



Therapeutic Goods (Medical Devices— Information that Must Accompany Application for Inclusion) Amendment (COVID-19 Measures—Class I Medical Devices) Determination 2020

I, Tracey Duffy, as delegate of the Secretary of the Department of Health, make the following determination.

Dated 25 September 2020

Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
Health Products Regulation Group
Department of Health

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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—Class I Medical Devices) Determination 2020*.

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	1 October 2020.	1 October 2020

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Before subsection 5(1)

Insert:

- (1A) An application for a Class I medical device that the manufacturer intends to be supplied in a non-sterile state and that does not have a measuring function 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 1 of Part 1 of Schedule 1, 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 Subsection 5(1)

Repeal the subsection, substitute:

- (1) An application for a Class I medical device that the manufacturer intends to be supplied in a sterile state or that has a measuring function must be accompanied by the following kind of information:
- (a) a conformity assessment document 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 1, which is issued or recognised by the regulatory authority in column 2 of that item; and
 - (b) a conformity assessment document that relates to product assessment specified for that item in column 4 (if any), which is issued or recognised by the regulatory authority in column 2 of that item.

3 Paragraph 5(2)(a)

Before “an application”, insert “for the purpose of subsection (1),”.

4 Paragraph 5(2)(b)

Repeal the paragraph, substitute:

- (b) a document which accompanies an application in accordance with subsection (1) or (1A) must relate to the kind of device to which the application relates.

5 Subsections 5(3), (5), (7) and (9)

Omit “Subject to section 8, an application”, substitute “An application”.

6 Subsections 6(1), (3), (5) and (7)

Omit “Subject to section 8, an application”, substitute “An application”.

7 Before subsection 7(1)

Insert:

(1A) An application for a medical device used for a special purpose that is a system or procedure pack that is classified under the Regulations as a Class I medical device that:

- (a) does not have a measuring function; and
- (b) the manufacturer intends to be supplied in a non-sterile state;

must be accompanied by the following kind of information:

- (c) 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
- (d) 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.

8 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:

- (a) a system or procedure pack classified under the Regulations as a Class 1 IVD medical device; or
- (b) mentioned in subsection (1A);

must be accompanied by the following kind of information:

- (c) 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
- (d) 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.

9 Subsections 8(1) and (2)

Omit “instead”.

10 At the end of subsections 8(1) and (2)

Add “, rather than the kind of information determined for that class of medical device under that section”.

11 Paragraph 9(a)

Repeal the paragraph.

12 After the heading to Part 1 of Schedule 1

Insert:

Division 1—Class I medical devices that are intended to be supplied in a non-sterile state and do not have a measuring function

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	

Division 2—Class I medical devices that are intended to be supplied in a sterile state or have a measuring function**13 After the heading to Part 1 of Schedule 3**

Insert:

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

Column 1 Item	Column 2 Regulatory authority	Column 3 Declaration of conformity in relation to the system or procedures pack	Column 4 Conformity assessment document in relation to each medical device
1	Therapeutic Goods Administration	a declaration of conformity made by the manufacturer under clause 7.5 of Schedule 3 to the Regulations	

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