Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination (No. 3) 2024

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

Dated 13 December 2024

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 Determination (No. 3) 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	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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 (definition of *EU IVD regulation*)

Repeal the definition, substitute:

EU IVD regulation means *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices,* as in force on 1 December 2024.

2 At the end of subsection 6(1)

Add:

; and (c) if the application is accompanied by the information specified in item 2 or 2B in the table in Part 1 of Schedule 2—evidence to demonstrate compliance with Article 110(3c) of the EU IVD regulation.

3 At the end of subsection 6(3)

Add:

; and (c) if the application is accompanied by the information specified in item 3, 3B or 4 in the table in Part 2 of Schedule 2—evidence to demonstrate compliance with Article 110(3c) of the EU IVD regulation.

4 At the end of subsection 6(5)

Add:

; and (c) if the application is accompanied by the information specified in item 3 or 4 in the table in Part 3 of Schedule 2—evidence to demonstrate compliance with Article 110(3c) of the EU IVD regulation.

5 Part 1 of Schedule 2 (cell at table item 2, column 3)

Repeal the cell, substitute:

for an application submitted before 1 January 2030—one of the following:

(a) a full quality assurance system certificate or other document issued under section 3 of Annex IV of Directive 98/79/EC;

(b) a production quality assurance certificate or other document issued under Annex VII of Directive 98/79/EC

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

Insert:

2B	a notified body within the meaning	for an application submitted before 1 January 2030—an EU declaration of conformity made

	of Directive 98/79/EC	by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022	

7 Part 1 of Schedule 2 (table item 7)

Repeal the item.

8 Part 2 of Schedule 2 (cell at table item 3, column 3)

Repeal the cell, substitute:

for an application submitted before 1 January 2029—a full quality assurance system certificate or other document issued under section 3 of Annex IV of Directive 98/79/EC

9 Part 2 of Schedule 2 (after table item 3A)

Insert:

3B	a notified body within the meaning of Directive 98/79/EC	for an application submitted before 1 January 2029—an EU declaration of conformity made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022	

10 Part 2 of Schedule 2 (table item 4)

Repeal the item, substitute:

4	a notified body within the meaning of Directive 98/79/EC	for an application submitted before 1 January 2029—a production quality assurance certificate or other document issued under Annex VII of Directive 98/79/EC	for an application submitted before 1 January 2029—an EC type-examination certificate issued under Annex V of Directive 98/79/EC

11 Part 2 of Schedule 2 (table item 11)

Repeal the item.

12 Part 3 of Schedule 2 (table item 3)

Repeal the item, substitute:

3	a notified body within the meaning of Directive 98/79/EC	for an application submitted before 1 January 2028—a full quality assurance system certificate or other document issued under section 3 of Annex IV of Directive 98/79/EC	for an application submitted before 1 January 2028—an EC design-examination certificate issued under Annex IV of Directive 98/79/EC

13 Part 3 of Schedule 2 (table item 4)

Repeal the item, substitute:

4	a notified body within the meaning of Directive 98/79/EC	for an application submitted before 1 January 2028—a production quality assurance certificate or other document issued under Annex VII of Directive 98/79/ EC	for an application submitted before 1 January 2028— an EC type-examination certificate issued under Annex V of Directive 98/79/EC