Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Class IIa and Class IIb) Determination 2023

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

Dated 16 October 2023

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

Contents

1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Class IIa and Class IIb) Determination 2023*.

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.	

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

implantable medical device has the same meaning as in the Regulations.

relevant implantable medical device means an implantable medical device other than a medical device:

(a) mentioned in paragraphs 13A.1(1)(b) or (ba) of Schedule 1 to the Regulations; or

(b) to which subclause 13A.1(2) of Schedule 1 to the Regulations applies.

Note: Medical devices mentioned in paragraph 13A.1(1)(b) of Schedule 1 to the Regulations include, for example, sutures, staples, dental fillings and dental braces. The medical devices mentioned in paragraph 13A.1(1)(ba) of Schedule 1 to the Regulations are medical devices that are intended by the manufacturer to be for export only.

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

Repeal the cell.

3 Part 3 of Schedule 1 (cell at table item 6, column 4)

Repeal the cell, substitute:

for a relevant implantable medical device—an EU technical documentation assessment certificate issued under Chapter II of Annex IX of the EU medical devices regulation