Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (COVID-19 Measures—Class 1 IVD Medical Devices) Determination 2020

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

Dated 2 December 2020

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

Contents

1 Name 1
2 Commencement 1
3 Authority 1
4 Schedules 1

Schedule 1—Amendments **2**

Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018 *2*

1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (COVID-19 Measures—Class 1 IVD 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	4 December 2020.	4 December 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Section 4

Insert:

Class 1 IVD medical device means a medical device that is classified under the Regulations as a Class 1 IVD medical device, other than a medical device used for a special purpose.

2 Before subsection 6(1)

Insert:

Class 1 IVD medical devices

(1A) An application for a Class 1 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 Part 1A of Schedule 2, 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.

(1B) To avoid doubt, a document which accompanies the application in accordance with subsection (1A) must relate to the kind of device to which the application relates.

3 Paragraph 9(c)

Repeal the paragraph.

4 Before Part 1 of Schedule 2

Insert:

Part 1A—Class 1 IVD medical devices

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	