Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (Singapore) Determination 2022

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

Dated 30 August 2022

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

Contents

1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (Singapore) Determination 2022*.

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	At the same time as the *Therapeutic Goods (Overseas Regulators) Amendment (Singapore) Determination 2022* commences. However, this instrument does not commence at all if the *Therapeutic Goods (Overseas Regulators) Amendment (Singapore) Determination 2022* does not commence.	

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Note: See section 4.

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

1 Section 4

Insert:

Singapore Health Products Act means the Health Products Act 2007 of Singapore as in force on 1 July 2022.

Singapore Register of Health Products means the Register of Health Products kept and maintained by the Health Sciences Authority of Singapore under section 34 of the Singapore Health Products Act.

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

Add:

9	Health Sciences Authority of Singapore	an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class B medical device

3 Part 3 of Schedule 1 (at the end of the table)

Add:

12	Health Sciences Authority of Singapore	an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class C medical device

4 Division 1 of Part 4 of Schedule 1 (at the end of the table)

Add:

13	Health Sciences Authority of Singapore	an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class D medical device

5 Division 1 of Part 5 of Schedule 1 (at the end of the table)

Add:

13	Health Sciences Authority of Singapore	an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class D medical device

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

Add:

9	Health Sciences Authority of Singapore	an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class B IVD

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

Add:

13	Health Sciences Authority of Singapore	an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class C IVD