



Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015

Select Legislative Instrument No. 188, 2015

I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd),
Governor-General of the Commonwealth of Australia, acting with the
advice of the Federal Executive Council, make the following regulation.

Dated 12 November 2015

Peter Cosgrove
Governor-General

By His Excellency's Command

Fiona Nash
Minister for Rural Health

OPC61083 - B

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No. 188, 2015 *Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015* i

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1 Name

This is the *Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	14 November 2015

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Part 1—Amendments relating to Class 4 in-house IVD medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

1 Regulation 3.6A (heading)

Repeal the heading, substitute:

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

2 Regulation 3.6A

Omit “or a Class 4 in-house IVD medical device, other than a device to be used for a special purpose,”, substitute “(other than a medical device to be used for a special purpose)”.

3 After regulation 3.6A

Insert:

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.

4 Paragraph 4.1(e)

Repeal the paragraph, substitute:

- (e) Class 4 IVD medical devices;
- (f) Class 4 in-house IVD medical devices (other than those to which the conformity assessment procedures set out in Part 6B of Schedule 3 are applied).

5 At the end of paragraph 5.3(1)(j)

Add:

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

6 Paragraph 9.7(1)(d)

Omit “and 1.14A”, substitute “, 1.14A, 1.14B and 1.14C”.

7 Subclause 4.7(1) of Part 4 of Schedule 3

Omit “Class 4 in-house IVD medical device,”.

8 Paragraph 4.8(1)(c) of Part 4 of Schedule 3

Omit “Class 4 in-house IVD medical device,”.

9 After Part 6A of Schedule 3

Insert:

**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.

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*, 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;

Schedule 1 Amendments

Part 1 Amendments relating to Class 4 in-house IVD medical devices

- (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
 - (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 (for example, the product name);
 - (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

Schedule 1 Amendments

Part 1 Amendments relating to Class 4 in-house IVD medical devices

- (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.

10 Part 1 of Schedule 5 (after table item 1.14A)

Insert:

Amendments **Schedule 1**
Amendments relating to Class 4 in-house IVD medical devices **Part 1**

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	59 900
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	14 600

Part 2—Amendments relating to Class 1, 2 and 3 in-house IVD medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

11 Part 6A of Schedule 3 (heading)

Repeal the heading, substitute:

Part 6A—Procedures applying to Class 1, 2 and 3 in-house IVD medical devices

12 Clauses 1.1 and 1.2 of Part 6A of Schedule 3

Repeal the clauses, substitute:

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 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.

13 Clause 1.3 of Part 6A of Schedule 3 (heading)

Repeal the heading, substitute:

6A.3 Information to be given to the Secretary

14 Subclause 1.3(1) of Part 6A of Schedule 3

Omit all the words before paragraph (a), substitute:

- (1) On request by an authorised person, the manufacturer of a Class 1, 2 or 3 in-house IVD medical device must:

15 Paragraph 1.3(1)(a) of Part 6A of Schedule 3

Omit all the words before subparagraph (i), substitute:

- (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:

16 Subparagraphs 1.3(1)(a)(ii) and (iii) of Part 6A of Schedule 3

Omit “kinds of medical”.

17 Paragraph 1.3(2)(c) of Part 6A of Schedule 3

Omit “kind of” (first occurring).

18 Subparagraph 1.3(2)(c)(ii) of Part 6A of Schedule 3

Repeal the subparagraph, substitute:

- (ii) a general description of the device;

19 Subparagraph 1.3(2)(c)(iii) of Part 6A of Schedule 3

Omit “kind of”.

20 Sub-subparagraphs 1.3(2)(c)(iii)(A) and (C) of Part 6A of Schedule 3

Omit “or conformity assessment standard”.

21 Subparagraphs 1.3(2)(c)(iv), (vi) and (vii) of Part 6A of Schedule 3

Omit “kind of”.

22 Paragraphs 1.3(2)(d), (e) and (f) of Part 6A of Schedule 3

Omit “kind of” (wherever occurring).

23 Paragraph 1.3(2)(f) of Part 6A of Schedule 3

Omit “such devices;”, substitute “such devices.”.

24 Paragraph 1.3(2)(g) of Part 6A of Schedule 3

Repeal the paragraph.

25 Clause 1.4 of Part 6A of Schedule 3

Repeal the clause, substitute:

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.

Schedule 1 Amendments

Part 2 Amendments relating to Class 1, 2 and 3 in-house IVD medical devices

26 Part 2 of Schedule 4 (table item 2.10, column headed “Conditions”, paragraph (b))

After “conformity”, insert “assessment”.

27 Part 2 of Schedule 4 (table item 2.10, column headed “Conditions”, at the end of paragraph (c))

Add “within 20 working days of receiving the request”.

28 Part 2 of Schedule 4 (table item 2.10, column headed “Conditions”, paragraph (d))

After “information”, insert “within 20 working days of receiving the request”.

29 Part 2 of Schedule 4 (table item 2.10, column headed “Conditions”, subparagraph (f)(ii))

Repeal the subparagraph, substitute:

- (ii) inspect the premises and the device, and examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the device or anything on those premises that relates to the device;

30 Part 1 of Schedule 5 (cell at table item 1.17, column headed “Matter”)

Repeal the cell, substitute:

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

Part 3—Other amendments

Therapeutic Goods (Medical Devices) Regulations 2002

31 Subclause 1.3(1) of Schedule 2A

Omit “(1) An”, substitute “An”.

32 Subclause 1.3(2) of Schedule 2A

Repeal the subclause.

33 Part 1 of Schedule 5 (table item 1.5, column headed “Matter”, paragraph (f))

Repeal the paragraph, substitute:

- (f) an IVD medical device, including a Class 4 in-house IVD medical device but not 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)

34 Part 1 of Schedule 5 (table item 1.5, column headed “Matter”, after the note)

Insert:

Note for paragraph (f): There is no fee for an application to include a Class 2 IVD medical device mentioned in paragraph (f) in the Register.

35 Dictionary (paragraph (a) of the definition of *in-house IVD medical device*)

Omit “Australian medical laboratory or Australian medical laboratory network”, substitute “Australian laboratory or Australian laboratory network”.

36 Dictionary (paragraph (b) of the definition of *in-house IVD medical device*)

Omit “medical laboratory or medical laboratory network”, substitute “laboratory or laboratory network”.

37 Dictionary

Insert:

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.

manufacturing licence—see subsection 38(1B) of the Act.

38 Dictionary (definition of *medical laboratory network*)

Repeal the definition.

39 Dictionary

Insert:

NATA means the National Association of Testing Authorities.

Part 4—Application and transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

40 Subregulation 11.1(1) (paragraphs (a), (b) and (c) of the definition of *transitional device*)

Omit “device;”, substitute “device that is in existence before 1 July 2017;”.

41 Subregulation 11.1(1) (paragraph (d) of the definition of *transitional device*)

Omit “device;”, substitute “device that is in existence before 1 July 2016;”.

42 Regulation 11.15

After “in relation to”, insert “a transitional device that is”.

43 Subregulation 11.17(1)

Repeal the subregulation, substitute:

- (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.

44 Subregulation 11.17(8)

Repeal the subregulation, substitute:

- (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.

45 Regulations 11.18 and 11.19

Repeal the regulations, substitute:

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.

Note: For circumstances in which an application for a medical device to be included in the Register under Chapter 4 of the Act is effective, see subsection 41FC(2) of the Act.

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.

46 Regulation 11.20

Omit “the following medical devices”, substitute “a transitional device that is any of the following”.

47 Regulation 11.21

Repeal the regulation, substitute:

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.

48 At the end of Part 11

Add:

**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.
- (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.