



Therapeutic Goods (Medical Devices— Information that Must Accompany Application for Inclusion) Amendment (COVID-19 Measures—Export Only and System or Procedure Packs) Determination 2021

I, Lisa Kerr, as delegate of the Secretary of the Department of Health, make the following determination.

Dated 14 May 2021

Lisa Kerr
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Medical Devices and Product Quality Division
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1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (COVID-19 Measures—Export Only and System or Procedure Packs) Determination 2021*.

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	19 May 2021.	19 May 2021

Note: This table relates only to the provisions of this instrument as originally made.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 subsection 41FDB(7) of 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018

1 Section 4 (definition of Class 1 IVD medical device)

Repeal the definition, substitute:

Class 1 IVD medical device has the same meaning as in the Regulations.

2 Section 4 (definition of Class 2 IVD medical device)

Repeal the definition, substitute:

Class 2 IVD medical device has the same meaning as in the Regulations.

3 Section 4 (definition of Class 3 IVD medical device)

Repeal the definition, substitute:

Class 3 IVD medical device has the same meaning as in the Regulations.

4 Section 4 (definition of Class 4 IVD medical device)

Repeal the definition, substitute:

Class 4 IVD medical device has the same meaning as in the Regulations.

5 Section 4 (definition of Class 4 in-house IVD medical device)

Repeal the definition, substitute:

Class 4 in-house IVD medical device has the same meaning as in the Regulations.

6 Section 4 (definition of Class I medical device)

Repeal the definition, substitute:

Class I medical device has the same meaning as in the Regulations.

7 Section 4 (definition of Class IIa medical device)

Repeal the definition, substitute:

Class IIa medical device has the same meaning as in the Regulations.

8 Section 4 (definition of Class IIb medical device)

Repeal the definition, substitute:

Class IIb medical device has the same meaning as in the Regulations.

9 Section 4 (definition of Class III medical device)

Repeal the definition, substitute:

Class III medical device has the same meaning as in the Regulations.

10 Section 4 (definition of *Class AIMD medical device*)

Repeal the definition, substitute:

Class AIMD medical device has the same meaning as in the Regulations.

11 At the end of section 5

Add:

Application of this section

- (11) This section does not apply to any of the following:
- (a) a medical device used for a special purpose;
 - (b) a medical device that is intended by the manufacturer to be for export only.

12 At the end of section 6

Add:

Application of this section

- (9) This section does not apply to any of the following:
- (a) a medical device used for a special purpose;
 - (b) a medical device that is intended by the manufacturer to be for export only.

13 After section 6

Insert:

6A Kind of information—medical devices intended for export only

- (1) An application for a medical device that is intended by the manufacturer to be for export only, including an IVD medical device, must be accompanied by the following kind of information:
- (a) a declaration of conformity that relates to the manufacturer's quality management system specified in column 3 of an item in the table in Schedule 2A, which is recognised by the regulatory authority in column 2 of that item; and
 - (b) a conformity assessment document in relation to the medical device specified for that item in column 4 (if any), which is issued or recognised by the regulatory authority in column 2 of that item.
- (2) To avoid doubt, a document which accompanies the application in accordance with this section must relate to the kind of device to which the application relates.

Application of this section

- (3) This section does not apply to a medical device used for a special purpose.

14 Subsection 7(1A)

Repeal the subsection, substitute:

(1A) An application for a medical device used for a special purpose that is a system or procedure pack and:

- (a) classified under the Regulations as a Class I medical device that:
 - (i) does not have a measuring function; and
 - (ii) the manufacturer intends to be supplied in a non-sterile state; or
- (b) classified under the Regulations as a Class 1 IVD medical device; or
- (c) intended by the manufacturer to be for export only;

must be accompanied by the following kind of information:

- (d) a declaration of conformity that relates to the manufacturer's quality management system specified in column 3 of an item in the table in Division 1 of Part 1 of Schedule 3, which is recognised by the regulatory authority in column 2 of that item; and
- (e) a conformity assessment document in relation to each medical device contained in the system or procedure pack specified for that item in column 4 (if any), which is issued or recognised by the regulatory authority in column 2 of that item.

15 Subsection 7(1)

Repeal the subsection, substitute:

- (1) An application for a medical device used for a special purpose that is a system or procedure pack, other than a medical device that is mentioned in subsection (1A), must be accompanied by the following kind of information:
 - (a) a declaration of conformity that relates to the manufacturer's quality management system specified in column 3 of an item in the table in Division 2 of Part 1 of Schedule 3, which is recognised by the regulatory authority in column 2 of that item; and
 - (b) a conformity assessment document in relation to each medical device contained in the system or procedure pack specified for that item in column 4 (if any), which is issued or recognised by the regulatory authority in column 2 of that item.

16 Paragraph 7(3)(b)

Omit "subsection (2)", substitute "this section".

17 Section 9

Repeal the section, substitute:

9 Classes of medical device for which accompanying information is not determined

To avoid doubt, no kind of information is determined for the purposes of subsection 41FDB(7) for an application in relation to a medical device in one of the following classifications:

- (a) an in-house IVD medical device other than a Class 4 in-house IVD medical device;
- (b) a medical device used for a special purpose that is not a system or procedure pack.

Note: In effect, this means that no information must accompany applications in relation to these classifications.

18 After Schedule 2

Insert:

Schedule 2A—Medical devices intended for export only

Note: See section 6A.

Column 1 Item	Column 2 Regulatory authority	Column 3 Declaration of conformity in relation to the medical device	Column 4 Conformity assessment document relating to the medical device
1	Therapeutic Goods Administration	a declaration of conformity made by the manufacturer under clause 6.6 of Schedule 3 to the Regulations	

19 Division 1 of Part 1 of Schedule 3 (at the end of the heading)

Add “, Class 1 IVD medical devices, or intended for export only”

20 Division 2 of Part 1 of Schedule 3 (heading)

Repeal the heading, substitute:

Division 2—System or procedure packs that are not Class I medical devices intended to be supplied in a non-sterile state and that do not have a measuring function, not Class 1 IVD medical devices, or not intended for export only

21 Part 2 of Schedule 3 (heading)

Repeal the heading, substitute:

Part 2—System or procedure packs that are intended to be supplied in a sterile state and that are not Class 1 IVD medical devices, or not intended for export only