arise due to any shortcomings of the protection measures adopted as mentioned in subclause 2(2)
6	(a) warnings about risks that could arise from the interaction of the device with other equipment; and (b) precautions and other measures that, because of those risks, should be taken by the patient or a health professional Example 1: The risk of electrical interference from electro-surgical devices. Example 2: The risk of magnetic field interference from magnetic resonance imaging devices.
7	(a) the nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken; and (b) symptoms that could indicate that the device is malfunctioning; and (c) precautions and other measures that should be taken by the patient if the performance of the device changes or the patient experiences any of the symptoms mentioned in paragraph (b); and (d) the expected device lifetime; and (e) anything that could shorten or lengthen the device lifetime; and (f) precautions and other measures that should be taken at, or near, the end of the expected device lifetime; and (g) other circumstances in which the patient should contact a health professional in relation to the operation of the device
8	(a) the materials and substances included in the device; and (b) any manufacturing residuals that could pose a risk to the patient
9	(a) a notice that any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration; and (b) the address of the Therapeutic Goods Administration's website

(4) The information covered by subclauses (2) and (3) must be written in a way that is readily understood by patients.

13A.4 General requirements for information to be made available for patients

(1) The information covered by subclause 13A.2(2) or 13A.3(2) or (3):
  (a) must be included in English; and
  (b) may also be included in any other language.

Note: The information may also include diagrams or drawings.

(2) Any number, letter or symbol, or letter or number in a symbol, that is part of the information covered by subclause 13A.2(2) or 13A.3(2) or (3) must be:
  (a) legible; and
  (b) if the number, letter or symbol, or letter or number in a symbol, is included in a patient implant card or patient information leaflet—at least 1 millimetre high.

13B Software—version numbers and build numbers

(1) For a medical device that is software, or that incorporates software, the current version number and current build number of the software must be accessible by, and identifiable to, users of the device.

(2) The current version number and current build number of the software:
  (a) must be in English; and
  (b) may also be in any other language.

14 Clinical evidence

Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the essential principles.

Note: See regulation 3.11 and the clinical evaluation procedures.

15 Principles applying to IVD medical devices only

(1) An IVD medical device must be designed and manufactured in a way in which the analytical and clinical characteristics support the intended use, based on appropriate scientific and technical methods.

(2) An IVD medical device must be designed in a way that addresses accuracy, precision, sensitivity, specificity, stability, control of known relevant interference and measurement of uncertainty, as appropriate.

(3) If performance of an IVD medical device depends in whole or part on the use of calibrators or control materials, the traceability of values assigned to the calibrators or control material must be assured through a quality management system.

(4) An IVD medical device must, to the extent reasonably practicable, include provision for the user to verify, at the time of use, that the device will perform as intended by the manufacturer.

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(5) An IVD medical device for self-testing must be designed and manufactured so that it performs appropriately for its intended purpose, taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in the user's technique and environment.

(6) The information and instructions provided by the manufacturer of an IVD medical device for self-testing must be easy for the user to understand and apply.

(7) An IVD medical device for self-testing must be designed and manufactured in a way that reduces, to the extent practicable, the risk of error in the use of the device, the handling of the sample and the interpretation of results.

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Schedule 2—Classification rules for medical devices other than IVD medical devices

Note: Regulation 3.2 provides for the making of classification rules. Regulation 3.3 sets out the principles for applying those rules.

Part 1—Interpretation

1.1 Transient, short-term and long-term use

(1) For the purposes of this Schedule:

(a) a medical device is intended for transient use if the manufacturer intends the device to be used continuously for less than 60 minutes; and

(b) a medical device is intended for short-term use if the manufacturer intends the device to be used continuously for at least 60 minutes but not more than 30 days; and

(c) a medical device is intended for long-term use if the manufacturer intends the device to be used continuously for more than 30 days.

(2) For the purposes of determining whether a medical device is intended to be used continuously, disregard any temporary interruption or removal.

Example: A temporary interruption or removal in order to clean or disinfect the medical device.

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Part 2—Rules for non-invasive medical devices

2.1 Non-invasive medical devices—general

A non-invasive medical device is classified as Class I, unless the device is classified at a higher level under another clause in this Part or in Part 4 or 5 of this Schedule.

2.2 Non-invasive medical devices intended to channel or store blood, etc

(1) This clause applies to:

(a) a non-invasive medical device that is intended by the manufacturer to be used to channel or store blood or body liquids that are to be infused, administered or introduced into a patient; and

(b) a non-invasive medical device that is intended by the manufacturer to be used to store an organ, part of an organ or body tissue that is to be later introduced into a patient; and

(c) a non-invasive medical device that:

(i) is intended by the manufacturer to be used to channel or store a liquid or gas that is to be infused, administered or introduced into a patient; and

(ii) may be connected to an active medical device classified as Class IIa or higher.

(2) The device is classified as Class IIa.

2.3 Non-invasive medical devices intended to modify the biological or chemical composition of blood, etc

(1) Subject to subclause (2), a non-invasive medical device that is intended by the manufacturer to be used to modify the biological or chemical composition of blood, other body liquids, or other liquids intended to be infused into a patient, is classified as Class IIb.

(2) If the treatment for which the device is designed consists of filtration, centrifugation or exchanges of gas or heat, the device is classified as Class IIa.

2.4 Non-invasive medical devices intended to have contact with injured skin or mucous membrane

(1) This clause applies to a non-invasive medical device that is intended by the manufacturer to be used in contact with injured skin or a mucous membrane (including a device the principal intention of which is to manage the micro-environment of a wound).

(2) Subject to subclauses (3) and (4), the device is classified as Class IIa.

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(3) If the device is intended to be used:

(a) as a mechanical barrier; or

(b) for compression; or

(c) for the absorption of exudates;

the device is classified as Class I.

(4) If the device is intended to be used principally for wounds that have breached the dermis and the wounds can only heal by secondary intent, the device is classified as Class IIb.

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Part 3—Rules for invasive medical devices and implantable medical devices

3.1 Invasive medical devices intended to be used by penetration of body orifices

(1) This clause applies to an invasive medical device (other than a surgically invasive medical device or a medical device covered by clause 5.10 or 5.11) that is intended by the manufacturer to be used to penetrate a body orifice of a patient.

(2) If the device is not intended to be connected to an active medical device, the following rules apply:

(a) if the device is intended for transient use, the device is classified as Class I;

(b) if the device is intended for short-term use:

(i) the device is classified as Class IIa; or

(ii) if the device is intended to be used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum, or in a nasal cavity—the device is classified as Class I;

(c) if the device is intended for long-term use:

(i) the device is classified as Class IIb; or

(ii) if the device is intended to be used in the oral cavity as far as the pharynx or in an ear canal up to the ear drum, or the device is intended to be used in a nasal cavity and the device is not liable to be absorbed by the skin or mucous membrane—the device is classified as Class IIa.

(3) If the device is intended to be connected to an active medical device that is classified as Class IIa or higher, the device is classified as Class IIa.

3.2 Surgically invasive medical devices intended for transient use

(1) This clause applies to a surgically invasive medical device that is intended for transient use.

(2) Subject to subclauses (3) to (5), the device is classified as Class IIa.

(3) If the device is intended by the manufacturer specifically to be used to diagnose, monitor, control or correct a defect of the heart, or the central circulatory system, of a patient through direct contact with these parts of the body, the device is classified as Class III.

(3A) If the device is not a reusable surgical instrument and the device is intended by the manufacturer specifically to be used in direct contact with the heart, the central circulatory system or the central nervous system of a patient, the device is classified as Class III.

(4) If the device is a reusable surgical instrument, the device is classified as Class I.

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(5) If:

(a) the device is intended by the manufacturer to be used to supply energy in the form of ionising radiation; or

(b) the device is intended by the manufacturer to have a biological effect; or

(c) the device is intended by the manufacturer to be wholly, or mostly, absorbed by the patient's body; or

(d) the device is intended by the manufacturer to be used to administer medicine to a patient by means of a delivery system, and the administration is potentially hazardous to the patient having regard to the characteristics of the device;

the device is classified as Class IIb.

3.3 Surgically invasive medical devices intended for short-term use

(1) This clause applies to a surgically invasive medical device that is intended for short-term use.

(2) Subject to subclauses (3) and (4), the device is classified as Class IIa.

(3) If:

(a) the device is intended by the manufacturer to be used to supply energy in the form of ionising radiation; or

(b) the device is intended by the manufacturer to undergo a chemical change in a patient's body (other than a device that is intended by the manufacturer to be placed in the teeth); or

(c) the device is intended by the manufacturer to administer medicine;

the device is classified as Class IIb.

Note for paragraph (b): A device that is intended by the manufacturer to be placed in the teeth, and to undergo a chemical change in the body, is classified as Class IIa—see subclause (2).

(4) If the device is intended by the manufacturer:

(a) specifically to be used to diagnose, monitor, control or correct a defect of the heart, or the central circulatory system, of a patient through direct contact with these parts of the body; or

(b) specifically to be used in direct contact with the heart, the central circulatory system or the central nervous system of a patient; or

(c) to have a biological effect; or

(d) to be wholly, or mostly, absorbed by a patient's body;

the device is classified as Class III.

(5) For this clause, a medical device that is intended by the manufacturer to be placed in the teeth includes a medical device that is intended by the manufacturer to penetrate a tooth, but does not include a medical device that is intended by the manufacturer to penetrate a tooth and enter the gum or bone beyond the tooth.

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Clause 3.4

3.4 Surgically invasive medical devices intended for long-term use and implantable medical devices

(1) This clause applies to:
  (a) a surgically invasive medical device that is intended for long-term use; and
  (b) an implantable medical device.

(2) Subject to subclauses (3), (4), (4A) and (4B), the device is classified as Class IIb.

(3) If the device is intended by the manufacturer to be placed in the teeth of a patient, the device is classified as Class IIa.

(4) If the device is intended by the manufacturer:
  (a) to be used in direct contact with the heart, the central circulatory system or the central nervous system of a patient; or
  (b) to have a biological effect; or
  (c) to be wholly, or mostly, absorbed by a patient's body; or
  (d) to undergo a chemical change in a patient's body (other than a device that is intended by the manufacturer to be placed in the teeth); or
  (e) to be used to administer medicine;

the device is classified as Class III.

Note for paragraph (d): A device that is intended by the manufacturer to be placed in the teeth, and to undergo a chemical change in the body, is classified as Class IIa—see subclause (3).

(4A) The device is classified as Class III if it is:
  (a) a joint replacement medical device; or
  (b) surgical mesh.

(4B) If the device is intended by the manufacturer to be a motion-preserving device for the spine (such as a spinal disc replacement), the device is classified as Class III.

(5) For this clause, a medical device that is intended by the manufacturer to be placed in the teeth includes a medical device that is intended by the manufacturer to penetrate a tooth, but does not include a medical device that is intended by the manufacturer to penetrate a tooth and enter the gum or bone beyond the tooth.

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Part 4—Special rules for active medical devices

4.1 Active medical devices—general

An active medical device is classified as Class I, unless the device is classified at a higher level under another clause in this Part or in Part 2, 3 or 5.

4.2 Active medical devices for therapy

(1) Subject to subclause (2), an active medical device for therapy that is intended by the manufacturer to be used to administer energy to a patient, or exchange energy to or from a patient, is classified as Class IIa.

(2) If the device is of a kind such that the administration or exchange of energy occurs in a potentially hazardous way, having regard to the nature, density and site of application of the energy, the device is classified as Class IIb.

(3) An active medical device that is intended by the manufacturer to be used to control or monitor, or directly influence, the performance of an active medical device for therapy of the kind mentioned in subclause (2) is classified as Class IIb.

(4) An active medical device for therapy that includes a diagnostic function the purpose of which is to significantly determine patient management by the device is classified as Class III.

Example: An automated external defibrillator.

4.3 Active medical devices for diagnosis

(1) This clause applies to an active medical device for diagnosis.

(2) If:

(a) the device is intended by the manufacturer to be used to supply energy that will be absorbed by a patient's body (other than a device that is intended only to illuminate the patient's body in the visible spectrum); or

(b) the device is intended by the manufacturer to be used to image in vivo distribution of radiopharmaceuticals in a patient; or

(c) the device is intended by the manufacturer to be used to allow direct diagnosis or monitoring of vital physiological processes of a patient (other than a device of a kind mentioned in paragraph (3)(a));

the device is classified as Class IIa.

Note for paragraph (a): A device that is intended only to illuminate the patient's body in the visible spectrum is classified as Class I—see clause 4.1 of this Schedule.

(3) If:

(a) the device is intended by the manufacturer specifically to be used to monitor vital physiological parameters of a patient, and the nature of the

variations monitored is of a kind that could result in immediate danger to the patient (for example, variations in cardiac performance, respiration, activity of the central nervous system); or

(b) the device is intended by the manufacturer to emit ionising radiation and to be used for diagnostic or therapeutic interventional radiology; or

(c) the device is intended by the manufacturer to be used to control or monitor, or directly influence, the performance of a device of the kind mentioned in paragraph (b);

the device is classified as Class IIb.

4.4 Active medical devices intended to administer or remove medicines, etc from a patient's body

(1) Subject to subclause (2), an active medical device that is intended by the manufacturer to be used to administer medicine, body liquids or other substances to a patient, or to remove medicine, body liquids or other substances from a patient, is classified as Class IIa.

(2) If the device is of a kind such that the administration or removal of the medicine, body liquids or other substances is potentially hazardous to the patient, having regard to the nature of the substances involved, the part of the patient's body concerned, and the characteristics of the device, the device is classified as Class IIb.

4.5 Programmed or programmable medical device or software that is a medical device for use in relation to diagnosing or screening for a disease or condition

(1) A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to:

(a) provide a diagnosis of a disease or condition; or

(b) screen for a disease or condition;

is classified as:

(c) in the case of a disease or condition that:

(i) may lead to the death of a person, or a severe deterioration in the state of a person's health, without urgent treatment; or

(ii) may pose a high risk to public health;

Class III; or

(d) in the case of a serious disease or serious condition or a disease or condition that may pose a moderate risk to public health, and where paragraph (c) does not apply—Class IIb; or

(e) in any other case—Class IIa.

(2) A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to provide information to a relevant health professional for the purposes of the health professional making a diagnosis of a disease or condition:

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(a) in the case of a disease or condition that:
  (i) may lead to the death of a person, or a severe deterioration in the state of a person's health, without urgent treatment; or
  (ii) may pose a high risk to public health;
  is classified as Class IIb; or
(b) in the case of a serious disease or serious condition or a disease or condition that may pose a moderate risk to public health, and where paragraph (a) does not apply—is classified as Class IIa; or
(c) in any other case—is classified as Class I.

4.6 Programmed or programmable medical device or software that is a medical device for use for monitoring the state or progression of a disease or condition etc.

A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to provide information that is to be used for monitoring the state or progression of a disease or condition of a person or the parameters in relation to a person:

(a) in the case where the information to be provided could indicate that the person or another person may be in immediate danger or that there may be a high risk to public health—is classified as Class IIb; or
(b) in the case where the information to be provided could indicate that the person or another person may be in other danger or that there may be a moderate risk to public health—is classified as Class IIa; or
(c) in any other case—is classified as Class I.

4.7 Programmed or programmable medical device or software that is a medical device for use in specifying or recommending treatment or intervention

(1) Subject to subclause (2), a programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to specify or recommend a treatment or intervention:
  (a) in the case where the absence of the treatment or intervention or where the treatment or intervention itself:
    (i) may lead to the death of a person or a severe deterioration in the state of a person's health; or
    (ii) may pose a high risk to public health;
    is classified as Class III; or
  (b) in the case where the absence of the treatment or intervention or where the treatment or intervention itself:
    (i) may otherwise be harmful to a person; or
    (ii) may pose a moderate risk to public health;
    is classified as Class IIb; or
  (c) in any other case—is classified as Class IIa.

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(2) A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to recommend a treatment or intervention (the ***recommended treatment or intervention***) to a relevant health professional for the purposes of the health professional making a decision about the treatment or intervention:

(a) in the case where the absence of the recommended treatment or intervention or where the recommended treatment or intervention itself:

(i) may lead to the death of a person or a severe deterioration in the state of a person's health; or

(ii) may pose a high risk to public health;

is classified as Class IIb; or

(b) in the case where the absence of the recommended treatment or intervention or where the recommended treatment or intervention itself:

(i) may otherwise be harmful to a person; or

(ii) may pose a moderate risk to public health;

is classified as Class IIa; or

(c) in any other case—is classified as Class I.

4.8 Programmed or programmable medical device or software that is a medical device that is to provide therapy to a person through the provision of information

A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to provide therapy to a person through the provision of information to the person:

(a) in the case of therapy that may result in the death of the person or a severe deterioration in the state of the person's health—is classified as Class III; or

(b) in the case of therapy that may cause serious harm to the person and where paragraph (a) does not apply—is classified as Class IIb; or

(c) in the case of therapy that may cause harm to the person and where neither paragraph (a) nor (b) applies—is classified as Class IIa; or

(d) in any other case—is classified as Class I.

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Part 5—Special rules for particular kinds of medical devices

5.1 Medical devices incorporating a medicine

(1) This clause applies to a medical device of any kind that incorporates, or is intended to incorporate, as an integral part, a substance that:
  (a) if used separately, would be a medicine; and
  (b) is liable to act on a patient's body with action ancillary to that of the device.

(2) The device is classified as Class III.

(3) For the purposes of this clause, any stable derivative of human blood or human plasma is considered to be a medicine.

5.2 Medical devices intended for contraception or prevention of sexually transmitted diseases

(1) Subject to subclause (2), a medical device that is intended by the manufacturer to be used for contraception, or the prevention of sexually transmitted diseases, is classified as Class IIb.

(2) If the device is an implantable medical device or an invasive medical device that is intended for long-term use, the device is classified as Class III.

5.3 Medical devices intended for disinfecting, cleaning, etc

(1) A medical device that is intended by the manufacturer specifically to be used for disinfecting, cleaning, rinsing or hydrating contact lenses is classified as Class IIb.

(2) A medical device that is intended by the manufacturer specifically to be used for disinfecting another medical device is classified as Class IIb.

(3) This clause does not apply to a medical device that is intended by the manufacturer to be used only to clean another medical device (other than contact lenses) by means of physical action.

Note: A medical device of the kind described in subclause (3) is classified as Class I—see clause 2.1 of this Schedule.

5.4 Medical devices that record patient images or that are anatomical models etc.

(1) If:
  (a) a medical device is intended by the manufacturer to be used to record patient images that are to be used for either or both of the following:
    (i) the diagnosis or monitoring of a disease, injury or disability;

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(ii) the investigation of the anatomy or of a physiological process; and

(b) the images are to be acquired through a method that relies on energy outside the visible spectrum;

the device is classified as Class IIa.

(2) A medical device that is an anatomical model (whether physical or virtual) that is intended by the manufacturer to be used for either or both of the following:

(a) the diagnosis or monitoring of a disease, injury or disability;

(b) the investigation of the anatomy or of a physiological process;

is classified as Class IIa.

(3) A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to generate a virtual anatomical model that is to be used for either or both of the following:

(a) the diagnosis or monitoring of a disease, injury or disability;

(b) the investigation of the anatomy or of a physiological process;

is classified as Class IIa.

5.5 Medical devices containing non-viable animal tissues, cells or other substances, or microbial or recombinant tissues, cells or other substances

(1) This clause applies to a medical device if the device contains:

(a) tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin; or

(b) a combination of tissues, cells or substances of the kind described in paragraph (a).

(2) The device is classified as Class III, unless:

(a) the device contains only tissues, cells or substances of animal origin that have been rendered non-viable; and

(b) the device is intended by the manufacturer to come into contact with intact skin only.

Note: A medical device that conforms with the description in paragraphs (2)(a) and (b) is classified as Class I under clause 2.1 of this Schedule.

5.6 Medical devices that are blood bags

A medical device that is a blood bag is classified as Class IIb.

5.7 Active implantable medical devices

(1) An active implantable medical device is classified as Class III.

(2) An implantable accessory to an active implantable medical device is classified as Class III.

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(3) An active medical device that is intended by the manufacturer to be used to control or monitor, or directly influence, the performance of an active implantable medical device is classified as Class III.

5.8 Medical devices intended for export only

Despite any other classification in this Schedule, a medical device that is intended by the manufacturer to be for export only is classified as Class I.

5.9 Medical devices that are mammary implants

A medical device that is a mammary implant is classified as Class III.

5.10 Medical devices that administer medicines or biologicals by inhalation

If a medical device is intended to be used to administer medicines or biologicals by inhalation:

(a) if the mode of action of the device has an essential impact on the efficacy and safety of the medicines or biologicals—the device is classified as Class IIb; or

(b) if the device is intended to treat a life-threatening condition—the device is classified as Class IIb; or

(c) if paragraphs (a) and (b) do not apply—the device is classified as Class IIa.

5.11 Medical devices that are substances to be introduced into the body or applied to and absorbed by the skin

If a medical device is composed of substances, or combinations of substances, that are intended to be:

(a) introduced into the human body through a body orifice; or

(b) applied to and absorbed by the skin;

the device is classified as follows:

(c) if the device is introduced into the nasal or oral cavity as far as the pharynx, or is applied to and absorbed by the skin, and achieves its intended purpose in that cavity or on the skin—Class IIa;

(d) in any other case—Class IIb.

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Clause 1.1

Schedule 2A—Classification rules for IVD medical devices

Note: Regulation 3.2 provides for the making of classification rules. Regulation 3.3 sets out the principles for applying those rules.

1.1 Detection of transmissible agents posing high public health risk

An IVD medical device intended to be used for any of the following purposes is classified as a Class 4 IVD medical device or a Class 4 in-house IVD medical device:

(a) to detect the presence of, or exposure to, transmissible agents in blood, blood components, blood products, cells, tissues or organs or any derivatives of these products of human or animal origin, in order to assess their suitability for transfusion or transplantation;

(b) to detect the presence of, or exposure to, a transmissible agent that causes a serious disease with a high risk of propagation in Australia.

1.2 Detection of red blood cell antigens and antibodies and non-red cell typing

(1) An IVD medical device is classified as a Class 3 IVD medical device or a Class 3 in-house IVD medical device if:

(a) the device is intended to be used for detection of biological markers in order to assess the immunological compatibility of blood, blood components, blood products, cells, tissues or organs that are intended for transfusion or transplantation; and

(b) the device is not a device mentioned in subclause (2).

(2) An IVD medical device intended to detect any of the following markers mentioned for the following blood group systems is classified as a Class 4 IVD medical device or a Class 4 in-house IVD medical device:

(a) ABO system—ABO1 (A), ABO2 (B), ABO3 (AB);

(b) Rhesus system—RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e);

(c) Kell system—KEL1 (K);

(d) Kidd system—JK1 (Jka), JK2 (Jkb);

(e) Duffy system—FY1 (Fya), FY2 (Fyb).

1.3 Detection of transmissible agents or biological characteristics posing moderate public health risk or high personal risk

An IVD medical device is classified as a Class 3 IVD medical device or a Class 3 in-house IVD medical device if it is intended for any of the following uses:

(a) detecting the presence of, or exposure to, a sexually transmitted agent;

(b) detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation;

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(c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested;

(d) pre-natal screening of women in order to determine their immune status towards transmissible agents;

(e) determining infective disease status or immune status, if there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient;

(f) the selection of patients:

(i) for selective therapy and management; or

(ii) for disease staging; or

(iii) in the diagnosis of cancer;

(fa) use as an IVD companion diagnostic;

(g) human genetic testing;

(h) to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient;

(i) the management of patients suffering from a life-threatening infectious disease;

(j) screening for congenital disorders in a foetus.

Note for paragraph (f): An IVD medical device (except an IVD companion diagnostic) would fall into Class 2 under clause 1.7 if:

(a) a therapy decision would usually be made only after further investigation; or

(b) the device is used for monitoring.

1.4 IVD medical devices for self-testing

An IVD medical device for self-testing is classified as a Class 3 IVD medical device unless:

(a) the result of the examination is not determining a serious condition, ailment or defect; or

(b) the examination is preliminary and follow-up additional testing is required.

1.5 Non assay-specific quality control material

Despite clauses 1.1 to 1.4, an IVD medical device that is intended to be used as non assay-specific quality control material is classified as a Class 2 IVD medical device or a Class 2 in-house IVD medical device.

1.6 Reagents, instruments etc

(1) A reagent or other article that possesses specific characteristics, intended by the manufacturer, to make it suitable for in vitro diagnostic procedures related to a specific examination is classified as a Class 1 IVD medical device or a Class 1 in-house IVD medical device.

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(2) Despite clauses 1.1 to 1.5, the following IVD medical devices are classified as Class 1 IVD medical devices or Class 1 in-house IVD medical devices:

(a) an instrument, intended by the manufacturer, to be specifically used for in vitro diagnostic procedures;

(b) a specimen receptacle, other than a specimen receptacle that is intended for use in self-testing;

(c) a microbiological culture medium.

(3) In this clause:

examination means a set of operations having the object of determining the value or characteristics of a property.

Note: In some disciplines (for example, microbiology) an examination is the combination of a number of tests, observations or measurements.

specimen receptacle means a device, whether vacuum-type or not, specifically intended by its manufacturer for the primary containment and preservation of a specimen derived from the human body for the purpose of in vitro diagnostic examination.

Note 1: A specimen receptacle is considered to be an IVD medical device.

Note 2: A product for general laboratory use is not an IVD medical device unless the product is specifically intended by its manufacturer to be used for in vitro diagnostic examination.

1.7 Other IVD medical devices are Class 2 IVD medical devices

An IVD medical device not mentioned in this Schedule is classified as a Class 2 IVD medical device or a Class 2 in-house IVD medical device.

1.8 IVD medical devices intended for export only

Despite clauses 1.1 to 1.7, an IVD medical device is classified as a Class 1 IVD medical device if it is intended by the manufacturer for export only.

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Schedule 3—Conformity assessment procedures

(regulation 3.4)

Part 1—Full quality assurance procedures

1.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device:

(a) to:
  (i) implement a quality management system for the design, production, packaging, labelling and final inspection of the kind of device; and
  (ii) arrange for assessment of the system by the Secretary or an Australian conformity assessment body; and

(b) for a Class 4 IVD medical device, Class 4 in-house IVD medical device or Class III medical device—to arrange for examination of the design of the kind of device by the Secretary or an Australian conformity assessment body; and

(c) to allow the Secretary or an Australian conformity assessment body to monitor the operation of, and carry out inspections of, the system; and

(d) to make a declaration of conformity in relation to the kind of device; and

(e) to:
  (i) notify the Secretary or an Australian conformity assessment body of any change to the system, or to the kinds of devices to which the system is to be applied; and
  (ii) arrange for assessment of any such change by the Secretary or an Australian conformity assessment body; and

(f) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

Note: See Division 3.2 in relation to the kinds of medical devices to which these conformity assessment procedures may be applied.

1.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

1.3 Implementation and assessment of quality management system

(1) The manufacturer of a kind of medical device must:
  (a) implement a quality management system for the design, production, packaging, labelling and final inspection of the kind of device; and
  (b) arrange for assessment of the system by the Secretary or an Australian conformity assessment body.

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(2) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, the following information and undertakings:

(a) the name and business address of the manufacturer;

(b) details of each manufacturing site where the system is to be applied;

(c) all relevant information about the kind of medical devices to which the system is to be applied;

(d) the documentation in relation to the system;

(e) an undertaking by the manufacturer to continue to comply with the requirements of the system after assessment;

(f) an undertaking by the manufacturer to ensure that the system is at all times adequate and efficacious;

(g) an undertaking by the manufacturer:

(i) if the manufacturer arranged for assessment of the system by the Secretary—to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in paragraph 1.4(3A)(a) or (b) that the manufacturer becomes aware of in relation to the kind of medical device; or

(ii) if the manufacturer arranged for assessment of the system by an Australian conformity assessment body—to notify the body, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in paragraph 1.4(3A)(a) or (b) that the manufacturer becomes aware of in relation to the kind of medical device.

1.4 Requirements of quality management system

(1) A quality management system that is to be assessed under clause 1.3 must meet the requirements of this clause.

(2) The system must be of a kind such that its application will ensure that each medical device to which the system is applied complies with the applicable provisions of the essential principles, the classification rules, and these conformity assessment procedures, at each stage, from the design of the device until its final inspection before being supplied.

(3) The system must include post-marketing requirements under which the manufacturer of a medical device to which the system is applied is required:

(a) to systematically review experience gained, post-production, in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

(c) to:

(i) if the manufacturer arranged for assessment of the system under clause 1.3 by the Secretary—notify the Secretary, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of information referred to in subclause (3A); or

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(ii) if the manufacturer arranged for assessment of the system under clause 1.3 by an Australian conformity assessment body—notify the body, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of information referred to in subclause (3A).

Note: See also paragraph 41FN(3)(d) and sections 41MP and 41MPA of the Act in relation to the requirement to give certain information about a medical device to the Secretary.

(3A) For the purposes of subparagraphs (3)(c)(i) and (ii), the information is the following:

(a) information relating to:

(i) any malfunction or deterioration in the characteristics or performance of the kind of device; or

(ii) any inadequacy in the design, production, labelling or instructions for use of the kind of device, or in the advertising material for the kind of device; or

(iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health;

(b) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (a)(i) that has led the manufacturer to take steps to recall devices of that kind that have been distributed.

(4) Each requirement of the system must be documented in a systematic and orderly way in the form of written policies and procedures (for example, as quality programs, quality plans, quality manuals or quality records).

(5) The documentation of the system must include adequate information in relation to the following matters:

(a) the manufacturer's quality objectives;

(b) the organisation of the manufacturer's business, including, in particular, a description of the following:

(i) the organisational structure of the business;

(ii) the responsibilities of managerial staff and their authority in relation to the quality of the design and production of medical devices manufactured by the manufacturer;

(iii) the methods of monitoring whether the system is operating effectively, in particular, whether the desired quality of design and product is being achieved and how products that fail to meet the desired quality are controlled;

(c) the design of the kind of medical device to which the system is to be applied, including, in particular, the following:

(i) details of the processes, systems and measures used for controlling, monitoring and verifying that at each stage of the design process, the device complies with the applicable provisions of the essential principles;

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(ii) a general description of the kind of device, and of any variants of the kind of device, that the manufacturer plans to manufacture;

(iii) details of the design specifications for the kind of device, including:

(A) any medical device standard or conformity assessment standard that has been applied to the device; and

(B) the results of the risk analysis carried out; and

(C) if no medical device standard or conformity assessment standard, or part only of such a standard, has been applied to the device—the solutions adopted to ensure that each device complies with the applicable provisions of the essential principles;

(iv) for a kind of device that is intended by the manufacturer to be connected to another device—evidence demonstrating that the device will comply with the applicable provisions of the essential principles when it is connected to the other device and both devices are being used for their intended purposes;

(v) a statement indicating whether or not the kind of device incorporates, or is intended to incorporate, as an integral part, a substance mentioned in clause 7.4 of the essential principles, and, for a device that will do so, data derived from tests conducted in relation to the device and the substance, and their interaction;

(vi) a statement indicating whether or not the device, other than an IVD medical device, contains tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin;

(via) for an IVD medical device—a statement indicating whether or not the device contains viable tissues, cells, or substances of human or animal origin;

(vii) a copy of the clinical evidence, in relation to the kind of device, required by the clinical evaluation procedures;

(viii) a copy of the information to be provided with the kind of device;

(d) the inspection and quality assurance techniques to be applied in the production of the kind of medical device to which the system is to be applied, including, in particular, information about the following:

(i) the processes and procedures to be used (particularly in relation to sterilisation) and the documents relating to those processes and procedures;

(ii) the procedures to be used for purchasing goods or services in relation to the production of the kind of device and the documents relating to those procedures;

(iii) product identification procedures to be prepared and kept up-to-date from drawings, specifications or other documents at each stage of production;

(e) the tests or trials to be carried out before, during and after production of the kind of medical device to which the system is to be applied, including, in particular, information about:

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(i) the frequency with which the tests or trials are to be carried out; and
(ii) the equipment (including the traceability of the calibration of the equipment) used, or to be used, to carry out the tests or trials;

(f) the system for reviewing experience gained in the post-production phase in relation to the kind of medical device to which the quality management system has been applied, and the means by which any necessary corrective action will be applied in relation to the design or production of such devices;

(g) whether a conformity assessment standard has been applied to the system and, if no conformity assessment standard, or part only of a conformity assessment standard, has been applied to the system—the solutions adopted to ensure that the system complies with subclause (2).

1.5 Changes to quality management system or kinds of medical device to which system is to be applied

(1) This clause applies to the manufacturer of a kind of medical device if:
(a) the manufacturer has implemented, and had assessed under clause 1.3 of this Schedule, a quality management system that is to be applied to the kind of device; and
(b) after assessment, the manufacturer plans to make:
(i) a substantial change to the system; or
(ii) a change to the kinds of medical devices to which the system is to be applied.

(2) The manufacturer must:
(a) notify the Secretary or an Australian conformity assessment body, in writing, of the proposed change; and
(b) arrange for assessment of the change by the Secretary or the Australian conformity assessment body to verify whether the system, as changed, meets the requirements of clause 1.4 of this Schedule.

(3) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, details of any consequential changes to the information and documentation required under subclause 1.3(2) of this Schedule in relation to the system or kinds of devices.

(4) After any change to the quality management system, the manufacturer must ensure that the changed system continues to meet the requirements of clause 1.4 of this Schedule.

1.6 Examination of design of Class 4 IVD medical device, Class 4 in-house IVD medical device or Class III medical device

(1) This clause applies to the manufacturer of a Class 4 IVD medical device, a Class 4 in-house IVD medical device or a Class III medical device, to which the quality management system that is to be assessed under clause 1.3 is to be applied.

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(2) For the purpose of assessing whether the kind of medical device complies with the applicable provisions of the essential principles, the manufacturer of the device must arrange for examination by the Secretary or an Australian conformity assessment body of the design of the kind of device.

(3) For the purpose of enabling the examination to be carried out, the manufacturer must have available:

(a) information, in writing, in relation to the following matters in relation to the kind of medical device:

(i) the design;

(ii) the production process;

(iii) the intended performance; and

(b) a copy of the documentation mentioned in paragraph 1.4(5)(c) of this Schedule necessary to assess whether the kind of medical device complies with the applicable provisions of the essential principles.

(4) If, after examination by the Secretary or an Australian conformity assessment body of the design of a kind of medical device, the manufacturer makes a substantial change to the design, or the intended performance, of the kind of device, the manufacturer must:

(a) notify the Secretary or an Australian conformity assessment body, in writing, of the change; and

(b) arrange for examination of the change by the Secretary or the Australian conformity assessment body to assess whether the design, or the intended performance, of the medical device, as changed, complies with the applicable provisions of the essential principles.

(5) For the purpose of enabling an examination to be carried out under subclause (4), the manufacturer must have available, in writing, details of any consequential changes to the documentation in relation to the design of the device mentioned in paragraph 1.4(5)(c) of this Schedule.

Note: This clause need not be applied to:

(a) a Class IIb medical device—see Division 3.2, paragraphs 3.7(1)(a) and (2)(a); or

(b) a Class 3 IVD medical device—see Division 3.2, paragraph 3.7A(a); or

(c) a Class IIa medical device—see Division 3.2, paragraphs 3.8(1)(a) and (2)(a); or

(d) a Class 2 IVD medical device—see Division 3.2, paragraph 3.8A(a).

1.7 Information to be given to authorised person

(1) If requested to do so by an authorised person, the manufacturer of a kind of medical device must:

(a) give to the Secretary the following information in relation to the quality management system or the kinds of medical device to which the system is applied:

(i) a copy of the documentation mentioned in subclause 1.4(5) of this Schedule;

(ii) data in relation to the design of the kinds of medical device (for example, the results of any analysis of the device, calculations, tests);

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(iii) data in relation to the manufacture of the kinds of medical device (for example, inspection reports, test data, calibration data, information about the qualifications of staff); and

(b) arrange for tests specified by the authorised person to be carried out for the purpose of checking whether the quality management system is operating effectively.

(2) If any inspections or tests are carried out by an authorised person in relation to the manufacturer's premises, or medical devices produced by the manufacturer, the manufacturer may ask the authorised person to give to the manufacturer a report stating the findings of the inspections or tests.

1.8 Declaration of conformity

(1) The manufacturer of a kind of medical device to which a quality management system that has been assessed under clause 1.3 of this Schedule has been applied must make a declaration of conformity in relation to the kind of device.

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 1.8 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information in relation to each kind of medical device to which the system has been applied:

(i) the unique product identifier;

(ii) the medical device classification;

(iii) the device nomenclature system code; and

(d) if the system has not been applied to all medical devices of that kind manufactured by the manufacturer—give details of the medical devices to which the system has been applied (for example, by reference to lot numbers, batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(e) state that each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied; and

(f) state the identification number of the conformity assessment certificate, or of the Australian conformity assessment body certificate, issued in relation to the system or the kind of medical devices to which the system has been applied; and

(g) give details of any conformity assessment standard or medical device standard that has been applied to a kind of device to which the system has been applied; and

(h) be signed by a person authorised by the manufacturer; and

(i) set out the name and position of the person signing the declaration; and

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(j) state the date when the declaration is signed.

1.9 Records

(1) The manufacturer of a kind of medical device to which a quality management system that has been assessed under clause 1.3 of this Schedule has been applied must keep the following records in relation to the system and the kind of device:

(a) the documentation mentioned in subclause 1.4(5) of this Schedule;

(b) details of any changes made to the system and to the information and documentation required under subclause 1.3(2) of this Schedule;

(c) if the device is a Class 4 IVD medical device, Class 4 in-house IVD medical device or Class III medical device, the information and documentation required under subclause 1.6(3) of this Schedule;

(d) details of any changes made to the kind of medical device and to the documentation in relation to the design of the device mentioned in paragraph 1.4(5)(c) of this Schedule;

(e) the declaration of conformity under clause 1.8 of this Schedule;

(f) details of the systematic review carried out, post-production, in relation to medical devices of that kind;

(g) any notice, report, certificate or other document in relation to the system issued to the manufacturer by the Secretary or an Australian conformity assessment body.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the quality management system was applied.

(3) On request from the Secretary, the manufacturer must make the records available to the Secretary.

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Part 2—Type examination procedures

2.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer to arrange for examination by the Secretary or an Australian conformity assessment body of a representative sample of a kind of medical device (the ***type***).

Note: See Division 3.2 in relation to the kinds of medical devices to which these conformity assessment procedures may be applied.

2.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

2.3 Examination of type

(1) The manufacturer of a medical device must arrange for examination of the type by the Secretary or an Australian conformity assessment body.

(2) For the purpose of enabling the examination to be carried out, the manufacturer must have available, in writing, the following information:
  (a) the name and business address of the manufacturer;
  (b) the documentation mentioned in subclause (3) in relation to the type.

(3) For paragraph (2)(b), the documentation must include adequate information about the design, production process and intended performance of the type, and must include, in particular, the following:
  (a) a general description of the type, and of any variants of the type that the manufacturer plans to manufacture;
  (b) diagrams or drawings of the design of the type, including diagrams or drawings of any components, sub-assemblies or circuits of the type;
  (c) any descriptions or explanations that are necessary to enable the diagrams or drawings mentioned in paragraph (b), or the intended operation of the type, to be properly understood;
  (d) the proposed method or methods of manufacture of the type;
  (e) if the type is intended by the manufacturer to be supplied in a sterile state—a description of the method used to sterilise the type;
  (f) details of each medical device standard or conformity assessment standard that has been applied, wholly or in part, to the type;
  (g) if no medical device standard or conformity assessment standard has been applied, or such a standard has been only partly applied, to the type—descriptions of the solutions adopted to ensure that the type complies with the applicable provisions of the essential principles;

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(h) the results of any design calculations, risk analyses, investigations, technical tests, or any other tests, carried out in relation to the type;

(i) a statement indicating whether or not the type incorporates, or is intended to incorporate, as an integral part, a substance mentioned in clause 7.4 of the essential principles, and, for a type that does so, data derived from tests conducted in relation to the type and the substance, and their interaction;

(j) a statement indicating whether or not the device, other than an IVD medical device, contains tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin;

(ja) for an IVD medical device—a statement indicating whether or not the device contains viable tissues, cells, or substances of human or animal origin;

(k) a copy of the clinical evidence, in relation to the kind of device, required by the clinical evaluation procedures;

(l) a copy of the information to be provided with the type.

(4) The manufacturer must make available to the Secretary or the Australian conformity assessment body for examination:

(a) a sample of the type; and

(b) on request from the Secretary or the Australian conformity assessment body, additional samples of the type.

(5) If the type is intended by the manufacturer to be connected to another medical device, the manufacturer must, on request from the Secretary or the Australian conformity assessment body, make available to the Secretary or the Australian conformity assessment body, or arrange for the Secretary or the Australian conformity assessment body to have access to, a sample of the device.

2.4 Changes to design of medical device after examination

(1) This clause applies if, after examination by the Secretary or an Australian conformity assessment body of a type, the manufacturer of the type plans to make a substantial change to the design, or intended performance, of the kind of medical device to which the type relates.

(2) The manufacturer must:

(a) notify the Secretary or an Australian conformity assessment body, in writing, of the proposed change; and

(b) arrange for examination of the change by the Secretary or the Australian conformity assessment body to verify whether the type, as changed, meets the requirements of clause 2.3 of this Schedule.

(3) For the purpose of enabling the examination to be carried out, the manufacturer must have available, in writing, details of any consequential changes to the documentation required under subclause 2.3(3) of this Schedule in relation to the type.

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2.5 Records

(1) The manufacturer of the type that has been examined under this Part must keep the following records:

(a) the documentation required under subclause 2.3(3) of this Schedule in relation to the type;

(b) details of any changes made to the type and to the documentation required under subclause 2.3(3) of this Schedule;

(c) any notice, report, certificate or other document in relation to the type issued to the manufacturer by the Secretary or an Australian conformity assessment body.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device of that type.

(3) On request from the Secretary, the manufacturer must make the records available to the Secretary.

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Part 3—Verification procedures

3.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device:

(a) to arrange for examination and testing of the kind of device by the Secretary or an Australian conformity assessment body; and

(b) to make a declaration of conformity in relation to the kind of device; and

(c) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

Note: See Division 3.2 in relation to the kinds of medical devices to which these conformity assessment procedures may be applied.

3.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

3.3 Verification of conformity

(1) The manufacturer of a medical device must arrange for examination and testing by the Secretary or an Australian conformity assessment body of each device of that kind, or a representative sample from a batch of medical devices of that kind, to verify that:

(a) for a kind of device in relation to which the type examination procedures have been applied—each device, or representative sample, conforms to the approved type; and

(b) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied—each device, or representative sample, is in accordance with the technical documentation prepared under clause 6.4 of those procedures for that kind of device; and

(c) each device, or representative sample, complies with the applicable provisions of the essential principles, the classification rules and these conformity assessment procedures.

(2) For the purpose of enabling the examination and testing to be carried out, the manufacturer must have available, in writing, the following information and undertakings:

(a) the name and business address of the manufacturer;

(b) the documentation describing the manufacturing process to be used to manufacture the kind of device;

(c) a description of the procedures that have been, or will be, implemented to ensure that all devices of that kind manufactured by the manufacturer will be uniform;

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(d) an undertaking to implement those procedures to ensure that all devices of that kind manufactured by the manufacturer will be uniform;

(e) an undertaking by the manufacturer:

(i) if the manufacturer arranged for examination and testing by the Secretary—to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in paragraph 3.4(2A)(a) or (b) that the manufacturer becomes aware of in relation to the kind of medical device; or

(ii) if the manufacturer arranged for examination and testing by an Australian conformity assessment body—to notify the body, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in paragraph 3.4(2A)(a) or (b) that the manufacturer becomes aware of in relation to the kind of medical device;

(f) for a kind of device in relation to which the type examination procedures have been applied—evidence that the device conforms to the approved type and a copy of the technical documentation required under subclause 2.3(3) of the type examination procedures for the approved type;

(g) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied—a copy of the technical documentation prepared under clause 6.4 of those procedures for that kind of device.

(3) The manufacturer must make available to the Secretary or the Australian conformity assessment body for examination and testing:

(a) for a kind of device in relation to which the type examination procedures have been applied:

(i) each medical device that is to be verified in relation to the approved type; or

(ii) each medical device selected by the Secretary or the Australian conformity assessment body on a statistical basis from a uniform batch of devices that are to be verified in relation to the approved type; and

(b) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied:

(i) each medical device of that kind to which those procedures have been applied; or

(ii) each medical device selected by the Secretary or the Australian conformity assessment body on a statistical basis from a uniform batch of devices of that kind to which those procedures have been applied.

3.4 Requirements of manufacturing system

(1) The manufacturer of a medical device must ensure that:

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(a) for a kind of device in relation to which the type examination procedures have been applied—the process used to manufacture the device results in the device conforming to the approved type; and

(b) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied—the process used to manufacture the device results in the device being in accordance with the technical documentation prepared under clause 6.4 of those procedures for that kind of device.

(2) The manufacturer of a medical device of a kind mentioned in subclause (1) must ensure that the process used to manufacture the device includes post-marketing requirements under which the manufacturer is required:

(a) to systematically review experience gained in the post-production phase in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

(c) to:

(i) if the manufacturer arranged for examination and testing under clause 3.3 by the Secretary—notify the Secretary, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of information referred to in subclause (2A); or

(ii) if the manufacturer arranged for examination and testing under clause 3.3 by an Australian conformity assessment body—notify the body, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of information referred to in subclause (2A).

Note: See also paragraph 41FN(3)(d) and sections 41MP and 41MPA of the Act in relation to the requirement to give certain information about a medical device to the Secretary.

(2A) For the purposes of subparagraphs (2)(c)(i) and (ii), the information is the following:

(a) information relating to:

(i) any malfunction or deterioration in the characteristics or performance of the kind of device; or

(ii) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or

(iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health;

(b) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (a)(i) that has led the manufacturer to take steps to recall devices of that kind that have been distributed.

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(3) Before manufacturing a medical device of a kind mentioned in subclause (1), the manufacturer must prepare documentation describing the manufacturing process to be used to produce the device.

(4) Without limiting subclause (3), the documentation must include a description of the procedures that have been, or will be, implemented to ensure that all devices of that kind manufactured by the manufacturer will be uniform.

3.5 Declaration of conformity

(1) The manufacturer of a Class III medical device or Class IIb medical device that has been verified under this Part must make a declaration of conformity in relation to the kind of device.

Note: This clause need not be applied to the following kinds of medical devices if the declaration of conformity (not requiring assessment by Secretary) procedures have been applied to the device:

(a) a Class IIa medical device (see Division 3.2, subparagraph 3.8(1)(b)(i));

(b) a Class I medical device that has a measuring function (see Division 3.2, paragraph 3.9(3)(a)).

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 3.5 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information in relation to each device that has been verified:

(i) the unique product identifier;

(ii) the medical device classification;

(iii) the device nomenclature system code; and

(d) if the verification does not relate to all medical devices of that kind manufactured by the manufacturer—give details of the medical devices to which the verification relates (for example, by reference to lot numbers, batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(e) for a kind of device in relation to which the type examination procedures have been applied:

(i) state the identification number of the conformity assessment certificate, or of the Australian conformity assessment body certificate, issued in relation to the approved type; and

(ii) state that the kind of device conforms to the approved type; and

(f) state that each kind of medical device or batch of devices complies with the applicable provisions of the essential principles and the classification rules;

(g) state the basis on which the declaration is made; and

(h) give details of any conformity assessment standard or medical device standard that has been applied to the kind of device or the processes used to manufacture the device; and

(i) be signed by a person authorised by the manufacturer; and

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(j) set out the name and position of the person signing the declaration; and
(k) state the date when the declaration is signed.

3.6 Records

(1) The manufacturer of a kind of medical device that has been verified under this Part must keep the following records:
  (a) the documentation mentioned in subclause 3.4(3) of this Schedule;
  (b) for a Class III medical device or Class IIb medical device—the declaration of conformity under clause 3.5 of this Schedule;
  (c) any notice, report, certificate or other document in relation to the device, or a batch of devices that includes the device, issued to the manufacturer by the Secretary or an Australian conformity assessment body.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the verification relates.

(3) On request from the Secretary, the manufacturer must make the records available to the Secretary.

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Part 4—Production quality assurance procedures

4.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device:

(a) to:
  (i) implement a quality management system for the production and final inspection of the kind of device; and
  (ii) arrange for assessment of the system by the Secretary or an Australian conformity assessment body; and
(b) to allow the Secretary or an Australian conformity assessment body to monitor the operation of, and carry out inspections of, the system; and
(c) to make a declaration of conformity in relation to the kind of device; and
(d) to:
  (i) notify the Secretary or an Australian conformity assessment body of any change to the system; and
  (ii) arrange for assessment of any such change by the Secretary or an Australian conformity assessment body; and
(e) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

Note: See Division 3.2 in relation to the kinds of medical devices to which these conformity assessment procedures may be applied.

4.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

4.3 Implementation and assessment of production quality management system

(1) The manufacturer of a medical device must:
  (a) implement a quality management system for the production and final inspection of the kind of device; and
  (b) arrange for assessment of the system by the Secretary or an Australian conformity assessment body.

(2) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, the following information and undertakings:
  (a) the name and business address of the manufacturer;
  (b) details of each manufacturing site where the system is to be applied;
  (c) all relevant information about the kinds of medical devices to which the system is to be applied;
  (d) the documentation in relation to the system;

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(e) an undertaking by the manufacturer to continue to comply with the requirements of the system after assessment;

(f) an undertaking by the manufacturer to ensure that the system is at all times adequate and efficacious;

(g) for a kind of device in relation to which the type examination procedures have been applied—evidence that the device conforms to the approved type and a copy of the technical documentation required under subclause 2.3(3) of the type examination procedures for the approved type;

(h) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied—a copy of the technical documentation prepared under clause 6.4 of those procedures for that kind of device;

(i) an undertaking by the manufacturer:

(i) if the manufacturer arranged for assessment of the system by the Secretary—to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in paragraph 4.4(3A)(a) or (b) that the manufacturer becomes aware of in relation to the kind of medical device; or

(ii) if the manufacturer arranged for assessment of the system by an Australian conformity assessment body—to notify the body, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in paragraph 4.4(3A)(a) or (b) that the manufacturer becomes aware of in relation to the kind of medical device.

4.4 Requirements of production quality management system

(1) A quality management system that is to be assessed under clause 4.3 must meet the requirements of this clause.

(2) The system must be of a kind such that its application will ensure that:

(a) each medical device to which the system is applied that is of a kind in relation to which the type examination procedures have been applied conforms to the approved type; and

(b) each medical device to which the system is applied that is of a kind to which the declaration of conformity (not requiring assessment by Secretary) procedures are applied is in accordance with the technical documentation prepared under clause 6.4 of those procedures for the device.

(3) The system must include post-marketing requirements under which the manufacturer of a medical device to which the system is applied is required:

(a) to systematically review experience gained in the post-production phase in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

(c) to:

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(i) if the manufacturer arranged for assessment of the system under clause 4.3 by the Secretary—notify the Secretary, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of information referred to in subclause (3A); or

(ii) if the manufacturer arranged for assessment of the system under clause 4.3 by an Australian conformity assessment body—notify the body, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of information referred to in subclause (3A).

Note: See also paragraph 41FN(3)(d) and sections 41MP and 41MPA of the Act in relation to the requirement to give certain information about a medical device to the Secretary.

(3A) For the purposes of subparagraphs (3)(c)(i) and (ii), the information is the following:

(a) information relating to:

(i) any malfunction or deterioration in the characteristics or performance of the kind of device; or

(ii) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or

(iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health;

(b) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (a)(i) that has led the manufacturer to take steps to recall devices of that kind that have been distributed.

(4) Each requirement of the system must be documented in a systematic and orderly way in the form of written policies and procedures (for example, as quality programs, quality plans, quality manuals or quality records).

(5) The documentation of the system must include adequate information in relation to the following matters:

(a) the manufacturer's quality objectives;

(b) the organisation of the manufacturer's business, including, in particular, a description of the following:

(i) the organisational structure of the business;

(ii) the responsibilities of managerial staff and their authority in relation to the production of the medical devices produced by the manufacturer;

(iii) the methods of monitoring whether the system is operating effectively, in particular, whether the desired quality of product is being achieved and how products that fail to meet the desired quality are controlled;

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(c) the inspection and quality assurance techniques applied in the manufacturing process, including, in particular, information about the following:

(i) the processes and procedures to be used (particularly in relation to sterilisation) and the documents relating to those procedures;

(ii) the procedures to be used for purchasing goods or services in relation to the production of the kind of device produced and the documents relating to those procedures;

(iii) product identification procedures to be prepared and kept up-to-date from drawings, specifications or other documents at each stage of manufacture;

(d) the tests or trials to be carried out before, during and after production of the kind of medical device to which the system is to be applied, including, in particular, information about:

(i) the frequency with which the tests or trials are to be carried out; and

(ii) the equipment (including the traceability of the calibration of the equipment) used, or to be used, to carry out the tests or trials;

(e) the system for reviewing experience gained in the post-production phase in relation to the kind of medical device to which the quality management system has been applied, and the means by which any necessary corrective action will be applied in relation to the design or production of such devices;

(f) whether a conformity assessment standard has been applied to the system and, if no conformity assessment standard, or part only of a conformity assessment standard, has been applied to the system—the solutions adopted to ensure that the system complies with subclause (2).

4.5 Changes to production quality management system

(1) This clause applies to the manufacturer of a medical device if:

(a) the manufacturer has implemented, and had assessed under clause 4.3 of this Schedule, a quality management system that is to be applied to the device; and

(b) after assessment, the manufacturer plans to make a substantial change to the system.

(2) The manufacturer must:

(a) notify the Secretary or an Australian conformity assessment body, in writing, of the proposed change; and

(b) arrange for assessment of the change by the Secretary or the Australian conformity assessment body to verify whether the system, as changed, meets the requirements of clause 4.4 of this Schedule.

(3) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, details of any consequential changes to the information and documentation required under subclause 4.3(2) of this Schedule in relation to the system.

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(4) After any change to the quality management system, the manufacturer must ensure that the changed system continues to meet the requirements of clause 4.4 of this Schedule.

4.6 Information to be given to authorised person

(1) If requested to do so by an authorised person, the manufacturer of a medical device must:

(a) give to the Secretary the following information in relation to the quality management system or the kinds of medical device to which the system is applied:

(i) a copy of the documentation mentioned in subclause 4.4(5) of this Schedule;

(ii) data in relation to the production of the kinds of medical device (for example, inspection reports, test data, calibration data, information about the qualifications of staff); and

(b) arrange for tests specified by the authorised person to be carried out for the purpose of checking whether the quality management system is operating effectively.

(2) If any inspections or tests are carried out by an authorised person under this clause, the manufacturer may ask the authorised person to give to the manufacturer a report stating the findings of the inspections or tests.

4.7 Declaration of conformity

(1) The manufacturer of a Class 4 IVD medical device, Class 3 IVD medical device, Class III medical device or Class IIb medical device to which a quality management system that has been assessed under clause 4.3 of this Schedule has been applied must make a declaration of conformity in relation to the kind of device.

Note: This clause need not be applied to the following kinds of medical devices, if the declaration of conformity (not requiring assessment by Secretary) procedures have been applied to the device:

(a) a Class IIa medical device—see Division 3.2, subparagraph 3.8(1)(b)(ii);

(b) a Class 2 IVD medical device—see Division 3.2, paragraph 3.8A(b);

(c) a Class I medical device that the manufacturer intends to be supplied in a sterile state—see Division 3.2, subclause 3.9(2);

(d) a Class I medical device that has a measuring function—see Division 3.2, paragraph 3.9(3)(b).

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 4.7 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information in relation to each kind of medical device to which the system has been applied:

(i) the medical device classification;

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(ii) the device nomenclature system code; and

(d) if the system has not been applied to all medical devices of that kind manufactured by the manufacturer—give details of the medical devices to which the system has been applied (for example, by reference to lot numbers, batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(e) for a kind of device in relation to which the type examination procedures have been applied—state that:

(i) the type examination procedures have been applied to the kind of device; and

(ii) the kind of device conforms to the approved type; and

(f) state the identification number of the conformity assessment certificate, or of the Australian conformity assessment body certificate, issued in relation to the system or the kind of medical devices to which the system has been applied; and

(g) state that each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules and the production quality assurance procedures before being supplied; and

(h) give details of any conformity assessment standard that has been applied to the system; and

(i) be signed by a person authorised by the manufacturer; and

(j) set out the name and position of the person signing the declaration; and

(k) state the date when the declaration is signed.

4.8 Records

(1) The manufacturer of a kind of medical device to which a quality management system that has been assessed under clause 4.3 of this Schedule has been applied must keep the following records in relation to the system and the kind of device:

(a) the documentation mentioned in subclause 4.4(5) of this Schedule;

(b) details of any changes made to the system and to the information and documentation required under subclause 4.5(3) of this Schedule;

(c) for a Class 4 IVD medical device, Class 3 IVD medical device, Class III medical device or Class IIb medical device—the declaration of conformity under clause 4.7 of this Schedule;

(d) any notice, report, certificate or other document in relation to the system issued to the manufacturer by the Secretary or an Australian conformity assessment body.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the quality management system was applied.

(3) On request from the Secretary, the manufacturer must make the records available to the Secretary.

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Part 5—Product quality assurance procedures

5.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device:

(a) to:
  (i) implement a product quality management system for the final inspection and testing of the kind of device; and
  (ii) arrange for assessment of the system by the Secretary or an Australian conformity assessment body; and
(b) to allow the Secretary or an Australian conformity assessment body to monitor the operation of, and carry out inspections of, the system; and
(c) to make a declaration of conformity in relation to the kind of device; and
(d) to:
  (i) notify the Secretary or an Australian conformity assessment body of any change to the system, or to the kinds of devices to which the system is to be applied; and
  (ii) arrange for assessment of any such change by the Secretary or an Australian conformity assessment body; and
(e) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

Note: See Division 3.2 in relation to the kinds of medical devices to which these conformity assessment procedures may be applied.

5.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

5.3 Implementation and assessment of product quality management system

(1) The manufacturer of a medical device must:
  (a) implement a product quality management system for the final inspection and testing of the kind of device; and
  (b) arrange for assessment of the system by the Secretary or an Australian conformity assessment body.

(2) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, the following information and undertakings:
  (a) the name and business address of the manufacturer;
  (b) details of each manufacturing site where the system is to be applied;
  (c) all relevant information about the kinds of medical devices to which the system is to be applied;
  (d) the documentation in relation to the system;

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(e) an undertaking by the manufacturer to continue to comply with the requirements of the system after assessment;

(f) an undertaking by the manufacturer to ensure that the system is at all times adequate and efficacious;

(g) for a kind of device in relation to which the type examination procedures have been applied—evidence that the device conforms to the approved type and the technical documentation required under subclause 2.3(3) of the type examination procedures for the device;

(h) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied—a copy of the technical documentation prepared under clause 6.4 of those procedures for that kind of device;

(i) an undertaking by the manufacturer:

(i) if the manufacturer arranged for assessment of the system by the Secretary—to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in paragraph 5.4(3A)(a) or (b) that the manufacturer becomes aware of in relation to the kind of medical device; or

(ii) if the manufacturer arranged for assessment of the system by an Australian conformity assessment body—to notify the body, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in paragraph 5.4(3A)(a) or (b) that the manufacturer becomes aware of in relation to the kind of medical device.

5.4 Requirements of product quality management system

(1) A quality management system that is to be assessed under clause 5.3 must meet the requirements of this clause.

(2) The system must be of a kind such that its application will ensure that each medical device, or representative sample of each batch of medical devices, is examined and tested to ensure that the device, or representative sample:

(a) for a kind of device in relation to which the type examination procedures have been applied—conforms to the approved type; or

(b) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied—is in accordance with the technical documentation prepared under clause 6.4 of those procedures for the device.

(3) The system must include post-marketing requirements under which the manufacturer of a medical device to which the system is applied is required:

(a) to systematically review experience gained in the post-production phase in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

(c) to:

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(i) if the manufacturer arranged for assessment of the system under clause 5.3 by the Secretary—notify the Secretary, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of information referred to in subclause (3A); or

(ii) if the manufacturer arranged for assessment of the system under clause 5.3 by an Australian conformity assessment body—notify the body, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of information referred to in subclause (3A).

Note: See also paragraph 41FN(3)(d) and sections 41MP and 41MPA of the Act in relation to the requirement to give certain information about a medical device to the Secretary.

(3A) For the purposes of subparagraphs (3)(c)(i) and (ii), the information is the following:

(a) information relating to:

(i) any malfunction or deterioration in the characteristics or performance of the kind of device; or

(ii) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or

(iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health;

(b) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (a)(i) that has led the manufacturer to take steps to recall devices of that kind that have been distributed.

(4) Each requirement of the system must be documented in a systematic and orderly way in the form of written policies and procedures (for example, as quality programs, quality plans, quality manuals or quality records).

(5) The documentation of the system must include adequate information in relation to the following matters:

(a) the manufacturer's quality objectives;

(b) the organisation of the manufacturer's business, including, in particular, a description of the following:

(i) the organisational structure of the business;

(ii) the responsibilities of managerial staff and their authority in relation to the quality of the medical devices manufactured by the manufacturer;

(iii) the methods of monitoring whether the system is operating effectively, in particular, whether the desired quality of product is being achieved and how products that fail to meet the desired quality are controlled;

(c) the examinations and tests to be carried out after manufacture, including, in particular, information about:

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(i) the frequency with which the examinations and tests are to be carried out; and

(ii) the equipment (including the traceability of the calibration of the equipment) to be used to carry out the examinations and tests;

(d) the quality records to be kept, including, for example, records in relation to inspections, tests, calibration of equipment and qualifications of staff.

5.5 Changes to product quality management system or kinds of medical device

(1) This clause applies to the manufacturer of a medical device if:

(a) the manufacturer has implemented, and had assessed under clause 5.3 of this Schedule, a quality management system that is to be applied to the device; and

(b) after assessment, the manufacturer plans to make:

(i) a substantial change to the system; or

(ii) a change to the kinds of medical devices to which the system is to be applied.

(2) The manufacturer must:

(a) notify the Secretary or an Australian conformity assessment body, in writing, of the proposed change; and

(b) arrange for assessment of the change by the Secretary or the Australian conformity assessment body to verify whether the system, as changed, meets the requirements of clause 5.4 of this Schedule.

(3) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, details of any consequential changes to the information and documentation required under subclause 5.3(2) of this Schedule in relation to the system or kinds of devices.

(4) After any change to the quality management system, the manufacturer must ensure that the changed system continues to meet the requirements of clause 5.4 of this Schedule.

5.6 Information to be given to authorised person

(1) If requested to do so by an authorised person, the manufacturer of a medical device must:

(a) give to the Secretary any of the following information in relation to the quality management system or the kinds of medical device to which the system is applied:

(i) a copy of the documentation mentioned in subclause 5.4(5) of this Schedule;

(ii) the quality records in relation to the final inspection and testing of the kinds of medical device to which the system is applied (for example, inspection reports, test data, calibration data, information about the qualifications of staff); and

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(b) arrange for tests specified by the authorised person to be carried out for the purpose of checking whether the quality management system is operating effectively.

(2) If any inspections or tests are carried out by an authorised person in relation to the manufacturer's premises, or medical devices manufactured by the manufacturer, the manufacturer may ask the authorised person to give to the manufacturer a report stating the findings of the inspections or tests.

5.7 Declaration of conformity

(1) The manufacturer of a Class IIb medical device to which a quality management system that has been assessed under clause 5.3 of this Schedule has been applied must make a declaration of conformity in relation to the kind of device.

Note: This clause need not be applied to the following kinds of medical devices if the declaration of conformity (not requiring assessment by Secretary) procedures have been applied to the device:

(a) a Class IIa medical device (see Division 3.2, subparagraph 3.8(1)(b)(iii));

(b) a Class I medical device that has a measuring function (see Division 3.2, paragraph 3.9(3)(c)).

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 5.7 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information in relation to each kind of medical device to which the system has been applied:

(i) the unique product identifier;

(ii) the medical device classification;

(iii) the device nomenclature system code; and

(d) if the system has not been applied to all medical devices of that kind manufactured by the manufacturer—give details of the medical devices to which the system has been applied (for example, by reference to lot numbers, batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(e) for a kind of device in relation to which the type examination procedures have been applied—state that:

(i) the type examination procedures have been applied to the kind of device; and

(ii) the kind of device conforms to the approved type; and

(f) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied—state that the kind of device is in accordance with the technical documentation prepared under clause 6.4 of those procedures for the kind of device; and

(g) state the identification number of the conformity assessment certificate, or of the Australian conformity assessment body certificate, issued in relation

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to the system or the kind of medical devices to which the system has been applied; and

(h) give details of any conformity assessment standard that has been applied to the system; and

(i) be signed by a person authorised by the manufacturer; and

(j) set out the name and position of the person signing the declaration; and

(k) state the date when the declaration is signed.

5.8 Records

(1) The manufacturer of a kind of medical device to which a quality management system that has been assessed under clause 5.3 of this Schedule has been applied must keep the following records in relation to the system and the kind of device:

(a) the documentation mentioned in subclause 5.4(5) of this Schedule;

(b) details of any changes made to the system and to the information and documentation required under subclause 5.5(3) of this Schedule;

(c) details of any changes made to the kinds of medical devices to which the system was applied;

(d) for a Class IIb medical device—the declaration of conformity under clause 5.7 of this Schedule;

(e) any notice, report, certificate or other document in relation to the system issued to the manufacturer by the Secretary or an Australian conformity assessment body.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the quality management system was applied.

(3) On request from the Secretary, the manufacturer must make the records available to the Secretary.

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Part 6—Declaration of conformity (not requiring assessment by Secretary) procedures

6.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device:

(a) to prepare technical documentation in relation to the kind of device to enable assessment of the device; and

(b) to make a declaration of conformity in relation to the kind of device; and

(c) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

Note: See Division 3.2 in relation to the kinds of medical devices to which these conformity assessment procedures may be applied.

6.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

6.3 Implementation

(1) The manufacturer of a medical device must prepare technical documentation in relation to the kind of device in a form that, if the Secretary decides to do so, would allow the Secretary to assess whether the device complies with the applicable provisions of the essential principles, the classification rules and these conformity assessment procedures.

(2) For the purpose of enabling an assessment to be carried out, the manufacturer must have available, in writing, the following information and undertakings:

(a) the name and business address of the manufacturer;

(b) details of each manufacturing site where these conformity assessment procedures are to be applied;

(c) all relevant information required to identify the kinds of medical devices to which these conformity assessment procedures are to be applied;

(d) an undertaking by the manufacturer to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in subparagraph 6.5(2)(c)(i) or (ii) that the manufacturer becomes aware of in relation to a kind of medical device.

6.4 Required technical documentation

(1) The technical documentation must include adequate information in relation to the kind of device, and must include, in particular, the following:

(a) a general description of the kind of device, and of any variants of the kind of device that the manufacturer plans to manufacture;

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(b) diagrams or drawings of the design of the kind of device, including diagrams or drawings of any components, sub-assemblies or circuits of the kind of device;

(c) any descriptions or explanations that are necessary to enable the diagrams or drawings mentioned in paragraph (b), or the intended operation of the kind of device, to be properly understood;

(d) if the kind of device is intended by the manufacturer to be supplied in a sterile state—a description of the method used to sterilise the kind of device;

(e) details of each medical device standard or conformity assessment standard that has been applied, wholly or in part, to the kind of device;

(f) if no medical device standard or conformity assessment standard has been applied, or a medical device standard or conformity assessment standard has been only partly applied, to the kind of device—the solutions adopted to ensure that each device complies with the applicable provisions of the essential principles;

(g) the results of any design calculations, risk analyses, investigations, technical tests, or any other tests, carried out in relation to the kind of device;

(h) if the kind of device is intended by the manufacturer to be connected to another device—evidence demonstrating that the device will comply with the applicable provisions of the essential principles when it is connected to the other device and both devices are being used for their intended purposes;

(i) a copy of the clinical evidence, in relation to the kind of device, required by the clinical evaluation procedures;

(j) a copy of the information to be provided with the kind of device.

(2) If the manufacturer makes a change to the design or the production of the kind of medical device after the technical documentation has been prepared (for example, because it was necessary to apply corrective action in relation to the kind of device), the manufacturer must revise the technical documentation to take account of the change.

6.5 Post-marketing system

(1) The manufacturer of a medical device to which technical documentation prepared under clause 6.4 of this Schedule applies must establish, and keep up-to-date, a post-marketing system that complies with subclause (2) for use in relation to devices of that kind.

(2) A post-marketing system complies with this subclause in relation to a medical device if the system requires the manufacturer of the device:

(a) to systematically review experience gained in the post-production phase in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

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(c) to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of:

(i) information relating to:

(A) any malfunction or deterioration in the characteristics or performance of the kind of device; or

(B) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or

(C) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or

(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recall devices of that kind that have been distributed.

Note: See also paragraph 41FN(3)(d) and sections 41MP and 41MPA of the Act in relation to the requirement to give certain information about a medical device to the Secretary.

6.6 Declaration of conformity

(1) The manufacturer of a kind of medical device to which technical documentation prepared under clause 6.4 of this Schedule applies must make a declaration of conformity in relation to the kind of device.

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 6.6 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information in relation to each kind of medical device to which the technical documentation applies:

(i) the unique product identifier;

(ii) the medical device classification;

(iii) the device nomenclature system code; and

(d) if the technical documentation applies to a Class IIa medical device that the manufacturer intends to be supplied in a sterile state or a Class I medical device that the manufacturer intends to be supplied in a sterile state—state that the production quality assurance procedures have also been applied to the device; and

(e) if the technical documentation applies to a Class IIa medical device that the manufacturer intends to be supplied in a non-sterile state, or a Class I medical device that has a measuring function and that the manufacturer intends to be supplied in a non-sterile state—state which of the following conformity assessment procedures have also been applied to the device:

(i) the verification procedures;

(ii) the production quality assurance procedures;

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(iii) the product quality management system procedures; and

(f) if the technical documentation does not apply to all medical devices of that kind manufactured by the manufacturer—give details of the medical devices to which the technical documentation applies (for example, by reference to lot numbers, batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(g) state that each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, the classification rules, and these procedures; and

(h) if the technical documentation applies to any of the following kinds of medical devices:

(i) a Class IIa medical device;

(ii) a Class 2 IVD medical device;

(iii) a Class I medical device that the manufacturer intends to be supplied in a sterile state;

(iv) a Class I medical device that has a measuring function;

state the identification number of the conformity assessment certificate, or of the Australian conformity assessment body certificate, issued in relation to the kind of medical device, or the quality management system that has been applied to the kind of device, as a result of the application to the device of the conformity assessment procedures set out in Part 3, 4 or 5 of this Schedule; and

(i) give details of any medical device standard or conformity assessment standard that has been applied to the device; and

(j) be signed by a person authorised by the manufacturer; and

(k) set out the name and position of the person signing the declaration; and

(l) state the date when the declaration is signed.

6.7 Records

(1) The manufacturer of a medical device to which technical documentation prepared under clause 6.4 of this Schedule applies must keep the following records:

(a) the technical documentation prepared under clause 6.4 of this Schedule, including any revisions of the documentation prepared as a result of changes to the design or production of the kind of device;

(b) details of any changes made to the design or production of the kind of medical device and to the documentation required under clause 6.4 of this Schedule;

(c) the declaration of conformity under clause 6.6 of this Schedule.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the technical documentation prepared clause 6.4 of this Schedule applies.

(3) On request from the Secretary, the manufacturer must make the records available to the Secretary.

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Part 6A—Procedures applying to Class 1, 2 and 3 in-house IVD medical devices

6A.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a Class 1 in-house IVD medical device, Class 2 in-house IVD medical device or Class 3 in-house IVD medical device to do the following:

(a) implement procedures relating to the application of a quality management system to the manufacture of the device;

(b) provide information to the Secretary about the quality management system and the device;

(c) establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

6A.2 Procedures

Notification of devices being manufactured

(1) The manufacturer of a Class 1 in-house IVD medical device, Class 2 in-house IVD medical device or Class 3 in-house IVD medical device must notify the Secretary, in accordance with subclauses (2) and (3), of all the Class 1, 2 or 3 in-house IVD medical devices being manufactured.

(2) A notification under subclause (1) must:

(a) be in a form approved in writing by the Secretary; and

(b) contain the information required by the form; and

(c) cover each Class 1, 2 or 3 in-house IVD medical device being manufactured at the time the notification is given.

(3) A notification under subclause (1) must be given to the Secretary:

(a) if the manufacturer manufactures one or more Class 1, 2 or 3 in-house IVD medical devices before 1 July 2017—no later than 20 working days after 1 July 2017; and

(b) if, in a financial year, the manufacturer starts to manufacture a Class 1, 2 or 3 in-house IVD medical device not covered by the most recent of any previous notification given to the Secretary under subclause (1)—by the later of the following:

(i) 1 July of the next financial year;

(ii) 20 working days after manufacturing the device for the first time.

Accreditation requirements etc.

(4) The laboratory in which the Class 1, 2 or 3 in-house IVD medical device is manufactured must:

(a) be accredited as a testing laboratory by NATA, or by a conformity assessment body determined by the Secretary, as meeting one of the following standards, as published by the International Organization for Standardization and as amended from time to time:
  (i) ISO 15189, *Medical laboratories—Requirements for quality and competence*;
  (ii) ISO/IEC 17025, *General requirement for the competence of testing and calibration laboratories*; and

(b) meet the National Pathology Accreditation Advisory Council standard *Requirements for the Development and Use of in-house In Vitro Diagnostic Devices (IVDs)*, as amended from time to time.

6A.3 Information to be given to the Secretary

(1) On request by an authorised person, the manufacturer of a Class 1, 2 or 3 in-house IVD medical device must:
  (a) give to the Secretary, within the period specified in the request (which must not be less than 20 working days after the request is made), the following information in relation to the device and the quality management system applied to the device:
    (i) a copy of the documentation mentioned in subclause (2);
    (ii) data for the design of the device (for example, the results of any analysis of the device, calculations or tests);
    (iii) data for the manufacture of the device (for example, inspection reports, test data, calibration data, information about the qualifications of staff); and
  (b) arrange for tests specified by the authorised person to be carried out for the purpose of checking whether the quality management system is operating effectively.

(2) The documentation must include the following information:
  (a) the manufacturer's quality objectives;
  (b) the organisation of the manufacturer's business, including a description of the following:
    (i) the organisational structure of the business;
    (ii) the responsibilities of managerial staff and their authority in relation to the quality of the design and production of medical devices manufactured by the manufacturer;
    (iii) the methods of monitoring whether the system is operating effectively, including whether the desired quality of design and product is being achieved and how products that fail to meet the desired quality are controlled;
  (c) the design of the medical device to which the system is to be applied, including the following:
    (i) details of the processes, systems and measures used for controlling, monitoring and verifying that, at each stage of the design process, the

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device complies with the applicable provisions of the essential principles;

(ii) a general description of the device;

(iii) details of the design specifications for the device, including:

(A) any medical device standard that has been applied to the device; and

(B) the results of the risk analysis carried out; and

(C) if no medical device standard, or part of it, has been applied to the device—the solutions adopted to ensure that each device complies with the applicable provisions of the essential principles;

(iv) for a device that is intended by the manufacturer to be connected to another device—evidence demonstrating that the device will comply with the applicable provisions of the essential principles when it is connected to the other device and both devices are being used for their intended purposes;

(v) a statement indicating whether or not the device contains viable tissues, cells or substances of human or animal origin;

(vi) a copy of the clinical evidence, in relation to the device, required by the clinical evaluation procedures;

(vii) a copy of the information to be provided with the device, when relevant;

(d) the inspection and quality assurance techniques to be applied in the production of the medical device to which the system is to be applied, including information about the following:

(i) the processes and procedures to be used and the documents relating to those processes and procedures;

(ii) the procedures to be used for purchasing goods or services in relation to the production of the device and the documents relating to those procedures;

(iii) product identification procedures to be prepared and kept up-to-date from drawings, specifications or other documents at each stage of production;

(e) the tests or trials to be carried out before, during and after production of the medical device to which the system is to be applied, including information about:

(i) the frequency with which the tests or trials are to be carried out; and

(ii) the equipment (including the traceability of the calibration of the equipment) used, or to be used, to carry out the tests or trials;

(f) the system for reviewing experience gained in the post-production phase for the medical device to which the quality management system has been applied, and the means by which any necessary corrective action will be applied to the design or production of such devices.

(3) If any inspections or tests are carried out by an authorised person in relation to the manufacturer's premises, or medical devices produced by the manufacturer,

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the manufacturer may ask the authorised person to give to the manufacturer a report stating the findings of the inspections or tests.

6A.4 Post-marketing system

(1) The manufacturer of a Class 1, 2 or 3 in-house IVD medical device must establish, and keep up-to-date, a post-marketing system for use for the device.

(2) The post-marketing system must require the manufacturer of the device to:
  (a) systematically review experience gained in the post-production phase for the device; and
  (b) implement appropriate means to apply any necessary corrective action for the design or production of the device; and
  (c) notify the Secretary as soon as practicable after becoming aware of information relating to any of the following that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health:
    (i) any malfunction or deterioration in the characteristics or performance of the device;
    (ii) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the device;
    (iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the device.

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Part 6B—Procedures applying to Class 4 in-house IVD medical devices

6B.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a Class 4 in-house IVD medical device to do the following:

(a) implement a quality management system for the design, production, packaging, labelling and final inspection of that kind of device;

(b) prepare technical documentation in relation to that kind of device;

(c) establish and keep up-to-date a post-market monitoring, reporting and corrective action system;

(d) make a declaration of conformity in relation to that kind of device;

(e) prepare and keep records in relation to these procedures;

(f) notify the Secretary of the manufacture of certain Class 4 in-house IVD medical devices.

6B.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

6B.3 Procedures

(1) The manufacturer of a Class 4 in-house IVD medical device must implement a quality management system for the design, production, packaging, labelling and final inspection of that kind of device.

(2) If the kind of device is used in relation to the manufacture of blood, blood components and plasma derivatives, human cell and tissue based therapeutic goods, either:

(a) the manufacturer must:

(i) satisfy the requirements in the *Australian Code of Good Manufacturing Practice for Blood and Blood Components, Human Tissues and Human Cellular Therapy Products*, published by the Therapeutic Goods Administration, as amended from time to time; and

(ii) hold a manufacturing licence that is in force and authorises the carrying out of a step in the manufacture of blood, blood components and plasma derivatives, human cell and tissue based therapeutic goods; or

(b) the laboratory in which the kind of device is manufactured must:

(i) be accredited as a testing laboratory by NATA as meeting ISO 15189, *Medical laboratories—Requirements for quality and competence*,

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published by the International Organization for Standardization, as amended from time to time; and

(ii) meet the National Pathology Accreditation Advisory Council standard *Requirements for the Development and Use of in-house In Vitro Diagnostic Devices (IVDs)*, as amended from time to time.

(3) If the kind of device is not used in relation to the manufacture of blood, blood components and plasma derivatives, human cell and tissue based therapeutic goods, the laboratory in which the kind of device is manufactured must:

(a) be accredited as a testing laboratory by NATA as meeting ISO 15189, *Medical laboratories—Requirements for quality and competence*, published by the International Organization for Standardization, as amended from time to time; and

(b) meet the National Pathology Accreditation Advisory Council standard *Requirements for the Development and Use of in-house In Vitro Diagnostic Devices (IVDs)*, as amended from time to time.

6B.4 Required technical documentation

(1) The manufacturer of a Class 4 in-house IVD medical device must have available technical documentation for that kind of device that:

(a) is up-to-date; and

(b) is in a form that, if requested by the Secretary, would allow an assessment to be carried out as to whether a device of that kind complies with the applicable provisions of the essential principles, the classification rules, and these conformity assessment procedures; and

(c) contains the information mentioned in subclauses (2) and (3).

(2) The technical documentation must contain information about the kind of device in relation to which the quality management system mentioned in subclause 6B.3(1) of this Part is to be applied, including the following:

(a) details of the processes, systems and measures used for controlling, monitoring and verifying that the kind of device complies with the applicable provisions of the essential principles;

(b) a general description of the kind of device;

(c) details of the design specifications for the kind of device, including:

(i) any medical device standard that has been applied to the kind of device; and

(ii) the results of the risk analysis carried out; and

(iii) if no medical device standard, or part only of such a standard, has been applied to the kind of device—the solutions adopted to ensure that each device of that kind complies with the applicable provisions of the essential principles;

(d) for a kind of device that is intended by the manufacturer to be connected to another device—evidence demonstrating that:

(i) the kind of device will comply with the applicable provisions of the essential principles when it is connected to the other device; and

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(ii) both devices are being used for their intended purposes;

(e) a statement indicating whether or not the kind of device contains viable tissues, cells or substances of human or animal origin;

(f) the results of any calculations, investigations, technical tests, or any other tests, carried out by the manufacturer in relation to the kind of device;

(g) a copy of the clinical evidence, in relation to the kind of device, required by the clinical evaluation procedures;

(h) a copy of the information to be provided with the kind of device (if any).

(3) The technical documentation must also contain information about the method or methods of manufacture of the kind of device.

6B.5 Post-marketing system

(1) The manufacturer of a Class 4 in-house IVD medical device must establish, and keep up-to-date, a post-marketing system for use for a device of that kind.

(2) The post-marketing system must require the manufacturer to:

(a) systematically review experience gained in the post-production phase for devices of that kind; and

(b) implement appropriate means to apply any necessary corrective action for the design or production of those devices; and

(c) notify the Secretary as soon as practicable after becoming aware of information relating to any of the following that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health:

(i) any malfunction or deterioration in the characteristics or performance of the kind of device;

(ii) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device;

(iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device.

6B.6 Declaration of conformity

(1) The manufacturer of a Class 4 in-house IVD medical device to which these conformity assessment procedures have been applied must make a declaration of conformity in relation to the kind of device.

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 6B.6 of Part 6B of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information for the kind of device in relation to which the quality management system mentioned in subclause 6B.3(1) of this Part has been applied:

(i) the unique product identifier;

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(ii) the medical device classification;
(iii) the device nomenclature system code; and

(d) state that the kind of device in relation to which the quality management system has been applied complies with the applicable provisions of the essential principles, the classification rules, and these conformity assessment procedures; and

(e) if the kind of device is used in relation to the manufacture of blood, blood components and plasma derivatives, human cell and tissue based therapeutic goods—either:
(i) state that the manufacturer satisfies the requirements in the *Australian Code of Good Manufacturing Practice for Blood and Blood Components, Human Tissues and Human Cellular Therapy Products*, as mentioned in subparagraph 6B.3(2)(a)(i), and state the number of the manufacturing licence held by the manufacturer, as mentioned in subparagraph 6B.3(2)(a)(ii); or
(ii) state that the laboratory in which the kind of device is manufactured meets the requirements mentioned in subparagraphs 6B.3(2)(b)(i) and (ii), and state the NATA accreditation number issued to the laboratory; and

(f) if the kind of device is not used in relation to the manufacture of blood, blood components and plasma derivatives, human cell and tissue based therapeutic goods—state that the laboratory in which the kind of device is manufactured meets the requirements mentioned in paragraphs 6B.3(3)(a) and (b), and state the NATA accreditation number issued to the laboratory; and

(g) be signed by a person authorised by the manufacturer; and

(h) set out the name and position of the person signing the declaration; and

(i) state the date when the declaration is signed.

6B.7 Records

(1) The manufacturer of a Class 4 in-house IVD medical device to which these conformity assessment procedures have been applied must keep the following records in relation to the procedures and the kind of device:
(a) the technical documentation mentioned in clause 6B.4 of this Part;
(b) details of any changes made to the kind of device and to the technical documentation in relation to the design or production of the kind of device;
(c) the declaration of conformity under clause 6B.6 of this Part;
(d) details of any systematic review carried out, after production, in relation to devices of that kind.

(2) The manufacturer must keep the records for at least 5 years after the manufacturer stops manufacturing devices of that kind.

(3) On request from the Secretary, and within such reasonable period as is set out in the request, the manufacturer must make the records available to the Secretary.

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6B.8 Notification of certain Class 4 in-house IVD medical devices being manufactured

(1) The manufacturer of a kind of Class 4 in-house IVD medical device that the manufacturer intends to be used to detect the presence of, or exposure to, transmissible agents in blood, stool or other specimens from a person's body in order to assess the suitability of the person to be a donor of human stool for use in the manufacture of a faecal microbiota transplant product must notify the Secretary, in accordance with subclauses (2) and (3), about that kind.

(2) A notification under subclause (1) must:
  (a) be in a form approved in writing by the Secretary; and
  (b) contain the information required by the form.

(3) A notification under subclause (1) must be given to the Secretary:
  (a) if the manufacturer manufactures such a kind of Class 4 in-house IVD medical device on or after the commencement of this clause and before 1 July 2021—no later than 20 working days after 1 July 2021; and
  (b) if, on or after 1 July 2021, the manufacturer manufactures such a kind of Class 4 in-house IVD medical device—no later than 20 working days after the manufacture.

(4) Only one notification is required under this clause in relation to each kind of Class 4 in-house IVD medical device manufactured by a manufacturer.

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Part 7—Procedures for medical devices used for a special purpose

7.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a medical device used for a special purpose:

(a) to prepare a written statement containing certain information in relation to the device and to provide a copy of the statement with the device; and

(b) to prepare and keep up-to-date particular documentation in relation to the device.

7.2 Custom-made medical devices

(1) This clause applies to a custom-made medical device.

(2) The manufacturer of the device must prepare a written statement in relation to the device including the following:

(a) the name and business address of the manufacturer;

(b) sufficient information to enable the user to identify the device or, if relevant, the contents of packaging;

(c) a statement to the effect that the device is intended by the manufacturer to be for the sole use of a particular patient or health professional;

(d) the name of the individual in relation to whom the device is intended to be used;

(e) the name and business address of the health professional who made the request for the device;

(f) the particular design characteristics of the device as specified by the health professional who made the request for the device;

(g) a statement to the effect that the device complies with the applicable provisions of the essential principles or, if the device does not comply with all applicable provisions of the essential principles, a statement explaining which provisions of the essential principles the device does not comply with and the reasons for the non-compliance.

(3) The statement must:

(a) be signed by a person authorised by the manufacturer of the device; and

(b) set out the name and position of the person signing the statement; and

(c) state the date when the statement is signed.

(3A) The manufacturer must provide a copy of the statement with the device.

(4) The manufacturer must prepare, and keep up-to-date, documentation in relation to the device, including information in relation to the design, production and intended performance of the device.

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(5) The manufacturer must take all measures necessary to ensure that the process used to manufacture the device results in the device complying with the documentation mentioned in subclause (4).

(6) The manufacturer must notify the Secretary as soon as practicable after becoming aware of:

(a) information relating to:

(i) any malfunction or deterioration in the characteristics or performance of the device; or

(ii) any inadequacy in the design, production, labelling or instructions for use of the device; or

(iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or

(b) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in paragraph (a) that has led the manufacturer to take steps to recall a device that has been distributed.

Note: Clauses 7.3 and 7.4 are intentionally not used.

7.5 System or procedure packs

(1) The manufacturer of a system or procedure pack must make a declaration of conformity in relation to the system or procedure pack.

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 7.5 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(b) state the name and business address of the manufacturer of the system or procedure pack; and

(c) state sufficient information to enable the user to identify the system or procedure pack or the contents of the system or procedure pack; and

(d) identify each item in the system or procedure pack; and

(e) except in relation to a medical device covered by paragraph (ia)—state that the manufacturer has:

(i) a conformity assessment document, a declaration of conformity under clause 6.6 or a statement under subclause 7.2(2) for each medical device in the system or procedure pack for which such a document, declaration or statement is required; and

(ii) evidence that each medical device in the system or procedure pack complies with the applicable provisions of the essential principles; and

(f) state the registration or listing number for each medicine or other therapeutic goods, or the biological number for each biological, in the system or procedure pack; and

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(g) state that each medical device in the system or procedure pack is intended to be used for its original intended purpose, and each medicine, biological or other therapeutic goods in the system or procedure pack is intended to be used within the approved indications of the medicine, biological or other therapeutic goods; and

(h) state that the mutual compatibility of each medical device, medicine, biological or other therapeutic goods, and any other goods, in the system or procedure pack has been verified in accordance with:

(i) the instructions for use of each medical device included in the system or procedure pack, being the instructions for use provided by the manufacturer of the device; and

(ii) the approved indications of each medicine, biological and other therapeutic goods (if any) included in the system or procedure pack; and

(ha) state that the manufacturer of the system or procedure pack has manufactured the system or procedure pack in accordance with the instructions referred to in subparagraph (h)(i) and the indications referred to in subparagraph (h)(ii); and

(i) state that the information supplied with the system or procedure pack for the use of the system or procedure pack includes instructions for use provided by the manufacturer of each item in the system or procedure pack; and

(ia) if the manufacturer of the system or procedure pack has modified the packaging of any medical device included in the system or procedure pack or modified any medical device included in the system or procedure pack—state the matters covered by subclause (2A); and

(j) state that the process of manufacturing the system or procedure pack, and the verification and packaging (if any) of the system or procedure pack, has been subjected to a documented method of internal control and inspection that ensures the safety, quality, performance and effectiveness of each item in the system or procedure pack; and

(k) if the system or procedure pack is intended by the manufacturer to be supplied in a sterile state—state that the full quality assurance procedures (other than clause 1.6), or the production quality assurance procedures (other than clause 4.7), have been applied to the system or procedure pack in accordance with:

(i) the instructions for use of each medical device included in the system or procedure pack, being the instructions for use provided by the manufacturer of the device; and

(ii) the approved indications of each medicine, biological and other therapeutic goods (if any) included in the system or procedure pack; and

(l) be signed by a person authorised by the manufacturer; and

(m) set out the name and position of the person signing the declaration; and

(n) state the date when the declaration is signed.

(2A) For the purposes of paragraph (2)(ia), the matters are the following:

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(a) that the modification has not affected the quality, safety or performance of the medical device;

(b) if the modification has not been done in accordance with the instructions for use of the medical device provided by the manufacturer of the device—that the manufacturer of the system or procedure pack has:

(i) if a conformity assessment document, a declaration of conformity under clause 6.6 or a statement under subclause 7.2(2) is required for the medical device—such a document, declaration or statement for the medical device, as affected by the modification; and

(ii) evidence that the medical device, as affected by the modification, complies with the applicable provisions of the essential principles.

(2B) If the manufacturer of a system or procedure pack has modified the packaging of any medical device included in the system or procedure pack or modified any medical device included in the system or procedure pack:

(a) the manufacturer of the system or procedure pack must ensure that the modification does not affect the quality, safety or performance of the medical device; and

(b) if the modification has not been done in accordance with the instructions for use of the medical device provided by the manufacturer of the device—the manufacturer of the system or procedure pack must have:

(i) if a conformity assessment document, a declaration of conformity under clause 6.6 or a statement under subclause 7.2(2) is required for the medical device—such a document, declaration or statement for the medical device, as affected by the modification; and

(ii) evidence that the medical device, as affected by the modification, complies with the applicable provisions of the essential principles.

(3) The manufacturer of a system or procedure pack must establish, and keep up-to-date, a post-marketing system that complies with subclause (4) for use in relation to the system or procedure pack.

(4) A post-marketing system complies with this subclause in relation to a system or procedure pack if the post-marketing system requires the manufacturer of the system or procedure pack:

(a) to systematically review experience gained in the post-production phase in relation to the system or procedure pack; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the production of the system or procedure pack; and

(c) to notify the Secretary as soon as practicable after becoming aware of:

(i) information relating to:

(A) any malfunction or deterioration in the characteristics or performance of the system or procedure pack; or

(B) any inadequacy in the production, labelling, instructions for use or advertising materials of the system or procedure pack; or

(C) any use in accordance with, or contrary to, the use intended by the manufacturer of the system or procedure pack;

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that might lead, or might have led, to the death of a patient or a user of the system or procedure pack, or to a serious deterioration in his or her state of health; or

(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recall system or procedure packs of that kind that have been distributed.

Note: See also paragraph 41FN(3)(d) and sections 41MP and 41MPA of the Act in relation to the requirement to give certain information about a medical device to the Secretary.

7.6 Records

(1) The manufacturer must keep the statement and documentation required under the relevant clause of this Schedule in relation to a medical device to which the conformity assessment procedures in this Part have been applied.

(2) The manufacturer must keep the statement and documentation for at least:

(a) if the device is not an implantable medical device—5 years after the manufacture of the medical device to which the statement and documentation relate; or

(b) if the device is an implantable medical device—15 years after the manufacture of the medical device to which the statement and documentation relate.

(3) On request from the Secretary, the manufacturer must make the statement and documentation available to the Secretary.

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Part 8—Clinical evaluation procedures

8.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device to obtain and evaluate clinical data in relation to the kind of device.

Note: See regulation 3.11 in relation to the kinds of medical devices to which these conformity assessment procedures must be applied.

8.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

8.3 Obtaining clinical data

(1) The manufacturer of a kind of medical device must obtain clinical data in relation to the device in the form of either or both of the following:
  (a) clinical investigation data in accordance with clause 8.4;
  (b) a literature review in accordance with clause 8.5.

(2) The manufacturer must ensure that the clinical data obtained takes account of any medical device standard or conformity assessment standard that may apply to the device.

8.4 Clinical investigation data

(1) For clause 8.3, ***clinical investigation data***, in relation to a kind of medical device, includes:
  (a) documentation in relation to the design, approval, conduct and results of each investigation carried out by the manufacturer of the device in relation to the use of the device in or on a human body; and
  (b) a record of qualitative or quantitative information obtained through observation, measurement, tests or any other means used to assess the operation of the device; and
  (c) a written report by an expert in the relevant field, being a report that contains a critical evaluation of all the clinical investigation data held in relation to the device.

(2) The documentation mentioned in paragraph (1)(a) must be in a form that allows the manufacturer to evaluate whether the device complies with the applicable provisions of the essential principles.

(3) The record mentioned in paragraph (1)(b) must be in a form that allows the information in it to be independently assessed and verified.

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(4) If clinical investigation data is collected in Australia, the investigation must have been conducted in accordance with the ethical standards set out in the 'National Statement on Ethical Conduct in Research Involving Humans', published by the National Health and Medical Research Council, as in force from time to time.

(5) If clinical investigation data is collected outside Australia, the investigation must have been conducted in accordance with the principles of the Declaration of Helsinki, as in force at the time and place where the investigation was conducted.

8.5 Literature review

For clause 8.3, a ***literature review***, in relation to a kind of medical device, includes:

(a) a compilation, prepared using a documented methodology, of published literature and unpublished scientific literature, both favourable and unfavourable, relating to medical devices of that kind, including the following:

(i) expert opinion;

(ii) information about the hazards and associated risks arising from the use of the device for its intended purpose, and the foreseeable misuse of the device;

(iii) information about the performance of devices of that kind, including a description of the techniques used to examine whether devices of that kind achieve their intended purpose; and

(b) a written report by an expert in the relevant field, being a report that contains a critical evaluation of the compilation of literature mentioned in paragraph (a).

8.6 Evaluation of clinical data

(1) The manufacturer of a kind of medical device must ensure that the clinical data is evaluated by competent clinical experts.

(2) The manufacturer must ensure that clinical evidence demonstrating that the device complies with the applicable provisions of the essential principles is documented in writing.

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Schedule 3AA—Requirements for Australian conformity assessment bodies

Note: See Part 4A.

1 Purpose of this Schedule

This Schedule sets out requirements for the purposes of making, suspending, revoking or varying a conformity assessment body determination under Part 4A of these Regulations.

2 EU Regulations

(1) The requirements are:

(a) to the extent the determination covers medical devices that are not IVD medical devices—the requirements of the EU medical devices regulation, as modified by clauses 3, 4 and 5 of this Schedule; and

(b) to the extent the determination covers IVD medical devices—the requirements of the EU IVD regulation, as modified by clauses 3, 4 and 6 of this Schedule.

(2) The ***EU medical devices regulation*** is Annex VII to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, as in force from time to time.

(3) The ***EU IVD regulation*** is Annex VII to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, as in force from time to time.

3 Modifications of EU Regulations—general

(1) For the purposes of subclause 2(1), the EU medical devices regulation and the EU IVD regulation (the ***EU regulations***) are taken to be modified as set out in this clause.

General modifications

(2) A reference in the EU regulations to a term mentioned in column 1 of an item of the following table is taken to be a reference to the term mentioned in column 2 of that item.

Modifications

Item	Column 1 Term used in the EU regulations	Column 2 Substituted term
1	(a) Union; or (b) national	Australian

Clause 3

Modifications		
Item	**Column 1** **Term used in the EU regulations**	**Column 2** **Substituted term**
2	(a) a competent authority; or (b) a Member State; or (c) the Commission; or (d) the MDCG	the Secretary
3	notified body	Australian conformity assessment body
4	authorised representative	sponsor
5	(a) this Regulation; or (b) Union devices legislation	these Regulations
6	notification requirements laid down in Chapter V of this Regulation	applicable requirements under these Regulations to notify the Secretary
7	(a) general safety and performance requirements set out in Annex I; or (b) requirements in, set out in or laid down in Annex I	the essential principles
8	(a) Annex IX to XI; or (b) the relevant conformity assessment Annex	Schedule 3 to these Regulations
9	Annex X	the type examination procedures in Part 2 of Schedule 3 to these Regulations
10	Part B of Annex XI	Part 3 of Schedule 3 to these Regulations
11	minimum requirements laid down in Annex XII	the requirements of these Regulations
12	Annex XIV	Part 8 of Schedule 3 to these Regulations
13	harmonised standards	conformity assessment standards and medical device standards
14	conformity assessment activities	certification-related activities
15	post-market surveillance	post-marketing requirements mentioned in Schedule 3 to these Regulations
16	class B device	Class 2 IVD medical device
17	class C device	Class 3 IVD medical device

(3) Subclause (2) has effect subject to subclause (6) and clauses 5 and 6.

(4) For the purposes of the EU regulations:

(a) an activity is taken to be designated, in relation to an Australian conformity assessment body, if the activity relates to conformity assessment procedures covered by the body's conformity assessment body determination; and

(b) a device is taken to be designated, in relation to an Australian conformity assessment body, if the device is covered by the body's conformity assessment body determination.

(5) A reference in the EU regulations to CS is disregarded.

Note: CS is short for common specifications.

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Modifications of specific provisions

(6) Each EU regulation is taken to be modified in the following ways:

(a) the following provisions are disregarded:

(i) Sections 1.1.1, 1.2.6, 1.2.8, 1.6.1, 3.2.1 and 4.5.6;

(ii) the words "unless liability is assumed by the Member State in question in accordance with national law or that Member State is directly responsible for their conformity assessment" in Section 1.4.1;

(iii) the words "and the results of the coordination activities referred to in Section 1.6" in Section 3.5.2;

(iv) the sentence "Refusals or withdrawals of applications shall be notified to the electronic system referred to in Article 57 and shall be accessible to other notified bodies." in Section 4.3;

(v) the words "and to perform unannounced on site audits" in Section 4.5.1;

(vi) the words "as referred to in Annexes II and III" in point (a) of Section 4.5.2;

(vii) all the words after "resultant decision" in Section 4.8;

(viii) the words "EU technical documentation assessment certificates or EU" in Section 4.11;

(b) in Section 3.1.1, the words "performance and safety of devices" are replaced with the words "compliance with the essential principles";

(c) in Section 4.3, a reference to an authorised representative is taken to be a reference to an applicant authorised by the manufacturer;

(d) in Section 4.5.1, a reference to relevant Annexes is taken to be a reference to Schedule 3 to these Regulations;

(e) in Section 4.5.3, the words "For assessment of the technical documentation conducted in accordance with Chapter II of Annex IX" are replaced with the words "For the assessment of compliance of manufacturers with clause 1.6 of Schedule 3 to these Regulations";

(f) in Section 4.10:

(i) the words "unannounced on-site audits of manufacturers and, where applicable, subcontractors" are replaced with the words "the audit of subcontractors"; and

(ii) the words "laid down in the relevant Annexes" are replaced with the words "for a quality management system set out in Schedule 3 for the conformity assessment procedure applied by the manufacturer"; and

(iii) the words "summary of safety and performance" are replaced with the words "evidence of compliance with the essential principles";

(g) in Section 4.11, the word "reviews" (wherever occurring) is replaced with the word "assessments".

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4 Additional requirements

(1) For the purposes of subclause 2(1), the EU medical devices regulation and the EU IVD regulation (the ***EU regulations***) are taken to include the requirements mentioned in this clause.

Independence and impartiality

(2) Section 1.2 of each EU regulation includes a requirement that an Australian conformity assessment body will take action:
  (a) to respond to any threats to its impartiality; and
  (b) to ensure that all internal or external personnel or committees who could influence the body's certification-related activities will:
    (i) act impartially; and
    (ii) not allow commercial, financial or other pressures to compromise impartiality.

Liability

(3) Section 1.4 of each EU regulation includes a requirement that an Australian conformity assessment body will:
  (a) document a justification for the cover and overall financial value of the liability insurance mentioned in that Section, including:
    (i) the types of medical devices and conformity assessment procedures in relation to which the body carries on certification-related activities; and
    (ii) the locations at which those activities are carried on; and
    (iii) the patient risk profile of the devices; and
    (iv) the compliance risk profiles of the manufacturing activities in relation to which the body carries on certification-related activities; and
  (b) give this justification to the body's liability insurer, and document having done so.

Process requirements

(4) Section 4 of each EU regulation includes a requirement that an Australian conformity assessment body will have documented procedures in place that cover the following in relation to the body's certification-related activities:
  (a) assigning internal or external personnel to activities on the basis of their documented competences;
  (b) following up corrections and corrective actions by manufacturers in relation to nonconformities identified during audits or assessments.

5 Additional modifications of EU medical devices regulations

(1) For the purposes of subclause 2(1), the EU medical devices regulation is taken to be modified as set out in this clause.

(2) A reference in the EU medical devices regulation to PMCF is disregarded.

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Note: PMCF is short for post-market clinical follow-up.

(3) The following provisions of the EU medical devices regulation are disregarded:
  (a) the last dash point of Section 1.1.6;
  (b) the eighth dash point of Section 4.5.1;
  (c) the words "referred to in Annexes II and III" in point (b) of Section 4.5.3;
  (d) the words "as specified in Section 15 of Annex XI" in point (d) of Section 4.5.3;
  (e) the words "any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures in accordance with Section 4.5.6" in Section 4.9.

(4) A reference in the EU medical devices regulation to Section 4.5.6 is taken to be a reference to Section 4.5.5.

6 Modifications of EU IVD regulations

(1) For the purposes of subclause 2(1), the EU IVD regulation is taken to be modified as set out in this clause.

(2) A reference in the EU IVD regulation to companion diagnostics or PMPF is disregarded.

Note: PMPF is short for post-market performance follow-up.

(3) The EU IVD regulation is modified in the following ways:
  (a) the following provisions are disregarded:
    (i) point (g) of Section 1.1.6;
    (ii) the seventh dash point of Section 4.5.1;
    (iii) the words ", and taking account of Sections 4.5.4. and 4.5.5" in section 4.5.3;
    (iv) the words ", taking account of Sections 4.5.4. and 4.5.5," in section 4.5.3;
    (v) the subsection headed **Verification by examination and testing of every product batch** in Section 4.5.3;
    (vi) Sections 4.5.4 and 4.5.5;
    (vii) the words "any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures in accordance with Section 4.5.5" in Section 4.9;
  (b) the words "self and near patient testing" in Section 3.2.2 are replaced with the words "self-testing and point of care testing".

7 Expressions used in modifications

To avoid doubt, an expression used in a modification of the EU medical devices regulation or EU IVD regulation made by this Schedule has the same meaning in that modification as it does elsewhere in these Regulations.

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Schedule 3A—Disposal of unused emergency medical devices

(regulation 6A.1)

1 Early end of exemption—notice of medical devices held

(1) This clause applies if:
  (a) the Minister makes an exemption under section 41GS of the Act in relation to kinds of medical devices; and
  (b) a person is given a copy of a revocation or variation of the exemption under paragraph 41GV(b) of the Act.

(2) The person must give the Secretary:
  (a) notice, in writing, of the quantity and location of:
    (i) for a revocation—the devices over which the person has control that have not been used; or
    (ii) for a variation—the devices mentioned in the variation over which the person has control that have not been used; and
  (b) a copy of any records about the devices that the person is required to keep under a condition of the exemption.

(3) The person must comply with subclause (2) in relation to the devices within 7 days after the day the exemption ends for the devices.

2 End of exemption period—notice of medical devices held

(1) This clause applies if an exemption under section 41GS of the Act ends because the period stated in the exemption ends.

(2) A person who has been importing, manufacturing, supplying or exporting medical devices under the exemption must, within 7 days after the day the period ends, give the Secretary:
  (a) notice, in writing, of the quantity and location of any unused emergency medical devices over which the person has control; and
  (b) a copy of any records about the devices that the person is required to keep under a condition of the exemption.

3 Storage and disposal of unused emergency medical devices

(1) A person who has control over unused emergency medical devices must ensure that the devices are stored in a way that ensures that:
  (a) the devices are only accessible for supply, export, use or disposal in accordance with the Act and these Regulations; and
  (b) the security of the devices is appropriate to the level of risk that the devices could pose to the public and the environment; and

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(c) the integrity of the condition of the devices is maintained.

(2) A person may dispose of unused emergency medical devices only in accordance with a direction given by the Secretary under subclause 4(1).

4 Direction for disposal of unused emergency medical devices

(1) The Secretary may direct, in writing, any person who has control over unused emergency medical devices to dispose of the devices in the way directed.

(2) A direction under subclause (1) must be in accordance with clause 5, 6, 7 or 8.

(3) A person who has been given a direction under subclause (1) must comply with the direction.

5 Relocation of unused emergency medical devices

If storage of unused emergency medical devices at a place poses, or would pose, a risk to the public or the environment, the Secretary may direct that the devices be stored at a stated place that will ensure compliance with subclause 3(1).

6 Disposal of unused emergency medical devices—destruction

(1) The Secretary may direct that unused emergency medical devices be destroyed within the time stated in the direction if any of the following applies:

(a) the devices have passed their expiry date;

(b) the devices no longer comply with the essential principles;

(c) conformity assessment procedures were not applied to the devices and requirements, comparable to the conformity assessment procedures, were not applied to the devices;

(d) use of the devices poses, or would pose, a risk to public health;

(e) storage of the devices at their current location and any other location poses, or would pose, a risk to the public or the environment;

(f) within 12 months after the exemption ends in relation to the devices, the devices have not become:

(i) devices of a kind included in the Register under Part 4-5 of the Act; or

(ii) exempt devices under section 41HA of the Act; or

(iii) devices that are the subject of an approval under section 41HB of the Act; or

(iv) devices that are the subject of an authority under section 41HC of the Act;

(g) the person who has control over the devices requests that the devices be destroyed.

(2) A person directed to destroy the devices may destroy them only in a way, approved by the Secretary, that ensures that the destruction avoids or minimises harm to the public and the environment.

7 Disposal of unused emergency medical devices—export

(1) This clause applies to unused emergency medical devices to which any of paragraphs 6(1)(a) to (e) applies.

(2) The Secretary may direct that the devices be exported to a country, instead of directing that they be destroyed, if a relevant authority of the country has confirmed in writing its willingness to accept the devices.

(3) A person directed to export the devices must ensure that, during exportation:
  (a) the devices are only accessible for purposes relating to the export; and
  (b) the security of the devices is appropriate to the level of risk that the devices could pose to the public and the environment; and
  (c) the integrity of the condition of the devices is maintained.

8 Disposal of unused emergency medical devices—supply

(1) This clause applies to:
  (a) unused emergency medical devices that are a kind of medical device if:
    (i) an exemption under section 41GS of the Act in relation to that kind of medical device ceases to have effect other than because that kind of medical device becomes included in the Register under Part 4-5 of the Act; and
    (ii) the devices later become devices of a kind included in the Register under Part 4-5 of the Act; and
  (b) unused emergency medical devices that have become:
    (i) devices that are the subject of an approval under section 41HB of the Act; or
    (ii) devices that are the subject of an authority under section 41HC of the Act.

(2) The Secretary may direct that the devices be supplied to an authorised person (otherwise than for therapeutic use on the person).

(3) In this clause:

authorised person means:
  (a) for paragraph (1)(a)—the person in relation to whom the kind of medical device is included in the Register under Part 4-5 of the Act; or
  (b) for an approval under section 41HB of the Act—the person to whom the approval is given; or
  (c) for an authority under subsection 41HC(1) of the Act—the person to whom the authority is given; or
  (d) for an authority given by rules made under subsection 41HC(6) of the Act—a health practitioner included in the class of health practitioners specified in the rules.

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9 Owner to be paid for medical devices supplied

A direction under clause 7 or 8 does not affect a person's liability to pay the owner of the unused emergency medical devices for the export or supply of the devices to the person.

10 Records about unused emergency medical devices

A person who has, or has had, control over unused emergency medical devices must:

(a) ensure that records are kept that include the following information:
  (i) the quantities of the devices under the person's control;
  (ii) how the devices are stored before being disposed of;
  (iii) if a direction under subclause 4(1) has been received—what actions have been taken to dispose of the devices as directed and when the actions were taken;
  (iv) if the devices have been exported or supplied—to whom they were exported or supplied and in what quantity; and

(b) keep the records for 7 years after the last entry is made; and

(c) if the Secretary asks the person, in writing, for a copy of a record mentioned in paragraph (a)—give the Secretary the copy:
  (i) within 14 days after the day the person is given the Secretary's request; or
  (ii) if the information is required to establish whether the devices pose imminent risk to the public or the environment—within 24 hours, or any shorter period, stated by the Secretary.

11 Failure to comply with this Schedule

If a person who has control over any unused emergency medical devices has not complied with a provision of this Schedule, the Secretary may direct a person, other than the person who has control over the devices, to destroy the devices in the way directed.

Schedule 4—Exempt devices

(regulation 7.1)

Part 1—Exempt devices—general

Item	Kinds of medical devices
1.1	Medical device that is imported into Australia for use in the treatment of the importer, or a member of the importer's immediate family, or for use in the in vitro examination of a specimen obtained from the importer or a member of the importer's immediate family, if: (a) the device does not contain a substance the importation of which is prohibited under the *Customs Act 1901*; and (b) in the case of: (i) a device, other than an IVD medical device, that is manufactured using tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of bacterial or recombinant origin; or (ii) a device, other than an IVD medical device, that incorporates, or is intended to incorporate, as an integral part, a stable derivative of human blood or blood plasma— the device is the subject of an approval under section 41HB of the Act; and (c) in the case of a Class 4 IVD medical device, Class III medical device, Class 3 IVD medical device, Class IIb medical device, Class 2 IVD medical device or Class IIa medical device: (i) the quantity imported in one importation is not more than the amount required to give 3 months treatment using the device according to the treating medical practitioner's directions; and (ii) the total quantity imported in a 12 month period is not more than the amount required to give 15 months treatment using the device according to the treating medical practitioner's directions; and (d) in the case of a device that is subject to Schedule 4 or Schedule 8 to the current Poisons Standard, or a device that incorporates, or is intended to incorporate, as an integral part, a substance that is subject to either of those Schedules—the device, or substance, is acknowledged in writing by a medical practitioner registered under a law of a State or Territory to be appropriate treatment for the importer or family member (unless the device is carried by the importer as a passenger on a ship or an aeroplane)
1.2	Medical device that is exported from Australia and: (a) is not intended for commercial supply; and (b) does not contain a substance the export of which is prohibited under the *Customs Act 1901*; and (c) is not intended for use for experimental purposes on humans
1.3	Samples of a medical device that is imported into Australia, exported from Australia, or manufactured or supplied in Australia for any of the following purposes (other than for supply for use in or on a human being): (a) submission to a regulatory authority; (b) subjection to developmental or quality control procedures; (c) examination, demonstration or display, with notice included to the effect that the device is not available for general supply unless it is included in the Register;

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Item	Kinds of medical devices
	(d) subjection to analysis, evaluation or laboratory testing procedures; (e) use in the manufacture of goods including therapeutic goods; (f) testing performed on a specimen taken from a cadaver (except to assess whether a part of the cadaver is suitable for transfusion or transplantation)
1.3A	Medical device that is an oxygen administration hood for use in a hyperbaric chamber for hyperbaric oxygen therapy
1.3B	Medical device that is: (a) manufactured by a health professional or by a person acting under the written instructions of a health professional; and (b) manufactured from other medical devices that are included in the Register and are covered by item 3A, 3B, 3C, 3D or 3E of the table in Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*, as that instrument is in force from time to time
1.4	Medical device that: (a) is imported into Australia solely for the purpose of being exported from Australia; and (b) while in Australia, remains subject to customs control under the *Customs Act 1901*; and (c) is not subject to any of the activities mentioned in section 41BG of the Act by a manufacturer in Australia
1.5	Medical device that is a vaping device referred to in paragraph (c) of the definition of ***nicotine vaping product*** in the *Therapeutic Goods Regulations 1990* and that is imported into Australia or manufactured or supplied in Australia.
1.6	The following: (a) a medical device that is a system or procedure pack where: (i) the system or procedure pack consists of a nicotine vaping product (within the meaning of the *Therapeutic Goods Regulations 1990*) and a medical device that is a vaping device referred to in paragraph (c) of the definition of ***nicotine vaping product*** in those regulations; and (ii) the system or procedure pack is imported into Australia; and (iii) the nicotine vaping product is covered by an item in the table in Schedule 5 or 5A to those regulations or the sponsor reasonably expects that the system or procedure pack will be supplied to its ultimate consumer in circumstances where the nicotine vaping product will be the subject of an approval under subsection 19(1) of the Act or an authority under subsection 19(5) of the Act; (b) a medical device that is a system or procedure pack where: (i) the system or procedure pack consists of a nicotine vaping product (within the meaning of the *Therapeutic Goods Regulations 1990*) and a medical device that is a vaping device referred to in paragraph (c) of the definition of ***nicotine vaping product*** in those regulations; and (ii) the system or procedure pack is manufactured in Australia; and (iii) the nicotine vaping product is covered by an item in the table in Schedule 5 or 5A to those regulations or the manufacturer reasonably expects that the system or procedure pack will be supplied to its ultimate consumer in circumstances where the nicotine vaping product will be the subject of an approval under subsection 19(1) of the Act or an authority under subsection 19(5) of the Act; (c) a medical device that is a system or procedure pack where: (i) the system or procedure pack consists of a nicotine vaping product (within the meaning of the *Therapeutic Goods Regulations 1990*) and a medical device that is

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Item	Kinds of medical devices
	a vaping device referred to in paragraph (c) of the definition of ***nicotine vaping product*** in those regulations; and (ii) the system or procedure pack is supplied in Australia by a person (the ***intermediate supplier***) to a person who is not the ultimate consumer of the system or procedure pack; and (iii) the nicotine vaping product is covered by an item in the table in Schedule 5 or 5A to those regulations or the intermediate supplier reasonably expects that the system or procedure pack will be supplied to its ultimate consumer in circumstances where the nicotine vaping product will be the subject of an approval under subsection 19(1) of the Act or an authority under subsection 19(5) of the Act; (d) a medical device that is a system or procedure pack where: (i) the system or procedure pack consists of a nicotine vaping product (within the meaning of the *Therapeutic Goods Regulations 1990*) and a medical device that is a vaping device referred to in paragraph (c) of the definition of ***nicotine vaping product*** in those regulations; and (ii) the system or procedure pack is supplied in Australia to its ultimate consumer; and (iii) at the time of that supply, the nicotine vaping product is covered by an item in the table in Schedule 5 or 5A to those regulations or is the subject of an approval under subsection 19(1) of the Act or an authority under subsection 19(5) of the Act.
1.7	Patient-matched medical device

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Part 2—Exempt devices—exemption subject to conditions

Item	Kinds of medical devices	Conditions
2.1	Medical device that is imported into Australia and is held under the direct control of the sponsor, until the device is: (a) the subject of a notification under item 2.3; or (b) approved for importation into Australia under section 41HB or 41HD of the Act; or (c) authorised for supply under section 41HC of the Act; or (d) used for a Category A patient, within the meaning of regulation 7.2; or (e) exported from Australia	(a) The supply of the device must be in accordance with the relevant notification, approval, authorisation or medical practitioner's direction. (b) The device must be kept in a warehouse or properly secured area under the control of the sponsor. (d) The sponsor must: (i) keep records relating to the source and supply of the device; and (iii) if requested by the Secretary, give the records to the Secretary.
2.2	Medical device affected by section 41FH of the Act that is imported into Australia and is held under the direct control of the sponsor until a decision is made under section 41FI of the Act in relation to the device	(a) The sponsor must: (i) keep records relating to the source of the device; and (ii) if requested by the Secretary, give the records to the Secretary; and (iii) before importing the device, have lodged an application under section 41FC of the Act for the device to be included in the Register. (b) If the application is not successful, the device must be destroyed or returned to the consignor of the device within 1 month of the decision not to include the device in the Register.
2.3	Medical device to be used solely for experimental purposes in humans	(a) Before starting to use the device, the sponsor must notify the Secretary: (i) in a form approved in writing by the Secretary; and (ii) in accordance with any requirements determined by the Secretary for the form of notification; that the sponsor intends to sponsor a clinical trial using the device. (b) The notification must be accompanied by the notification fee specified in item 1.8 of Schedule 5.

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		(c) The approval of the device for this purpose must be given by the sponsor (if the sponsor is conducting the trial), or by the body or organisation conducting the trial for the sponsor, having regard to the advice of the ethics committee that has, or will assume, responsibility for monitoring the conduct of the trial. (d) The terms of the approval by the sponsor, body or organisation mentioned in paragraph (c) must be no less restrictive than the terms advised by the responsible ethics committee. (e) The trial must not be the subject of a direction by the Secretary that the trial not be conducted, or that it be stopped, because the Secretary has become aware that to conduct or continue the trial would be contrary to the public interest. (f) The sponsor (if the sponsor is conducting the trial), or the body or organisation conducting the trial for the sponsor, must not receive, or have received, advice from the responsible ethics committee that is inconsistent with the continuation of the trial. (g) The conditions stated in regulation 7.5 must be complied with, as if that regulation applied to a person using a medical device under this item.
2.4	Medical device that is imported into Australia by a member of a group of persons who are visiting Australia to participate in a national or international sporting event	(a) The device must be for use in the treatment of a member or members of the visiting group. (b) The importation of the device must not be prohibited under the *Customs (Prohibited Imports) Regulations 1956*. (c) The device must not be supplied to, or used in the treatment of, a person who is not a member of the visiting group. (d) The device must be destroyed or removed from Australia at the end of the visit. (e) A member of the group must be responsible for the control and custody of the device while the group is in Australia. (f) The person mentioned in paragraph (e) must: (i) carry a list, in English, of the quantity and nature of the device imported; and (ii) keep a record of the use of the device while the group is in Australia; and (iii) produce the list or record for inspection at the request of a customs officer or a person who is an authorised person for the purposes of section 41FN of the Act.

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Item	Kinds of medical devices	Conditions
2.5	Medical device that is imported into Australia by a member of a group of persons, being members of the military forces of another country who are visiting Australia for military training	(a) The device must be for use in the treatment of a member or members of the visiting group. (b) The device must not be supplied to, or used in the treatment of, a person other than a member of: (i) the visiting group; or (ii) the Australian Defence Force. (c) The device must be destroyed or removed from Australia at the end of the visit. (d) A member of the group to whom the device has been issued must be responsible for the control and custody of the device while the group is in Australia. (e) The person mentioned in paragraph (d) must: (i) carry a list, in English, of the quantity and nature of the device imported; and (ii) keep a record of the use of the device while the group is in Australia; and (iii) produce the list or record for inspection at the request of a customs officer or a person who is an authorised person for the purposes of section 41FN of the Act.
2.6	Medical device that is imported into Australia by a medical practitioner or a member of a medical team (being 1 or more persons under the professional supervision of a medical practitioner)	(a) The medical practitioner or medical team must be accompanying a person to Australia who: (i) has a critical illness; and (ii) is under the direct care and supervision of the practitioner or team. (b) The device must be for use in the treatment of the person who has the critical illness. (c) The importation of the device must not be prohibited under the *Customs (Prohibited Imports) Regulations 1956*. (d) The quantity of the device imported must be consistent with the quantity required for the treatment of the person mentioned in paragraph (b). (e) The device must not be supplied to, or used in the treatment of, a person other than the person mentioned in paragraph (b). (f) The device must be destroyed or removed from Australia at the end of the visit. (g) The medical practitioner, or a member of the medical team, must be responsible for the control and custody of the device while the practitioner or team is in Australia.

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		(h) The person mentioned in paragraph (g) must: (i) carry a list, in English, of the quantity and nature of the device imported; and (ii) keep a record of the use of the device while the medical practitioner or medical team is in Australia; and (iii) produce the list or record for inspection at the request of a customs officer or a person who is an authorised person for the purposes of section 41FN of the Act.
2.7	Medical device that is imported into Australia by a member of a group of persons, being a group that includes a person who is the Head of State or Head of Government of a foreign country and senior Government officials of that country, who are visiting Australia on official business	(a) The device must be for use in the treatment of a member or members of the visiting group. (b) The importation of the device must not be prohibited under the *Customs (Prohibited Imports) Regulations 1956*. (c) The device must not be supplied to, or used in the treatment of, a person other than a member of the visiting group. (d) The device must be destroyed or removed from Australia at the end of the visit. (e) A member of the visiting group must be responsible for the control and custody of the device while the group is in Australia. (f) The person mentioned in paragraph (e) must: (i) carry a list, in English, of the quantity and nature of the device imported; and (ii) keep a record of the use of the device while the group is in Australia; and (iii) produce the list or record for inspection at the request of a customs officer or a person who is an authorised person for the purposes of section 41FN of the Act.
2.8	Medical device that is part of the medical supplies of a ship (including a yacht or other marine vessel) or aircraft visiting Australia	(a) The device must be for use in the treatment of a passenger or a member of the crew travelling on the ship or aircraft. (b) The importation of the device must not be prohibited under the *Customs (Prohibited Imports) Regulations 1956*. (c) The quantity of the device imported must be consistent with the quantity required for the treatment of passengers and members of the crew travelling on the ship or aircraft. (d) The device must not be supplied to, or used in the treatment of, a person other than a passenger or a member of the crew travelling on the ship or aircraft. (e) The device must not be removed from the ship or aircraft while the ship or aircraft is in Australia.

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		(f) The master of the ship or the pilot of the aircraft must be responsible for the control and custody of the device while the ship or aircraft is in Australia. (g) The person mentioned in paragraph (f) must: (i) carry a list, in English, of the quantity and nature of the device imported; and (ii) keep a record of the use of the device while the ship or aircraft is in Australia; and (iii) produce the list or record for inspection at the request of a customs officer or a person who is an authorised person for the purposes of section 41FN of the Act.
2.9	Medical device that is a system or procedure pack under section 41BF of the Act that: (a) is imported, supplied or manufactured by or on behalf of the Commonwealth; and (b) is certified by the Secretary to be emergency supplies for stockpiling for use in the event of a public health emergency.	(a) The device must be imported, supplied or manufactured on or before 31 December 2010. (b) The importation, supply or manufacture of the device must be approved in writing by the Secretary. (c) The use and supply of the device must be in accordance with the written approval of the Secretary. (d) Records in relation to the importation, supply or manufacture of the device must be kept in accordance with the directions of the Secretary. (e) The disposal of any unused device must be in accordance with the directions of the Secretary.
2.10	Medical device that is a Class 1, Class 2 or Class 3 in-house IVD medical device	(a) The device must comply with the essential principles. (b) The manufacturer of the device must apply the appropriate conformity assessment procedures at all times. (d) The manufacturer of the device must, on request by the Secretary, provide the following information within 20 working days of receiving the request: (i) whether the device complies with the essential principles; (ii) whether the conformity assessment procedures have been applied to the device; (iii) whether the device complies with every requirement (if any) relating to advertising applicable under Part 5-1 of the Act or the *Therapeutic Goods Regulations 1990*.

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		(e) The manufacturer of the device must, at all times, have available: (i) sufficient information to substantiate that the conformity assessment procedures have been applied to the device; or (ii) information relating to changes to the device and quality management system. (f) The manufacturer of the device must allow an authorised person to do any of the following: (i) enter, at any reasonable time, any premises at which the manufacturer manufactures the device; (ii) inspect the premises and the device, and examine, take measurements of, conduct tests on or require tests to be conducted on the device or anything on those premises that relates to the device; (iii) make any still or moving image or any recording of those premises or anything on those premises. (g) If asked to do so by an authorised person, the manufacturer of the device must give to the person any documents relating to the device that the person requires and allow the person to copy the documents. (h) The Secretary must not have directed that the supply of the device be stopped or should cease because the supply compromises public health and safety.
2.10A	Medical device that is a Class 4 in-house IVD medical device and that is intended by its manufacturer to be used to detect the presence of, or exposure to, transmissible agents in blood, stool or other specimens from a person's body in order to assess the suitability of the person to be a donor of human stool for use in the manufacture of a faecal microbiota transplant product	(a) The device must comply with the essential principles. (b) The manufacturer of the device must apply the appropriate conformity assessment procedures at all times. (c) The manufacturer of the device must, on request by the Secretary, provide the following information within 20 working days of receiving the request: (i) whether the device complies with the essential principles; (ii) whether the conformity assessment procedures have been applied to the device; (iii) whether the device complies with every requirement (if any) relating to advertising applicable under Part 5-1 of the Act or the *Therapeutic Goods Regulations 1990*. (d) The manufacturer of the device must, at all times, have available:

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		(i) sufficient information to substantiate that the conformity assessment procedures have been applied to the device; or (ii) information relating to changes to the device and quality management system. (e) The manufacturer of the device must allow an authorised person to do any of the following: (i) enter, at any reasonable time, any premises at which the manufacturer manufactures the device; (ii) inspect the premises and the device, and examine, take measurements of, conduct tests on or require tests to be conducted on the device or anything on those premises that relates to the device; (iii) make any still or moving image or any recording of those premises or anything on those premises. (f) If asked to do so by an authorised person, the manufacturer of the device must give to the person any documents relating to the device that the person requires and allow the person to copy the documents. (g) The Secretary must not have directed that the supply of the device be stopped or should cease because the supply compromises public health and safety.
2.11	Unused emergency medical devices directed by the Secretary, under clause 7 of Schedule 3A, to be exported	compliance with Schedule 3A, as if section 41GY of the Act applies to the devices
2.11A	Medical device that: (a) is intended, by the person under whose name the device is or is to be supplied, to be used for the vaporisation, and administration by inhalation, of a medicine that is registered goods: (i) whose only active ingredient is nicotine; and (ii) whose only indication accepted in relation to inclusion of the goods in the Register relates to use, by means of the device, for smoking cessation; or (b) is a system or procedure pack consisting of a device described in paragraph (a) and a medicine	(a) The device must comply with the essential principles. (b) The manufacturer of the device must apply the appropriate conformity assessment procedures at all times. (c) The manufacturer of the device must, on request by the Secretary, provide the following information within 20 working days of receiving the request: (i) whether the device complies with the essential principles; (ii) whether the conformity assessment procedures have been applied to the device; (iii) whether the device complies with every requirement (if any) relating to advertising applicable under Part 5-1 of the Act or the *Therapeutic Goods Regulations 1990*.

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	described in paragraph (a)	(d) The manufacturer of the device must, at all times, have available: (i) sufficient information to substantiate that the conformity assessment procedures have been applied to the device; or (ii) information relating to changes to the device and quality management system. (e) The manufacturer of the device must allow an authorised person to do any of the following: (i) enter, at any reasonable time, any premises at which the manufacturer manufactures the device; (ii) inspect the premises and the device, and examine, take measurements of, conduct tests on or require tests to be conducted on the device or anything on those premises that relates to the device; (iii) make any still or moving image or any recording of those premises or anything on those premises. (f) If asked to do so by an authorised person, the manufacturer of the device must give to the person any documents relating to the device that the person requires and allow the person to copy the documents. (g) The Secretary must not have directed that the supply of the device be stopped or should cease because the supply compromises public health and safety. (h) The manufacturer or sponsor of the device must provide information of a kind mentioned in subsection 41MP(2) or 41MPA(2) of the Act to the Secretary within the following periods: (i) if the information relates to an event or other occurrence that represents a serious threat to public health—48 hours after the manufacturer or sponsor becomes aware of the event or occurrence; (ii) if the information relates to an event or other occurrence that led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—10 days after the manufacturer or sponsor becomes aware of the event or occurrence; (iii) if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a

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		patient, a user of the device, or another person—30 days after the manufacturer or sponsor becomes aware of the event or occurrence; (iv) in any other case—60 days after the manufacturer or sponsor becomes aware of the information. (i) The person under whose name the device is or is to be supplied must keep records relating to the importation or supply of the device by or on behalf of the person. (j) The person under whose name the device is or is to be supplied must, on request by the Secretary, provide to the Secretary those records within 20 working days of receiving the request or a longer period agreed to by the Secretary.
2.12	Custom-made medical device that is manufactured in Australia	(a) The manufacturer of the device must, at all times, have available: (i) sufficient information to substantiate that the conformity assessment procedures have been applied to the device; or (ii) information relating to the design and manufacture of the device and to any changes to the device. (b) The manufacturer of the device must allow an authorised person to do any of the following: (i) enter, at any reasonable time, any premises (including premises outside Australia) at which the manufacturer or any other person deals with the device; (ii) inspect those premises; (iii) if the device is on those premises—inspect the device and examine, take measurements of, conduct tests on or require tests to be conducted on the device; (iv) inspect any thing on those premises that relates to the device and examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of any such thing; (v) make any still or moving image or any recording of those premises or any thing on those premises. (c) If asked to do so by an authorised person, the manufacturer of the device must produce to the authorised person any documents relating to the device that the authorised person requires and allow the authorised person to copy the documents.

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Item	Kinds of medical devices	Conditions
		(d) The manufacturer of the device must, on request from the Secretary, give the Secretary a copy of the health professional's request for the device within the period requested by the Secretary (which must be at least 10 working days starting on the day on which the Secretary's request is made).
2.13	Custom-made medical device that is manufactured outside Australia	(a) The sponsor must have procedures in place to ensure that the manufacturer of the device, at all times, has available: (i) sufficient information to substantiate that the conformity assessment procedures have been applied to the device; or (ii) information relating to the design and manufacture of the device and to any changes to the device. (b) The sponsor must have procedures in place to ensure that the manufacturer of the device allows an authorised person to do any of the following: (i) enter, at any reasonable time, any premises at which the manufacturer or any other person deals with the device; (ii) inspect those premises; (iii) if the device is on those premises—inspect the device and examine, take measurements of, conduct tests on or require tests to be conducted on the device; (iv) inspect any thing on those premises that relates to the device and examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of any such thing; (v) make any still or moving image or any recording of those premises or any thing on those premises. (c) The sponsor must have procedures in place to ensure that the manufacturer of the device, if the manufacturer is asked to do so by an authorised person, produces to the authorised person any documents relating to the device that the authorised person requires and allows the authorised person to copy the documents. (d) The sponsor must, on request from the Secretary, give the Secretary a copy of the health professional's request for the device within the period requested by the Secretary (which must be at least 10 working days starting on the day on which the Secretary's request is made).
2.14	Patient-matched medical device	The sponsor must, before 25 August 2022, notify the Secretary in writing of each kind of patient-matched

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Item	Kinds of medical devices	Conditions
		medical device that is intended to be supplied in Australia on or after 1 November 2024 and of the following: (a) the name and address of the sponsor; (b) the name and address of the manufacturer of that kind of medical device; (c) the device nomenclature system code of that kind of medical device; (d) the medical device classification of that kind of medical device; (e) the unique product identifier given to each medical device of that kind.
2.15	Medical device that is clinical decision support system software that is: (a) intended by its manufacturer to be for the sole purpose of providing or supporting a recommendation to a health professional about preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; and (b) not intended by its manufacturer to directly process or analyse a medical image or signal from another medical device; and (c) not intended by its manufacturer to replace the clinical judgement of a health professional in relation to making a clinical diagnosis or decision about the treatment of patients	(a) The device must comply with the essential principles. (b) The manufacturer of the device must apply the appropriate conformity assessment procedures at all times. (c) The manufacturer of the device must, on request by the Secretary, provide the following information within 20 working days of receiving the request: (i) whether the device complies with the essential principles; (ii) whether the conformity assessment procedures have been applied to the device; (iii) whether the device complies with every requirement (if any) relating to advertising applicable under Part 5-1 of the Act or the *Therapeutic Goods Regulations 1990*. (d) The manufacturer of the device must, at all times, have available: (i) sufficient information to substantiate that the conformity assessment procedures have been applied to the device; or (ii) information relating to changes to the device and quality management system. (e) The manufacturer of the device must allow an authorised person to do any of the following: (i) enter, at any reasonable time, any premises at which the manufacturer manufactures the device; (ii) inspect the premises and the device, and examine, conduct tests on or require tests to be conducted on the device or anything on those premises that relates to the device; (iii) make any still or moving image or any

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Item	Kinds of medical devices	Conditions
		recording of those premises or anything on those premises. (f) If asked to do so by an authorised person, the manufacturer of the device must give to the person any documents relating to the device that the person requires and allow the person to copy the documents. (g) The Secretary must not have directed that the supply of the device be stopped or should cease because the supply compromises public health and safety. (h) The manufacturer or sponsor of the device must provide information of a kind mentioned in subsection 41MP(2) or 41MPA(2) of the Act to the Secretary within the following periods: (i) if the information relates to an event or other occurrence that represents a serious threat to public health—48 hours after the manufacturer or sponsor becomes aware of the event or occurrence; (ii) if the information relates to an event or other occurrence that led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—10 days after the manufacturer or sponsor becomes aware of the event or occurrence; (iii) if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—30 days after the manufacturer or sponsor becomes aware of the event or occurrence; (iv) in any other case—60 days after the manufacturer or sponsor becomes aware of the information. (i) The sponsor of the device must notify the Secretary, using a form approved in writing by the Secretary: (i) as far as it is reasonably practicable, of any supply of the device by or on behalf of the sponsor that occurred before 25 February 2021, being a notification within 60 working days (or such longer period as is agreed to by the Secretary) of that day; and (ii) of any importation or supply of the device by or on behalf of the sponsor on or after 25 February 2021, being a notification

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Item	Kinds of medical devices	Conditions
		within 20 working days (or such longer period as is agreed to by the Secretary) of the importation or supply.
2.16	Medical device that is a surgical loan kit, where: (a) the kit is intended by its manufacturer to be supplied to hospitals in Australia; and (b) the kit is intended by its manufacturer to be used in a surgical procedure; and (c) the kit contains 2 or more reusable surgical instruments and the only other therapeutic goods (if any) in the kit are either or both of the following: (i) one or more implantable medical devices; (ii) one or more Class I, Class IIa, Class IIb or Class III medical devices; and (d) each of the medical devices in the kit is included in the Register	(a) The device must comply with the essential principles. (b) The manufacturer of the device must apply the appropriate conformity assessment procedures (if any) at all times. (c) The manufacturer of the device must, on request by the Secretary, provide the following information within 20 working days of receiving the request: (i) whether the device complies with the essential principles; (ii) whether the conformity assessment procedures (if any) have been applied to the device; (iii) whether the device complies with every requirement (if any) relating to advertising applicable under Part 5-1 of the Act or the *Therapeutic Goods Regulations 1990*. (d) The manufacturer of the device must, at all times, have available sufficient information to substantiate that the conformity assessment procedures (if any) have been applied to the device. (e) The manufacturer of the device must allow an authorised person to do any of the following: (i) enter, at any reasonable time, any premises at which the manufacturer manufactures the device; (ii) inspect the premises and the device, and examine, take measurements of, conduct tests on or require tests to be conducted on the device or anything on those premises that relates to the device; (iii) make any still or moving image or any recording of those premises or anything on those premises. (f) If asked to do so by an authorised person, the manufacturer of the device must give to the person any documents relating to the device that the person requires and allow the person to copy the documents. (g) The Secretary must not have directed that the supply of the device be stopped or should cease because the supply compromises public health and safety. (h) The manufacturer or sponsor of the device must

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Item	Kinds of medical devices	Conditions
		provide information of a kind mentioned in subsection 41MP(2) or 41MPA(2) of the Act to the Secretary within the following periods: (i) if the information relates to an event or other occurrence that represents a serious threat to public health—48 hours after the manufacturer or sponsor becomes aware of the event or occurrence; (ii) if the information relates to an event or other occurrence that led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—10 days after the manufacturer or sponsor becomes aware of the event or occurrence; (iii) if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—30 days after the manufacturer or sponsor becomes aware of the event or occurrence; (iv) in any other case—60 days after the manufacturer or sponsor becomes aware of the information.
		(i) The person under whose name the device is or is to be supplied must keep records relating to the supply of the device by or on behalf of the person.
		(j) The person under whose name the device is or is to be supplied must, on request by the Secretary, provide to the Secretary those records within 20 working days of receiving the request or a longer period agreed to by the Secretary.

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Schedule 5—Fees

(regulation 9.1)

Part 1—General

Item	Matter	Provision of Act or these Regulations	Amount ($)
1.1	Application for conformity assessment certificate	Paragraph 41EB(2)(a) of the Act	1,077
1.1A	Application for conformity assessment (priority applicant) determination in relation to a medical device	Paragraph 41ECA(3)(d) of the Act	10,568
1.2	(a) Review of conformity assessment certificate—surveillance assessment for conformity assessment certificate issued under conformity assessment procedures set out in Schedule 3, Part 1, 4 or 5 Note 1: If the assessment involves an assessment of a medicinal component, an additional fee is payable—see item 1.11. Note 2: If a supplementary assessment, or an assessment outside Australia, is required, an additional fee is payable—see item 1.12 and clause 2.1 of this Schedule.	Subsection 41EJ(4) of the Act	9,296
	(b) Review of conformity assessment certificate for an IVD medical device—surveillance assessment for conformity assessment certificate issued under conformity assessment procedures set out in Schedule 3, Part 1 or 4		9,347
1.3	Review of conformity assessment certificate for a medical device, other than an IVD medical device—in relation to certification of compliance with the essential principles for conformity assessment certificate issued under conformity assessment procedures set out in:	Subsection 41EJ(4) of the Act	
	(a) Schedule 3, clause 1.6; or		56,840
	(b) Schedule 3, Part 2 (including management of testing, analysis, and reporting on examination of the type)		43,810

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Item	Matter	Provision of Act or these Regulations	Amount ($)
	Note 1: If the assessment involves an assessment of a medicinal component, an additional fee is payable—see item 1.11. Note 2: If a supplementary assessment, or an assessment outside Australia, is required, an additional fee is payable—see item 1.12 and clause 2.1 of this Schedule. Note 3: For an assessment under paragraph (b), an additional fee to cover the costs of testing the relevant kind of medical device is also payable—see clause 2.2 of this Schedule.		
1.3A	Review of conformity assessment certificate for an IVD medical device in relation to certification of compliance with the essential principles for conformity assessment certificate issued under conformity assessment procedures set out in:	Subsection 41EJ(4) of the Act	
	(a) Schedule 3, Part 1—Full Quality Management System; or		32,114
	(b) Schedule 3, clause 1.6—Design Examination; or		68,434
	(c) Schedule 3, clause 1.6—Design Examination – Immunohaematology reagent medical devices; or		16,621
	(d) Schedule 3, clause 1.6—Abridged Design Examination – previously registered IVDs; or		4,032
	(e) Schedule 3, Part 2—Type Examination; or		44,221
	(f) Schedule 3, Part 4—Production Quality Management System		28,215
	Note 1: If a supplementary assessment, or an assessment outside Australia, is required, an additional fee is payable—see item 1.12 and clause 2.1 of this Schedule. Note 2: For an assessment under paragraph (e), an additional fee to cover the costs of testing the relevant kind of medical device is also payable—see item 2.2 of this Schedule.		

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Item	Matter	Provision of Act or these Regulations	Amount ($)
1.4	Considering a submission to the Secretary in relation to a proposed suspension of a conformity assessment certificate, including a conformity assessment certificate for an IVD medical device	Subsection 41EN(2) and paragraph 63(2)(h) of the Act	For a medical device, other than an IVD medical device—the fee applicable under item 1.14 to the kind of work to be undertaken For an IVD medical device—the fee applicable under item 1.14A to the kind of work to be undertaken
1.4A	Application for full designation conformity assessment body determination	Paragraph 41EWA(3)(d) of the Act	4,832
1.4B	Application for partial designation conformity assessment body determination (full QMS)	Paragraph 41EWA(3)(d) of the Act	2,657
1.4C	Application for partial designation conformity assessment body determination (partial QMS or partial devices)	Paragraph 41EWA(3)(d) of the Act	2,657
1.4D	Assessment of application for full designation conformity assessment body determination	Paragraph 41EWA(3)(g) of the Act	78,899
1.4E	Assessment of application for partial designation conformity assessment body determination (full QMS)	Paragraph 41EWA(3)(g) of the Act	56,635
1.4F	Assessment of application for partial designation conformity assessment body determination (partial QMS or partial devices)	Paragraph 41EWA(3)(g) of the Act	56,635
1.5	Application for the following kinds of medical devices to be included in the Register:	Paragraph 41FDB(2)(b) of the Act	
	(b) a Class III medical device;		1,416
	(c) a Class IIb medical device;		1,098
	(d) a Class IIa medical device;		1,098
	(e) a Class I medical device that the manufacturer intends to be supplied in a sterile state or that has a measuring function, except a device that is intended by the manufacturer to be for export only;		1,098
	(f) a Class I medical device that is intended		92

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Item	Matter	Provision of Act or these Regulations	Amount ($)
	by the manufacturer to be for export only;		
	(g) a Class I medical device except one described in paragraph (e) or (f);		575
	(h) an IVD medical device, including a Class 4 in-house IVD medical device, but not a device that is intended by the manufacturer to be for export only or a Class 2 IVD medical device that was, immediately before the commencement of the *Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015*: (i) included in the Register; and (ii) classified as a Class 3 IVD medical device because of subclause 1.3(2) of Schedule 2A (as in force immediately before the commencement of that regulation) Note: Paragraph (h)—there is no fee for an application to include in the Register a Class 2 IVD medical device mentioned in the paragraph.		1,098
	(i) an IVD medical device that is intended by the manufacturer to be for export only		92
1.5A	Application for medical devices (priority applicant) determination in relation to a medical device	Paragraph 41FKA(3)(d) of the Act	10,568
1.6	Considering submissions to the Secretary in relation to a proposed suspension of a kind of medical device, including an IVD medical device, from the Register	Subsection 41GB(2) and paragraph 63(2)(h) of the Act	The fee applicable under item 1.14 to the kind of work to be undertaken
1.6A	Request for the revocation of the cancellation of an entry of a kind of medical device from the Register:	Paragraph 41GLA(1)(c) of the Act	
	(a) if the request relates to one entry;		164
	(b) if the request relates to more than one entry		164 for the first entry plus 51 for each additional entry
1.6B	Request for the revocation of the cancellation of an entry of a kind of medical device from the Register:	Paragraph 41GLB(1)(d) of the Act	

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Item	Matter	Provision of Act or these Regulations	Amount ($)
	(a) if the request relates to one entry; (b) if the request relates to more than one entry		164 164 for the first entry plus 51 for each additional entry
1.7	Application for approval to use a specified kind of medical device, including an IVD medical device, solely for experimental purposes in humans	Paragraph 41HB(5)(c) of the Act	19,699
1.7A	Request to vary a medical device, or kind of medical device, specified in an approval to use that device or kind of device solely for experimental purposes in humans, or to vary the conditions of such an approval	Paragraph 41HB(8)(e) of the Act	5,376
1.8	Notification of intention to sponsor a clinical trial of a medical device, including an IVD medical device, to be used solely for experimental purposes in humans	Paragraph 63(2)(h) of the Act, and Schedule 4, item 2.3, paragraph (b) of these Regulations	390
1.9	Conformity assessment—initial assessment under conformity assessment procedures for a medical device, other than an IVD medical device, set out in:	Subsections 41LA(1) and (2) of the Act	
	(a) Schedule 3, Part 1; or		32,011
	(b) Schedule 3, clause 1.6; or		62,894
	(c) Schedule 3, Part 2 (including management of testing, analysis, and reporting on examination of the type); or		43,810
	(d) Schedule 3, Part 3 (including management of testing, analysis, and reporting on verification of the type); or		30,677
	(e) Schedule 3, Part 4; or		28,010
	(f) Schedule 3, Part 5		23,906
	Note 1: If the assessment involves an assessment of a medicinal component, an additional fee is payable—see item 1.11.		
	Note 2: If a supplementary assessment, or an assessment outside Australia, is required, an additional fee is payable—see item 1.12 and clause 2.1 of this Schedule.		

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Item	Matter	Provision of Act or these Regulations	Amount ($)
	Note 3: For an assessment under paragraph (c) or (d), an additional fee to cover the costs of testing the relevant kind of medical device is also payable—see clause 2.2 of this Schedule.		
	Note 4: If the assessment is abridged, a reduced fee is payable—see regulation 9.4.		
1.9A	Conformity assessment for an IVD medical device—initial assessment under conformity assessment procedures set out in:	Subsections 41LA(1) and (2) of the Act	
	(a) Schedule 3, Part 1—Full Quality Management System; or		32,114
	(b) Schedule 3, clause 1.6—Design Examination; or		68,434
	(c) Schedule 3, clause 1.6—Design Examination – Immunohaemotology reagent medical devices; or		16,621
	(d) Schedule 3, clause 1.6—Abridged Design Examination – previously registered IVDs; or		4,032
	(e) Schedule 3, Part 2—Type Examination; or		44,221
	(f) Schedule 3, Part 4—Production Quality Management System		28,215
	Note 1: If a supplementary assessment, or an assessment outside Australia, is required, an additional fee is payable—see item 1.12 and clause 2.1 of this Schedule.		
	Note 2: For an assessment under paragraph (e), an additional fee to cover the costs of testing the relevant kind of medical device is also payable—see clause 2.2 of this Schedule.		
	Note 3: If the assessment is abridged, a reduced fee is payable—see regulation 9.4.		
1.10	Conformity assessment—assessment consequent on change to medical device, other than an IVD medical device, or quality management system applying to medical device, other than an IVD medical device, under conformity assessment procedures set out in:	Subsections 41LA(1) and (2) of the Act	

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Item	Matter	Provision of Act or these Regulations	Amount ($)
	(a) Schedule 3, Part 1; or		19,289
	(b) Schedule 3, clause 1.6; or		37,962
	(c) Schedule 3, Part 2 (including management of testing, analysis, and reporting on examination of the type); or		26,471
	(d) Schedule 3, Part 4; or		16,621
	(e) Schedule 3, Part 5		14,569
	Note 1: If the assessment involves an assessment of a medicinal component, an additional fee is payable—see item 1.11.		
	Note 2: If a supplementary assessment, or an assessment outside Australia, is required, an additional fee is payable—see item 1.12 and clause 2.1 of this Schedule.		
	Note 3: For an assessment under paragraph (c), an additional fee to cover the costs of testing the relevant kind of medical device, or quality management system, is also payable—see clause 2.2 of this Schedule.		
1.10A	Conformity assessment—assessment because of changes or proposed changes to the IVD medical device or quality management system applying to that device	Subsections 41LA(1) and (2) of the Act	60% of initial fee under item 1.9A
	Note 1: If a supplementary assessment, or an assessment outside Australia, is required, an additional fee is payable—see item 1.12 and clause 2.1 of this Schedule.		
	Note 2: For an assessment under Schedule 3, Part 2, an additional fee to cover the costs of testing the relevant kind of medical device, or quality management system, is also payable—see clause 2.2 of this Schedule.		
1.11	If an assessment of a medical device involves an assessment of the medicinal component of the device—for an assessment of the data relating to the medicinal component (and in addition to the fee required under item 1.2, 1.3, 1.9 or 1.10)	Subsections 41EJ(4) and 41LA(1) and (2) of the Act	The fee applicable under item 4, or paragraph (b) or (d) of item 5, of Part 2 of Schedule 9 to the *Therapeutic Goods Regulations 1990*

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Item	Matter	Provision of Act or these Regulations	Amount ($)
1.12	If a supplementary assessment of a medical device is required, in addition to the assessment mentioned in item 1.2, 1.3, 1.9, 1.9A, 1.10 or 1.10A Note: For an assessment conducted outside Australia, an additional fee is payable—see clause 2.1 of this Schedule.	Subsections 41EJ(4) and 41LA(1) and (2) of the Act	451 for each hour for each assessor involved
1.13	Application audit assessment, Level 1—verification of sponsor's application and evidence of conformity	Subsections 41LA(3) and (4) of the Act	4,135
1.14	Application audit assessment, Level 2—for Level 1 activities and review of evidence of conformity	Subsections 41LA(3) and (4) of the Act	7,582
1.14A	Application audit assessment for Class 1, Class 2 and Class 3 IVD medical devices	Subsections 41LA(3) and (4) of the Act	7,387
1.14B	Application audit assessment for Class 4 in-house IVD medical devices (other than a device to which item 1.14C applies)	Subsections 41LA(3) and (4) of the Act	68,434
1.14C	Application audit assessment for Class 4 in-house IVD medical devices that are immunohaematology reagent IVD medical devices	Subsections 41LA(3) and (4) of the Act	16,621
1.15	Application for consent of Secretary to importation into Australia, supply for use in Australia, or exportation from Australia of a medical device, including an IVD medical device:	Sections 41MA and 41MAA and paragraph 63(2)(h) of the Act	
	(a) for an application relating to a medical device that is not included in the Register or to a medical device to which a single entry in the Register relates; or		Subject to regulation 9.1AA, 513 (for all the devices to which the application relates)
	(b) for an application relating to medical devices to which both of the following apply: (i) there are separate entries in the Register in relation to the devices; (ii) the way in which the devices do not comply with essential principles is the same for all the devices		Subject to regulation 9.1AA, 513 for the first entry plus 103 for each additional entry

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Item	Matter	Provision of Act or these Regulations	Amount ($)
1.16	Intermediate stage assessment or verification procedures to be carried out in relation to the application of the conformity assessment procedures to an article	Subregulation 3.13(1) of these Regulations	The fee applicable under item 1.9, 1.10 or 1.12 to the kind of work to be undertaken
1.17	Notification by a manufacturer, under subclause 6A.2(1) of Part 6A of Schedule 3, of Class 1, 2 or 3 in-house IVD medical devices being manufactured	Subsection 63(1) and paragraph 63(2)(h) of the Act	1,098

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Part 2—Additional fees

2.1 Supplementary assessment

In addition to the assessment fee mentioned in item 1.2, 1.3, 1.9, 1.9A, 1.10 or 1.10A of this Schedule, the following fees apply:

(a) for each assessment that is required to be conducted—an amount that reimburses the costs and reasonable expenses of travel by each assessor involved, including travel both in and outside Australia;

(b) for an assessment that is required to be conducted outside Australia—an amount calculated at the rate of $451 for each hour of preparation by each assessor involved.

2.2 Costs of testing

(1) In addition to the assessment fee mentioned in paragraph 1.3(b), 1.3A(e), 1.9(c) or (d), 1.9A(e) or paragraph 1.10(c) of this Schedule, a fee for the costs of testing the relevant kind of medical device, or quality management system, applies.

(2) The fee is the amount that reimburses the Department for:

(a) the costs incurred in purchasing, establishing and setting-up the equipment to be used to conduct the tests; and

(b) the direct costs of conducting the tests (including the cost of any consumables used in conducting the tests).

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Dictionary

(regulation 1.3)

Note: A number of expressions used in these Regulations are defined in the Act.

Act means the *Therapeutic Goods Act 1989*.

active implantable medical device means an active medical device, other than an implantable medical device, that is intended by the manufacturer:

(a) either:

(i) to be, by surgical or medical intervention, introduced wholly, or partially, into the body of a human being; or

(ii) to be, by medical intervention, introduced into a natural orifice in the body of a human being; and

(b) to remain in place after the procedure.

active medical device:

(a) means a medical device that is intended by the manufacturer:

(i) to depend for its operation on a source of electrical energy or other source of energy (other than a source of energy generated directly by a human being or gravity); and

(ii) to act by converting this energy; but

(b) does not include a medical device that is intended by the manufacturer to transmit energy, a substance, or any other element, between an active medical device and a human being without any significant change in the energy, substance or other element being transmitted.

Software that is a medical device is an ***active medical device***.

active medical device for diagnosis means an active medical device that is intended by the manufacturer to be used on a human being, either alone or in combination with another medical device, to supply information for the purpose of detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

active medical device for therapy means an active medical device that is intended by the manufacturer to be used on a human being, either alone or in combination with another medical device, to support, modify, replace or restore biological functions or structures for the purpose of treating or alleviating an illness, injury or handicap.

adaptable medical device means a mass-produced medical device that is intended by the manufacturer to be assembled or adapted after it has been supplied, in accordance with the manufacturer's instructions, to:

(a) address either or both of the anatomical and physiological features of a particular individual; or

(b) address a pathological condition of a particular individual; or

(c) otherwise perform as intended by the manufacturer.

AHPRA number, of a health practitioner, means the registration number published by the Australian Health Practitioner Regulation Agency in relation to the health practitioner.

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ancillary medical device means an implantable medical device that:

(a) consists of screws, plates or wedges; or

(b) is intended by the manufacturer to be used to:

(i) provide stability for an implantable medical device that is intended to (either alone or together with one or more other implantable medical devices) replace the shoulder joint, hip joint or knee joint; or

(ii) provide bone substitution in relation to, or additional fixation for, any such device; or

(iii) otherwise assist any such device;

where the individual requirements of a patient make it appropriate to do so.

animal means an invertebrate or vertebrate member of the animal kingdom.

approved indications, of a medicine, biological or other therapeutic goods, means:

(a) if the medicine, biological or other therapeutic goods are entered on the Register—the indications included in the Register in relation to the medicine, biological or other therapeutic goods; or

(b) otherwise—the indications in relation to the medicine, biological or other therapeutic goods.

Note: For ***indications***, see subsection 3(1) of the Act.

approved type means a type that has been examined and approved by the Secretary under the type examination procedures.

Australian legal unit of measurement has the meaning given by the *National Measurement Act 1960*.

authorised person—see regulation 10.1.

body orifice:

(a) means a natural opening, or a permanent artificial opening, in a human being's body; and

(b) includes the external surface of a human being's eyeball.

central circulatory system means the system in a human being comprising the following vessels:

(a) *arteriae pulmonales*;

(b) *aorta ascendens*;

(c) *arteriae coronariae*;

(d) *arteria carotis communis*;

(e) *arteria carotis externa*;

(f) *arteria carotis interna*;

(g) *arteriae cerebrales*;

(h) *trucus brachicephalicus*;

(i) *venae cordis*;

(j) *venae pulmonales*;

(k) *venae cava superior*;

(l) *venae cava inferior*;

(m) *arcus aorta*;

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(n) *thoracica aorta*;
(o) *abdominalis aorta*;
(p) *arteriae ilica communis.*

central nervous system means the system in a human being comprising the brain, meninges and spinal cord.

Class 1 in-house IVD medical device means an in-house IVD medical device that, under Division 3.1 of Part 3, is classified as Class 1.

Class 1 IVD medical device means an IVD medical device that, under Division 3.1 of Part 3, is classified as Class 1.

Class I medical device means a medical device that, under Division 3.1 of Part 3, is classified as Class I.

Class 2 in-house IVD medical device means an in-house IVD medical device that, under Division 3.1 of Part 3, is classified as Class 2.

Class 2 IVD medical device means an IVD medical device that, under Division 3.1 of Part 3, is classified as Class 2.

Class IIa medical device means a medical device that, under Division 3.1 of Part 3, is classified as Class IIa.

Class IIb medical device means a medical device that, under Division 3.1 of Part 3, is classified as Class IIb.

Class 3 in-house IVD medical device means an in-house IVD medical device that, under Division 3.1 of Part 3, is classified as Class 3.

Class 3 IVD medical device means an IVD medical device that, under Division 3.1 of Part 3, is classified as Class 3.

Class III medical device means a medical device that, under Division 3.1 of Part 3, is classified as Class III.

Class 4 in-house IVD medical device means an in-house IVD medical device that, under Division 3.1 of Part 3, is classified as Class 4.

Class 4 IVD medical device means an IVD medical device that, under Division 3.1 of Part 3, is classified as Class 4.

classification means a medical device classification.

classification rules, in relation to a medical device, means the rules for classifying the device set out in Schedule 2.

client of an Australian conformity assessment body means a manufacturer with whom the body has an agreement under which the body will carry on certification-related activities, including issuing Australian conformity assessment body certificates to the manufacturer.

clinical evaluation procedures means the conformity assessment procedures set out in Part 8 of Schedule 3.

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conformity assessment body determination assessment fee means a fee payable under regulation 9.1B for assessing an application for a conformity assessment body determination.

conformity assessment (priority applicant) determination has the meaning given by subsection 41ECA(2) of the Act.

custom-made medical device means a medical device that:

(a) is intended by the manufacturer to be for:
  (i) the sole use of a particular patient (the ***intended recipient***); or
  (ii) the sole use of a particular health professional (the ***intended recipient***) in the course of the health professional's practice; and

(b) is manufactured by the manufacturer in accordance with a written request of a health professional (the ***requesting health professional***) and with particular design characteristics specified by that health professional in the request (even if the design is developed in consultation with the manufacturer), where those design characteristics are intended to address:
  (i) either or both of the anatomical and physiological features of the intended recipient; or
  (ii) a pathological condition of the intended recipient; and

(c) the requesting health professional has determined is necessary to address the matters covered by paragraph (b) because there is no kind of medical device included in the Register to address those matters or to address those matters to an appropriate level.

However, a custom-made medical device does not include a patient-matched medical device, an adaptable medical device or other mass-produced medical device.

declaration of conformity (not requiring assessment by Secretary) procedures means the conformity assessment procedures set out in Part 6 of Schedule 3.

device lifetime, in relation to a medical device, means the period, indicated by the manufacturer, during which:

(a) the device can be safely used; and

(b) the characteristics and performance of the device are not affected by its age.

device nomenclature system code, for a medical device, means the device nomenclature system code mentioned for the device in regulation 1.7.

essential principles means the essential principles set out in Schedule 1.

EU IVD regulation has the meaning given by subclause 2(3) of Schedule 3AA.

EU medical devices regulation has the meaning given by subclause 2(2) of Schedule 3AA.

faecal microbiota transplant product means a thing that:

(a) comprises, contains or is derived from human stool; and

(b) is for introduction into a person for a therapeutic use.

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full designation conformity assessment body determination means a conformity assessment body determination that is of general application.

full quality assurance procedures means the conformity assessment procedures set out in Part 1 of Schedule 3.

health professional includes a person who is:

(a) a medical practitioner, a dentist or any other kind of health care worker registered under a law of a State or Territory; or

(b) a biomedical engineer, chiropractor, optometrist, orthodontist, osteopath, pharmacist, physiotherapist, podiatrist, prosthetist or rehabilitation engineer.

hip joint means the ball and socket formed by the reception of the head of the femur into the cup-shaped cavity of the acetabulum.

immunohaematology reagent IVD medical device means an IVD medical device that is a reagent, reagent product or related material that is intended by the manufacturer to be used to provide information about blood groups, red cell antigens or red cell antibodies, or to determine compatibility of blood or blood components for transfusion.

implantable breast medical device means any of the following implantable medical devices:

(a) breast implants or mammary implants;

(b) breast tissue expanders;

(c) any other medical device that is of a similar kind, or has a similar function, to a medical device mentioned in paragraph (a) or (b).

implantable cardiac medical device means any of the following implantable medical devices or active implantable medical devices:

(a) cardiac stents;

(b) cardiac valves (whether mechanical or of biological origin);

(c) electronic devices for regulating heart rate or managing dysrhythmia;

(d) any other medical device that is of a similar kind, or has a similar function, to a medical device mentioned in paragraph (a), (b) or (c).

implantable medical device means a medical device (other than an active implantable medical device) that is intended by the manufacturer:

(a) to be, by surgical intervention, wholly introduced into the body of a human being, and to remain in place after the procedure; or

(b) to replace, by surgical intervention, an epithelial surface, or the surface of an eye, of a human being, and to remain in place after the procedure; or

(c) to be, by surgical intervention, partially introduced into the body of a human being, and to remain in place for at least 30 days after the procedure.

in-house IVD medical device means an IVD medical device that is:

(a) within the confines or scope of an Australian laboratory or Australian laboratory network:

(i) developed from first principles; or

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(ii) developed or modified from a published source; or
(iii) developed or modified from any other source; or
(iv) used for a purpose, other than the intended purpose assigned by the manufacturer; and

(b) not supplied for use outside that laboratory or laboratory network.

injured skin or mucous membrane means an area of skin or mucous membrane that has evidence of:

(a) a pathological change; or
(b) a change following:
(i) disease; or
(ii) a wound.

instructions for use, in relation to a medical device, includes information provided by the manufacturer of the device to inform a user of the device of the intended purpose of the device, of the proper use of the device and of any precautions to be taken in relation to the use of the device.

Note: These Regulations contain requirements relating to instructions for use of a medical device. For example, clauses 13.1 to 13.4 of Schedule 1 (about essential principles) deal with information that must be included in instructions for the use of a medical device.

intended purpose, of a medical device, means the purpose for which the manufacturer of the device intends it to be used, as stated in:

(a) the information provided with the device; or
(b) the instructions for use of the device; or
(c) any advertising material applying to the device; or
(d) any technical documentation describing the mechanism of action of the device.

invasive medical device means a medical device that is intended by the manufacturer to be used, in whole or in part, to penetrate the body of a human being through a body orifice or through the surface of the body.

IVD companion diagnostic means an IVD medical device:

(a) that is intended by the manufacturer to be used for the examination of a specimen from the body of an individual:
(i) to identify whether the individual would be likely to benefit from the use of a particular medicine or biological; or
(ii) to identify whether the individual is likely to be at particular risk of a serious adverse reaction to the use of a particular medicine or biological; or
(iii) to monitor the individual's response to the use of a particular medicine or biological; and

(b) that is mentioned in product information for the medicine or biological as being essential for the safe and effective use of the medicine or biological; and

(c) if the medicine or biological comprises blood, a blood component, cells, tissue or an organ, from a donor other than the individual—that is not

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intended by the manufacturer to be used for the examination of the specimen merely to determine whether the medicine or biological is compatible with the individual.

IVD medical device, or in vitro diagnostic medical device, means a medical device that is:

(a) a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with another diagnostic product for in vitro use; and

(b) intended by the manufacturer to be used in vitro for the examination of a specimen derived from the human body, solely or principally for:
  (i) giving information about a physiological or pathological state or a congenital abnormality; or
  (ii) determining safety and compatibility with a potential recipient; or
  (iii) monitoring therapeutic measures; and

(c) not a product that is:
  (i) intended for general laboratory use; and
  (ii) not manufactured, sold or presented for use as an IVD medical device.

IVD medical device for self-testing means an IVD medical device intended to be used:

(a) in the home or similar environment by a lay person; or

(b) in the collection of a sample by a lay person and, if that sample is tested by another person, the results are returned directly to the person from whom the sample was taken without the direct supervision of a health professional who has formal training in a medical field or discipline to which the self-testing relates.

joint replacement medical device means an implantable medical device:

(a) that is intended by the manufacturer to operate (either alone or together with one or more other implantable medical devices) as a replacement (in whole or in part) for the shoulder joint, hip joint or knee joint; and

(b) that (either alone or together with one or more other implantable medical devices):
  (i) replaces or substitutes for the articulating surface of a shoulder joint, hip joint or knee joint (in whole or in part); or
  (ii) provides primary fixation to the bone for the replacement articulating surface; or
  (iii) connects directly or indirectly with an implantable medical device that has a function mentioned in subparagraph (i) or (ii) and operates as an intrinsic element of the joint replacement;

but does not include an ancillary medical device.

kind, in relation to a medical device—see section 41BE of the Act.

knee joint means the joint consisting of:

(a) the articulations between each of the 2 condyles of the femur and the corresponding surface of the tibia; and

(b) the articulation between the patella and the trochlear groove of the femur.

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laboratory network means a network of laboratory organisations that satisfies the following:

(a) the network operates with a single quality management system;

(b) either:

(i) the activities of the network span more than one field of testing or program; or

(ii) the network operates at multiple sites within a field, or involves a combination of multiple sites and fields or programs.

lay person, for the use of an IVD medical device for self-testing, means an individual who does not have formal training in a medical field or discipline to which the self-testing relates.

manufacturing licence—see subsection 38(1B) of the Act.

mass-produced medical device means a medical device that:

(a) is manufactured according to standardised dimensions or designs; and

(b) is not designed for a particular individual; and

(c) is manufactured in a continuous production process or in a homogenous batch.

measuring function, in relation to a medical device—see regulation 1.4.

medical device production system means a system that consists of raw materials and main production equipment (whether or not the system also consists of software), where the system is intended by the manufacturer to be used (whether or not with ancillary inputs or equipment) by a health professional, or suitably qualified person within a healthcare facility, to produce a particular medical device for use in relation to a patient of the health professional or healthcare facility.

medical devices (priority applicant) determination has the meaning given by subsection 41FKA(2) of the Act.

medical device used for a special purpose means a medical device to which regulation 3.10 applies.

medical practitioner means a person registered as a medical practitioner under a law of a State or Territory that provides for the registration of medical practitioners.

NATA means the National Association of Testing Authorities.

partial designation conformity assessment body determination (full QMS) means a conformity assessment body determination that is not:

(a) a full designation conformity assessment body determination; or

(b) a partial designation conformity assessment body determination (partial QMS or partial devices).

partial designation conformity assessment body determination (partial QMS or partial devices) means a conformity assessment body determination that:

(a) is not a full designation conformity assessment body determination; and

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(b) covers:

(i) the conformity assessment procedures set out in clause 1.6 or Part 2 of Schedule 3 (whether or not the determination also covers other procedures); or

(ii) a Class III medical device (whether or not the determination also covers other medical devices).

patient implant card has the meaning given by clause 13A.2 of Schedule 1.

patient information leaflet has the meaning given by clause 13A.3 of Schedule 1.

patient-matched medical device means a medical device that:

(a) is manufactured by the manufacturer, within a specified design envelope, to match:

(i) either or both of the anatomical and physiological features of a particular individual; or

(ii) a pathological condition of a particular individual; and

(b) is designed by the manufacturer (even if the design is developed in consultation with a health professional); and

(c) is manufactured using production processes that are capable of being:

(i) either or both validated and verified; and

(ii) reproduced.

point of care testing, for an IVD medical device, means testing performed outside the laboratory environment, near to or at the side of the patient, that is not done under the supervision of a trained laboratory professional.

post-production phase, in relation to a medical device, means the period during which the device is stored, transported, supplied for use and used (whether in Australia or not).

principal investigator, in relation to a clinical trial of a kind of medical device, means the person who is in charge of the conduct of the trial.

procedures for medical devices used for a special purpose means the conformity assessment procedures set out in Part 7 of Schedule 3.

production quality assurance procedures means the conformity assessment procedures set out in Part 4 of Schedule 3.

product quality assurance procedures means the conformity assessment procedures set out in Part 5 of Schedule 3.

refurbishment, of a medical device—see regulation 1.5.

residual risk for a medical device has the meaning given by subclause 2(3) of Schedule 1.

reusable surgical instrument means a medical device that is intended by the manufacturer:

(a) to be used surgically, without being connected to an active medical device, for cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or any other similar procedure; and

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(b) to be reused after the appropriate procedures (such as cleaning, disinfection and sterilisation) specified by the manufacturer in the instructions for use have been carried out.

sample, for an IVD medical device for self-testing, means 1 or more specimens, taken from the human body, that:

(a) are intended to provide information on the human body; and

(b) may serve as a basis for a decision on the human body or its processes.

serious, for a condition, ailment or defect, means a condition, ailment or defect that is:

(a) generally accepted as not being appropriate to be diagnosed or treated without consulting a medical practitioner, dentist or other kind of health care worker registered under a law of a State or Territory; or

(b) generally accepted to be beyond the ability of the average person to evaluate accurately, or treat safely, without supervision by a medical practitioner, dentist or other kind of health care worker registered under a law of a State or Territory.

serious disease means a disease that:

(a) may result in death or long-term disability; and

(b) may be incurable or require major therapeutic interventions; and

(c) must be diagnosed accurately, to mitigate the public health impact of the disease.

shoulder joint means the ball and socket formed by the reception of the head of the humerus onto the glenoid cavity of the scapula.

specialist has the same meaning as in the *Health Insurance Act 1973*.

specified design envelope means minimum and maximum dimensions, performance limits or other relevant factors that:

(a) characterise a medical device for production purposes; and

(b) may be based on a standard device template.

surgically invasive medical device means:

(a) an invasive medical device that is intended by the manufacturer to be used with the aid, or in the context, of a surgical operation; and

(b) a medical device that is intended by the manufacturer to be used to penetrate the body of a human being in any way other than through a body orifice.

type means a representative sample of a kind of medical device.

type examination procedures means the conformity assessment procedures set out in Part 2 of Schedule 3.

unique product identifier of a medical device means the unique product identifier (for example, the product name or model number) given to the device by its manufacturer to identify the device and any variants.

unused emergency medical devices means medical devices to which section 41GY of the Act applies.

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user of a medical device means any person (including a health professional) who uses the device.

variant means a medical device, the design of which has been varied, to accommodate different patient anatomical requirements (for example, relating to the shape, size, length, diameter or gauge of the device) or any other variation approved by the Secretary for this definition, if the variation does not change the intended purpose of the device.

verification procedures means the conformity assessment procedures set out in Part 3 of Schedule 3.

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Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Editorial changes
The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and "(md not incorp)" is added to the amendment history.

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Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

ed = editorial change

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Number and year	FRLI registration or gazettal	Commencement	Application, saving and transitional provisions
2002 No. 236	4 Oct 2002	4 Oct 2002	
2003 No. 153	26 June 2003	1 July 2003	—
2003 No. 259	16 Oct 2003	rr. 1–3 and Schedule 1: 16 Oct 2003 Remainder: 4 Oct 2007	—
2003 No. 361	23 Dec 2003	23 Dec 2003	—
2004 No. 78	30 Apr 2004	30 Apr 2004	—
2004 No. 128	18 June 2004	1 July 2004	—
2005 No. 193	19 Aug 2005 (F2005L02313)	20 Aug 2005	—
2006 No. 214	10 Aug 2006 (F2006L02575)	11 Aug 2006	—
2007 No. 163	25 June 2007 (F2007L01522)	1 July 2007	—
2008 No. 119	20 June 2008 (F2008L01366)	1 July 2008	—
2008 No. 270	18 Dec 2008 (F2008L04296)	19 Dec 2008	—
2009 No. 181	9 July 2009 (F2009L02090)	10 July 2009	—
2010 No. 25	3 Mar 2010 (F2010L00469)	1 July 2010	rr. 4–7
2010 No. 132	18 June 2010 (F2010L01281)	1 July 2010	—
2010 No. 267	29 Oct 2010 (F2010L02787)	30 Oct 2010	—
2011 No. 32	16 Mar 2011 (F2011L00430)	31 May 2011 (*see* r. 2)	—
2011 No. 104	21 June 2011 (F2011L01102)	1 July 2011	—
2011 No. 282	9 Dec 2011 (F2011L02627)	10 Dec 2011	—
2012 No. 146	29 June 2012 (F2012L01464)	1 July 2012	—
2012 No. 147	29 June 2012 (F2012L01466)	1 July 2012	—
94, 2013	3 June 2013 (F2013L00896)	Sch 1 (item 2): 1 July 2013	—

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Endnote 3—Legislation history

Number and year	FRLI registration or gazettal	Commencement	Application, saving and transitional provisions
38, 2014	26 Mar 2014 (F2014L00349)	27 Mar 2014	—
44, 2014	30 Apr 2014 (F2014L00456)	1 May 2014	—
62, 2014	30 May 2014 (F2014L00630)	1 July 2014	—
63, 2014	30 May 2014 (F2014L00632)	1 July 2014	—
159, 2014	3 Nov 2014 (F2014L01465)	5 Nov 2014 (s 2)	—
196, 2014	16 Dec 2014 (F2014L01716)	17 Dec 2014 (s 2)	—
46, 2015	20 Apr 2015 (F2015L00574)	21 Apr 2015 (s 2)	—
75, 2015	1 June 2015 (F2015L00778)	Sch 1 (items 7, 8): 1 July 2015 (s 2)	—
87, 2015	18 June 2015 (F2015L00837)	Sch 1 (item 1): 1 July 2015 (s 2(1) item 1)	—
90, 2015	19 June 2015 (F2015L00854)	Sch 2 (item 196): 1 July 2015 (s 2(1) item 2)	—
188, 2015	13 Nov 2015 (F2015L01791)	14 Nov 2015 (s 2(1) item 1)	—

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods Legislation Amendment (Charges Exemptions and Other Measures) Regulation 2016	15 Feb 2016 (F2016L00109)	Sch 3: 16 Feb 2016 (s 2(1) item 3)	—
Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulation 2016	5 May 2016 (F2016L00667)	Sch 1 (item 1): 1 July 2016 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2017	19 May 2017 (F2017L00552)	Sch 1 (items 1, 2): 1 July 2017 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (2017 Measures No. 1) Regulations 2017	30 June 2017 (F2017L00853)	Sch 2 (items 1–6), Sch 6 (item 1) and Sch 8 (items 1–6): 1 July 2017 (s 2(1) item 4)	—
Therapeutic Goods Legislation Amendment (2017 Measures No. 2) Regulations 2017	1 Dec 2017 (F2017L01561)	Sch 1: 1 Jan 2018 (s 2(1) item 2) Sch 4 (items 5, 7–10): 2 Dec 2017 (s 2(1) item 6)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017	20 Dec 2017 (F2017L01692)	1 Dec 2018 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018	19 Mar 2018 (F2018L00311)	Sch 3, Sch 6 (items 1–8) and Sch 7: 20 Mar 2018 (s 2(1) items 4, 8)	—
Therapeutic Goods Legislation Amendment (Exempt Devices and Goods) Regulations 2018	26 Apr 2018 (F2018L00516)	Sch 1 (items 1–5): 27 Apr 2018 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2018	12 June 2018 (F2018L00759)	Sch 1 (items 1–4): 1 July 2018 (s 2(1) item 2)	—
Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018	25 June 2018 (F2018L00865)	Sch 1 (items 1–3): 1 July 2018 (s 2(1) item 2)	—
Therapeutic Goods Legislation Amendment (2018 Measures No. 3) Regulations 2018	15 Oct 2018 (F2018L01434)	Sch 1 (items 1, 2, 35, 36): 16 Oct 2018 (s 2(1) item 2)	—
Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2019	25 Mar 2019 (F2019L00396)	Sch 1 (items 1–3): 1 July 2019 (s 2(1) item 2)	—
Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019	18 Dec 2019 (F2019L01660)	Sch 1 (items 1–43): 25 Nov 2021 (s 2(1) item 2) Sch 2 and 3: 25 Feb 2021 (s 2(1) item 2A) Sch 4: 1 Feb 2020 (s 2(1) item 3) Sch 10 (item 1): 19 Dec 2019 (s 2(1) item 10)	—
as amended by			
Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020	23 July 2020 (F2020L00946)	Sch 8 (item 1): 24 July 2020 (s 2(1) item 7)	—
Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2020	15 June 2020 (F2020L00720)	Sch 1 (items 1, 3): 1 July 2020 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020	23 July 2020 (F2020L00946)	Sch 1: 25 Aug 2020 (s 2(1) item 2) Sch 2, 3, 7, Sch 8 (items 2–23) and Sch 10 (item 1): 24 July 2020 (s 2(1) items 3, 6, 7, 9) Sch 8 (item 32): 25 Nov 2021 (s 2(1) item 8)	—

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Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods Legislation Amendment (2020 Measures No. 2) Regulations 2020	14 Dec 2020 (F2020L01598)	Sch 1 (items 1, 2): 25 Feb 2021 (s 2(1) item 2)	—
Therapeutic Goods (Medical Devices) Amendment (Vaporisers for Smoking Cessation) Regulations 2020	18 Dec 2020 (F2020L01645)	19 Dec 2020 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (2021 Measures No. 1) Regulations 2021	16 Apr 2021 (F2021L00450)	Sch 2: 17 Apr 2021 (s 2(1) item 4)	—
Therapeutic Goods Legislation Amendment (Fees) Regulations 2021	3 June 2021 (F2021L00688)	Sch 1 (item 1): 1 July 2021 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021	27 July 2021 (F2021L01032)	Sch 1 (items 3–5, 9–12, 14): 28 July 2021 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021	28 Oct 2021 (F2021L01474)	Sch 1 (items 14–37, 44–48, 50–53, 62–69, 83–86): 29 Oct 2021 (s 2(1) items 3, 5, 7) Sch 1 (items 1–13, 38–43, 49): 25 Nov 2021 (s 2(1) items 2, 4, 6)	—
Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021	17 Dec 2021 (F2021L01809)	Sch 1 (items 1–4): 18 Dec 2021 (s 2(1) item 2)	—
Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022	4 Mar 2022 (F2022L00243)	Sch 3 (items 1–3): 5 Mar 2022 (s 2(1) item 4)	—
Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2022	13 Apr 2022 (F2022L00600)	Sch 1 (items 1–4): 1 July 2022 (s 2(1) item 1)	—

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Endnote 4—Amendment history

Provision affected	How affected
Part 1	
r 1.2	rep LA s 48D
r 1.4	am F2016L00109
r 1.6	rs No 25, 2010
	am F2019L01660
r 1.7	am No 25, 2010; F2019L01660
r 1.8	ad F2019L01660
Part 3	
Division 3.1	
r 3.1	rs No 25, 2010
	am F2019L01660
r. 3.2	rs. 2010 No. 25
r 3.3	am No 25, 2010; F2019L01660
Division 3.2	
r. 3.4	am. 2010 No. 25
r 3.5	am No 159, 2014
r 3.6	am F2019L01660
r. 3.6A	ad. 2010 No. 25
	am No 188, 2015
r 3.6B	ad No 188, 2015
r. 3.7A	ad. 2010 No. 25
r. 3.7B	ad. 2010 No. 25
r. 3.8A	ad. 2010 No. 25
r. 3.8B	ad. 2010 No. 25
r. 3.9A	ad. 2010 No. 25
r. 3.9B	ad. 2010 No. 25
r 3.10	am No 25, 2010; No 32, 2011; F2020L00946; F2021L01474
r 3.11	am F2019L01660
Part 4	
Division 4.1	
r. 4.1	am No 25, 2010; No 159, 2014; No 188, 2015
	rep F2021L01032
Division 4.1A	
Division 4.1A	ad F2017L01561
r 4.3A	ad F2017L01561
r 4.3B	ad F2017L01561
r 4.3C	ad F2017L01561

Endnote 4—Amendment history

Provision affected	How affected
r 4.3D	ad F2017L01561
r 4.3E	ad F2017L01561
Division 4.1B	
Division 4.1B	ad F2018L00311
r 4.3F	ad F2018L00311
	am F2019L01660
Division 4.1C	
Division 4.1C	ad F2018L00865
r 4.3G	ad F2018L00865
Part 4A	
Part 4A	ad F2018L00311
Division 4A.1	
r 4A.1	ad F2018L00311
Division 4A.2	
r 4A.2	ad F2018L00311
r 4A.3	ad F2018L00311
r 4A.4	ad F2018L00311
r 4A.5	ad F2018L00311
r 4A.6	ad F2018L00311
	am F2022L00600
r 4A.7	ad F2018L00311
r 4A.8	ad F2018L00311
r 4A.9	ad F2018L00311
Division 4A.3	
Subdivision A	
r 4A.10	ad F2018L00311
r 4A.11	ad F2018L00311
r 4A.12	ad F2018L00311
r 4A.13	ad F2018L00311
r 4A.14	ad F2018L00311
r 4A.15	ad F2018L00311
r 4A.16	ad F2018L00311
r 4A.17	ad F2018L00311
r 4A.18	ad F2018L00311
Subdivision B	
r 4A.19	ad F2018L00311
Division 4A.4	
r 4A.20	ad F2018L00311
r 4A.21	ad F2018L00311
r 4A.22	ad F2018L00311

Endnote 4—Amendment history

Provision affected	How affected
r 4A.23	ad F2018L00311
r 4A.24	ad F2018L00311
Division 4A.5	
r 4A.25	ad F2018L00311
r 4A.26	ad F2018L00311
r 4A.27	ad F2018L00311
Division 4A.6	
r 4A.28	ad F2018L00311
r 4A.29	ad F2018L00311
r 4A.30	ad F2018L00311
Division 4A.7	
r 4A.31	ad F2018L00311
	am F2019L01660
Part 5	
Division 5.1	
Subdivision A	
Subdivision A heading	ad F2017L01561
Subdivision C	
Subdivision C heading	ad F2017L01561
r 5.3	am No 25, 2010; No 282, 2011; No 38, 2014; No 159, 2014; No 188, 2015; F2016L00109; F2018L00311; F2018L01434; F2019L01660; F2021L01032
Subdivision D	
Subdivision D	ad F2017L01561
r 5.4	rep No 282, 2011
	ad F2017L01561
r 5.4A	ad F2017L01561
r 5.4B	ad F2017L01561
r 5.4C	ad F2017L01561
	am F2018L00311
r 5.4D	ad F2017L01561
	am F2018L00311
Division 5.2	
r 5.7	am F2020L00946; F2021L01474
r 5.8A	ad F2021L01474
r 5.9	ad F2017L00853
r 5.10	ad F2017L00853
	am F2019L01660
r 5.11	ad F2017L00853
	am F2019L01660; F2020L00946
r 5.12	ad F2017L00853

Endnote 4—Amendment history

Provision affected	How affected
	am F2019L01660
r 5.13	ad F2018L00865
	am F2018L01434
Part 6A	
Part 6A	ad. 2010 No. 267
r. 6A.1	ad. 2010 No. 267
Part 7	
Division 7.1	
r 7.1	am F2021L01032; F2021L01474
r 7.2	am F2017L01561; F2018L00311
Division 7.2	
r 7.3	am F2016L00109
r 7.5	am F2020L00946
Division 7.3	
r 7.7	am F2017L00853
r 7.8	ad F2017L00853
Part 8	
r. 8.1A	ad. 2011 No. 104
	am No 75, 2015; F2016L00109
r 8.1	am F2019L01660
r 8.2	am F2017L00853
	rep F2017L01561
Part 9	
Division 9.1	
Division 9.1 heading	ad F2018L00311
Division 9.1A	
Division 9.1A	ad F2021L01474
r 9.1AA	ad F2021L01474
Division 9.2	
Division 9.2	ad F2018L00311
r 9.1A	ad F2018L00311
r 9.1B	ad F2018L00311
r 9.1C	ad F2018L00311
r 9.1D	ad F2018L00311
r 9.1E	ad F2018L00311
r 9.1F	ad F2018L00311
Division 9.3	
Division 9.3 heading	ad F2018L00311
	am F2021L01474
r 9.2	am 2011 No 282

Endnote 4—Amendment history

Provision affected	How affected
r 9.4	am 2003 No 153; 2004 No 128; 2005 No 193; 2006 No 214; 2007 No 163; 2008 No 119; 2009 No 181; 2010 No 132; 2011 No 104; 2012 No 147; No 94, 2013; No 62, 2014; No 87, 2015; F2016L00667; F2017L00552
	rep F2018L00759
r. 9.6	ad. 2003 No. 153
r. 9.7	ad. 2003 No. 153
	am. 2010 No. 267; No 188, 2015
r 9.8	ad F2021L01474
Division 9.4	
Division 9.4	ad F2021L01474
r 9.9	ad F2021L01474
Part 10	
r. 10.1	rs. 2003 No. 361
r. 10.2	am. 2003 No. 259
r 10.3	am F2016L00109
r 10.3A	ad F2019L01660
r 10.4AA	ad F2020L00946
r 10.4A	ad No 196, 2014
r 10.5	am F2016L00109
r 10.6A	ad F2016L00109
	am F2017L00853; F2017L01561
r 10.6B	ad F2018L00311
r 10.7	am F2016L00109; F2017L01561; F2018L00311; F2021L01474
Part 11	
Part 11 heading	rs No 63, 2014
Part 11	ad. 2012 No. 146
Division 11.1	
Division 11.1	ad No 63, 2014
Subdivision A	
r 11.1	ad No 63, 2014
	am No 188, 2015; F2018L00311
r 11.2	ad No 63, 2014
Subdivision B	
r 11.3	ad No 63, 2014
r 11.4	ad No 63, 2014
r 11.5	ad No 63, 2014
Subdivision C	
r 11.6	ad No 63, 2014
r 11.7	ad No 63, 2014
r 11.8	ad No 63, 2014

Provision affected	How affected
	am F2018L00311
r 11.9	ad No 63, 2014
r 11.10	ad No 63, 2014
r 11.11	ad No 63, 2014
Subdivision D	
r 11.12	ad No 63, 2014
r 11.13	ad No 63, 2014
r 11.14	ad No 63, 2014
Subdivision E	
r 11.15	ad No 63, 2014
	am No 188, 2015
r 11.16	ad No 63, 2014
r 11.17	ad No 63, 2014
	am No 188, 2015; F2018L00311
r 11.18	ad No 63, 2014
	rs No 188, 2015
	am F2018L00311
r 11.19	ad No 63, 2014
	rep No 188, 2015
Subdivision F	
r 11.20	ad No 63, 2014
	am No 188, 2015
r 11.21	ad No 63, 2014
	rs No 188, 2015
Division 11.2	
Division 11.2 heading	ad No 63, 2014
	rs No 46, 2015
r 11.22A	ad No 46, 2015
r 11.22 (prev r 11.1)	ad No 146, 2012
	am No 38, 2014; No 44, 2014
	renum No 63, 2014
	am No 46, 2015
r 11.23	ad No 46, 2015
Division 11.3	
Division 11.3	ad No 188, 2015
r 11.24	ad No 188, 2015
r 11.25	ad No 188, 2015
r 11.26	ad No 188, 2015
Division 11.4	
Division 11.4	ad F2016L00109

Endnote 4—Amendment history

Provision affected	How affected
r 11.27	ad F2016L00109
Division 11.5	
Division 11.5	ad F2017L01692
r 11.28	ad F2017L01692
r 11.29	ad F2017L01692
	am F2021L01474
r 11.30	ad F2017L01692
	rep F2021L01474
r 11.31	ad F2017L01692
Division 11.6	
Division 11.6	ad F2017L01561
r 11.32	ad F2017L01561
r 11.33	ad F2017L01561
Division 11.7	
Division 11.7	ad F2018L00516
r 11.34	ad F2018L00516
Division 11.8	
Division 11.8	ad F2018L00865
r 11.35	ad F2018L00865
r 11.36	ad F2018L00865
Division 11.9	
Division 11.9	ad F2018L01434
r 11.37	ad F2018L01434
Division 11.10	
Division 11.10	ad F2019L01660
Subdivision A	
r 11.38	ad F2019L01660
Subdivision B	
r 11.39	ad F2019L01660
	am F2020L00946; F2021L01474
r 11.40	ad F2019L01660
	am F2020L00946; F2021L01474
r 11.41	ad F2019L01660
	am F2020L00946
r 11.42	ad F2019L01660
r 11.43	ad F2019L01660
	am F2020L00946
	exp end of 24 Nov 2022 (r 11.43(3))
Subdivision C	
r 11.44	ad F2019L01660

Endnote 4—Amendment history

Provision affected	How affected
	am F2020L00946
r 11.45	ad F2019L01660
	am F2020L00946
r 11.46	ad F2019L01660
	am F2020L00946
r 11.47	ad F2019L01660
	am F2020L00946
Subdivision D	
r 11.48	ad F2019L01660
	am F2020L00946
r 11.49	ad F2019L01660
	am F2020L00946
r 11.50	ad F2019L01660
	am F2020L00946
r 11.51	ad F2019L01660
	am F2020L00946; F2021L00450
r 11.52	ad F2019L01660
	am F2020L00946
r 11.53	ad F2019L01660
	am F2020L00946
Subdivision E	
r 11.54	ad F2019L01660
Division 11.11	
Division 11.11	ad F2020L00946
r 11.55	ad F2020L00946
r 11.56	ad F2020L00946
r 11.57	ad F2020L00946
Division 11.12	
Division 11.12	ad F2021L01032
r 11.58	ad F2021L01032
Division 11.13	
Division 11.13	ad F2021L01474
r 11.59	ad F2021L01474
r 11.60	ad F2021L01474
r 11.61	ad F2021L01474
r 11.62	ad F2021L01474
r 11.63	ad F2021L01474
r 11.64	ad F2021L01474
r 11.65	ad F2021L01474
r 11.66	ad F2021L01474

Endnote 4—Amendment history

Provision affected	How affected
Division 11.14	
Division 11.14	ad F2021L01809
r 11.67	ad F2021L01809
Schedule 1	
Schedule 1	am No 259, 2003; No 25, 2010; F2016L00109
	ed C33
	am F2017L01692
	ed C39
	am F2019L01660; F2021L01474; F2021L01809; F2022L00243
Schedule 2	
Schedule 2 heading	rs No 25, 2010
Schedule 2	am F2019L01660
Part 1	
c 1.1	am F2019L01660
Part 2	
c 2.4	am F2019L01660
Part 3	
c 3.1	am F2019L01660; F2021L01474
c 3.2	am F2019L01660; F2021L01474
c 3.3	am F2019L01660
c 3.4	am No 146, 2012; No 46, 2015; F2017L01692; F2019L01660; F2021L01474
Part 4	
c 4.2	am F2019L01660
c 4.3	ed C32
c 4.5	ad F2019L01660
c 4.6	ad F2019L01660
c 4.7	ad F2019L01660
c 4.8	ad F2019L01660
Part 5	
c 5.4	rs F2019L01660
c 5.7	am F2019L01660
c 5.8	am No 25, 2010
c 5.10	ad F2021L01474
c 5.11	ad F2021L01474
Schedule 2A	
Schedule 2A	ad No 25, 2010
	am F2019L01660
c 1.1	ad No 25, 2010
c 1.2	ad No 25, 2010
c 1.3	ad No 25, 2010

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Provision affected	How affected
	am No 188, 2015; F2019L01660
c 1.4	ad No 25, 2010
c 1.5	ad No 25, 2010
c 1.6	ad No 25, 2010
c 1.7	ad No 25, 2010
c 1.8	ad No 25, 2010
Schedule 3	
Part 1	
c 1.1	am No 25, 2010; F2018L00311; F2019L01660
c 1.3	am F2018L00311
c 1.4	am No 25, 2010; F2017L00853; F2018L00311; F2020L00946
c 1.5	am F2018L00311
c 1.6	am No 25, 2010; F2018L00311; F2019L01660
c 1.8	am F2018L00311; F2019L01660
c 1.9	am No 25, 2015; F2018L00311; F2019L01660
Part 2	
c 2.1	am F2018L00311
c 2.3	am No 25, 2010; F2018L00311
c 2.4	am F2018L00311
c 2.5	am F2018L00311
Part 3	
c 3.1	am F2018L00311
c 3.3	am F2018L00311
c 3.4	am F2017L00853; F2018L00311; F2020L00946
c 3.5	am F2018L00311; F2019L01660
c 3.6	am F2018L00311; F2019L01660
Part 4	
c 4.1	am F2018L00311
c 4.3	am F2018L00311
c 4.4	am F2017L00853; F2018L00311; F2020L00946
c 4.5	am F2018L00311
c 4.7	am No 25, 2010; No 188, 2015; F2018L00311; F2019L01660
c 4.8	am No 25, 2010; No 188, 2015; F2018L00311; F2019L01660
Part 5	
c 5.1	am F2018L00311
c 5.3	am F2018L00311
c 5.4	am F2017L00853; F2018L00311; F2020L00946
c 5.5	am F2018L00311
c 5.7	am F2018L00311; F2019L01660
c 5.8	am F2018L00311

Endnote 4—Amendment history

Provision affected	How affected
Part 6	
c 6.5	am F2017L00853; F2020L00946
c 6.6	am No 25, 2010; F2018L00311; F2019L01660
Part 6A	
Part 6A heading	rs No 188, 2015
Part 6A	ad No 25, 2010
c 1.1	ad No 25, 2010
	rs and renum No 188, 2015
c 6A.1 (prev c 1.1)	
c 1.2	ad No 25, 2010
	am No 63, 2014
	rs and renum No 188, 2015
c 6A.2 (prev c 1.2)	am F2018L00311
c 1.3	ad No 25, 2010
	am No 188, 2015
	renum No 188, 2015
c 6A.3 (prev c 1.3)	
c 1.4	ad No 25, 2010
	rs and renum No 188, 2015
c 6A.4 (prev c 1.4)	
Part 6B	
Part 6B	ad No 188, 2015
c 6B.1	ad No 188, 2015
	am F2020L00946
c 6B.2	ad No 188, 2015
c 6B.3	ad No 188, 2015
c 6B.4	ad No 188, 2015
c 6B.5	ad No 188, 2015
c 6B.6	ad No 188, 2015
	am F2019L01660
c 6B.7	ad No 188, 2015
c 6B.8	ad F2020L00946
Part 7	
c 7.1	am F2019L01660
c 7.2	am No 25, 2010; F2017L00853; F2019L01660
c 7.5	am No 32, 2011; F2017L00853; F2020L00946; F2021L01474
c 7.6	am F2019L01660
Schedule 3AA	
Schedule 3AA	ad F2018L00311
c 1	ad F2018L00311

Endnote 4—Amendment history

Provision affected	How affected
c 2	ad F2018L00311
c 3	ad F2018L00311
c 4	ad F2018L00311
c 5	ad F2018L00311
c 6	ad F2018L00311
c 7	ad F2018L00311
Schedule 3A	
Schedule 3A	ad No 267, 2010
	am No 104, 2011; F2017L00853; F2018L00311
Schedule 4	
Schedule 4	am No 78, 2004; No 270, 2008; No 25, 2010; No 267, 2010; No 90, 2015; No 188, 2015; F2017L00853
	ed C32
	am F2018L00311; F2018L00516; F2019L01660; F2020L00946; F2020L01598; F2020L01645; F2021L01032; F2021L00450; F2021L01474; F2021L01809
Schedule 5	
Schedule 5	am No 153, 2003; No 128, 2004; No 193, 2005; No 214, 2006; No 163, 2007; No 119, 2008; No 181, 2009; No 25, 2010; No 132, 2010; No 104, 2011; No 147, 2012; No 94, 2013; No 62, 2014; No 87, 2015; No 188, 2015; F2016L00667; F2017L00552; F2017L00853; F2017L01561; F2018L00311; F2018L00759; F2018L01434; F2019L00396; F2019L01660; F2020L00720; F2021L00688; F2021L01474
	ed C52
	am F2022L00600
Dictionary	
Dictionary	am No 25, 2010; No 267, 2010; No 196, 2014; No 46, 2015; No 188, 2015; F2016L00109; F2017L00853; F2017L01561; F2017L01692; F2018L00311
	ed C40
	am F2019L01660; F2020L00946; F2021L01474; F2022L00243