



Therapeutic Goods (Medical Devices— Information that Must Accompany Application for Inclusion) Amendment (European Union— Consequential Amendments) Determination 2022

I, John Skerritt, as delegate of the Secretary of the Department of Health, make the following determination.

Dated 2 May 2022

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health

Contents

| | |
|---|----------|
| 1 Name..... | 1 |
| 2 Commencement | 1 |
| 3 Authority..... | 1 |
| 4 Schedules | 1 |
| Schedule 1—Amendments | 2 |
| <i>Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018</i> | 2 |

1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Consequential Amendments) 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 | 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Part 1 of Schedule 2 (table item 2, column 3)

Omit “26 May 2022”, substitute “26 May 2023”.

2 Part 1 of Schedule 2 (after table item 2)

Insert:

| | | | |
|----|--|---|---|
| 2A | a notified body within the meaning of Directive 98/79/EC | for an application submitted before 26 May 2027—a document certifying compliance with ISO 13485 | an EU declaration of conformity made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022 |
|----|--|---|---|

3 Part 1 of Schedule 2 (table item 7, column 3)

Omit “26 May 2022”, substitute “26 May 2023”.

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

Add:

| | | | |
|---|--|---|---|
| 8 | an IAF accredited conformity assessment body | for an application submitted before 26 May 2027—a document certifying compliance with ISO 13485 | an EU declaration of conformity made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022 |
|---|--|---|---|

5 Part 2 of Schedule 2 (table item 3, column 3)

Omit “26 May 2022”, substitute “26 May 2023”.

6 Part 2 of Schedule 2 (after table item 3)

Insert:

| | | | |
|----|--|---|---|
| 3A | a notified body within the meaning of Directive 98/79/EC | for an application submitted before 26 May 2026—a document certifying compliance with ISO 13485 | an EU declaration of conformity made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022 |
|----|--|---|---|

7 Part 2 of Schedule 2 (table item 11, column 3)

Omit “26 May 2022”, substitute “26 May 2023”.

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

Add:

| | | | |
|----|--|---|---|
| 12 | an IAF accredited conformity assessment body | for an application submitted before 26 May 2026—a document certifying compliance with ISO 13485 | an EU declaration of conformity made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022 |
|----|--|---|---|