Therapeutic Goods (Medical Devices—Specified Articles) Amendment Instrument 2025

I, Tracey Duffy, as delegate of the Secretary of the Department of Health, Disability and Ageing, make the following instrument.

Dated 10 December 2025

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

Authorised Version F2025L01529 registered 10/12/2025

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1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment Instrument 2025*.

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 January 2026.	1 January 2026

Note: This table relates only to the provisions of this instrument as originally made.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 41BD(2B) 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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Schedule 1—Amendments

Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020

1 Section 4 (note 1)

Repeal the note, substitute:

Note 1: A number of expressions used in this instrument are defined in subsection 3(1) of the Act including:

(a) conformity assessment certificate;
(b) health practitioner;
(c) included in the Register;
(d) listed goods;
(e) manufacturer;
(f) medical device;
(g) medicine;
(h) Register;
(i) registered goods;
(j) supply;
(k) therapeutic goods.

2 After section 5

Insert:

6 Application, saving and transitional provisions

(1) This section applies to therapeutic goods in items 8 to 14 of the table in Schedule 1 that, immediately before the commencement of the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment Instrument 2025*, were registered goods or listed goods.

(2) Items 8 to 14 of the table in Schedule 1, as inserted by Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment Instrument 2025*, do not apply to the therapeutic goods mentioned in subsection (1) until the earlier of:

(a) the date on which the goods are included in the Register as a kind of medical device; and
(b) 1 January 2031.

(3) Despite subsection (2), the therapeutic goods mentioned in subsection (1) may be dealt with in accordance with the amendments made by the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment Instrument 2025*, including for the purposes of the following:

(a) an application for a conformity assessment certificate;
(b) an application for inclusion in the Register as a kind of medical device;
(c) any applicable provisions in Part 4-4 of the Act in relation to conformity assessment certificates and Part 4-5 in relation to the inclusion of kinds of medical devices in the Register.

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3 Schedule 1 (at the end of the table)

Add:

8	locking solutions to be used in vascular access devices that are intended, by the person under whose name the articles are, or are to be, supplied, to be used solely to maintain the patency of the device
9	substances generated by ozone generators that are intended, by the person under whose name the substances are, or are to be supplied, to be used in: (a) sanitising or disinfecting another medical device, or medical equipment; or (b) cleaning of the oral cavity
10	pre-filled saline flush syringes where the saline is intended, by the person under whose name the articles are, or are to be, supplied, to be used solely to maintain the patency, or to flush the lumen, of another medical device
11	weight loss treatments that are ingested into the body and that achieve their principal intended action only by means of physical action
12	head or body lice treatments that achieve their principal intended action only by means of physical action
13	toothpastes and other dentifrices that achieve their principal intended action only by means of physical action
14	moisturisers and emollients that achieve their principal intended action only by means of physical action

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