



Therapeutic Goods (Medical Devices— Information that Must Accompany Application for Inclusion) Amendment Determination 2024

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

Dated 21 June 2024

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

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1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination 2024*.

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 July 2024.	1 July 2024

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 (definitions of active implantable medical device and Class AIMD medical device)

Repeal the definitions.

2 Section 4

Insert:

clinical evaluation report means a report prepared by a manufacturer detailing the assessment and analysis of clinical data to verify the safety and performance of a medical device when used as intended by the manufacturer.

generic device group has the same meaning as in the EU IVD regulation.

instructions for use has the same meaning as in the Regulations.

IVD companion diagnostic has the same meaning as in the Regulations.

IVD medical device for self-testing has the same meaning as in the Regulations.

point of care testing has the same meaning as in the Regulations.

3 Section 4 (definition of specified medical device)

Repeal the definition.

4 Subsection 5(7)

Repeal the subsection, substitute:

- (7) An application for a Class III medical device 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 1 of Part 4 of Schedule 1, which is issued or recognised by the regulatory authority in column 2 of that item;
 - (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;
 - (c) if the application is not accompanied by a conformity assessment certificate issued by the TGA—a clinical evaluation report and the instructions for use.

5 Subsections 5(8A) to (10B)

Repeal the subsections.

6 Part 2 of Schedule 1 (cell at item 7, column 3)

Repeal the cell, substitute:

a MDSAP certificate

7 Part 3 of Schedule 1 (cell at item 9, column 3)

Repeal the cell, substitute:

a MDSAP certificate

8 Division 1 of Part 4 of Schedule 1 (heading)

Repeal the heading.

9 Division 1 of Part 4 of Schedule 1 (cell at item 10, column 3)

Repeal the cell, substitute:

a MDSAP certificate

10 Division 2 of Part 4 of Schedule 1

Repeal the Division.

11 Part 5 of Schedule 1

Repeal the Part.

12 Part 1 of Schedule 2 (cell at item 3, column 4)

Repeal the cell, substitute:

for an IVD medical device
for self-testing or an IVD
medical device for point of
care testing—an
assessment of technical
documentation referred to
in section 5.1 of Annex IX
of the EU IVD regulation

13 Part 1 of Schedule 2 (cell at item 4, column 3)

Repeal the cell, substitute:

a MDSAP certificate

14 Part 1 of Schedule 2 (cell at item 4, column 4)

Insert:

a Class II medical device
licence issued under the
Canadian medical devices
regulations

15 Part 1 of Schedule 2 (at the end of the table)

Add:

10	Japan’s Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency	either of the following: (a) a MDSAP certificate; or (b) a quality management system certificate for the purposes of the Japanese PMD Act	for an IVD medical device for self-testing or an IVD medical device for point of care testing—one or more of the following: (a) a pre-market certification issued under the Japanese PMD Act; (b) a pre-market approval issued under the Japanese PMD Act
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16 Part 2 of Schedule 2 (cell at item 5, column 4)

Insert:

one of the following:

- (a) for an IVD medical device for self-testing or an IVD medical device for point of care testing—an assessment of technical documentation set out in section 5.1 of Annex IX of the EU IVD regulation; or
- (b) for an IVD companion diagnostic—an assessment of technical documentation set out in section 5.2 of Annex IX of the EU IVD regulation; or
- (c) for other IVD medical devices—the assessment of technical documentation as set out in section 4 of Annex IX of the EU IVD regulation for at least one representative device in a generic device group

17 Part 2 of Schedule 2 (cell at item 7, column 3)

Repeal the cell, substitute:

a MDSAP certificate

18 Part 2 of Schedule 2 (cell at item 7, column 4)

Insert:

a Class III medical device
licence issued under the
Canadian medical devices
regulations

19 Part 2 of Schedule 2 (cell at item 9, column 4)

Insert:

an order approving an
application for premarket
approval under section 515
of the US FDC Act

20 Part 2 of Schedule 2 (at the end of the table)

Add:

14	Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency	either of the following: (a) a MDSAP certificate; or (b) a quality management system certificate for the purposes of the Japanese PMD Act	for an IVD medical device for self-testing or an IVD medical device for point of care testing—either of the following: (a) a pre-market certification issued under the Japanese PMD Act; or (b) a pre-market approval issued under the Japanese PMD Act
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21 Part 3 of Schedule 2 (at the end of the table)

Add:

7	Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency	either of the following: (a) a MDSAP certificate; or (b) a quality management system certificate for the purposes of the Japanese PMD Act	a pre-market approval issued under the Japanese PMD Act
8	United States Food and Drug Administration	an order approving an application for premarket approval under section 515 of the US FDC Act	an order approving an application for premarket approval under section 515 of the US FDC Act

9	Health Canada	a MDSAP certificate	a Class IV medical device licence issued under Canadian medical device regulations
10	Health Sciences Authority of Singapore	an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class D IVD	
