



Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023

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

Dated 16 August 2023

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

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1 Name

This instrument is the *Therapeutic Goods (Articles that are Not Medical Devices) Declaration 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Note: This table relates only to the provisions of this instrument as originally made.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 41BD(3) of the *Therapeutic Goods Act 1989*.

4 Definitions

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

- (a) medical device;
- (b) medicine.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

fungicide has the same meaning as in the Regulations.

hospital grade disinfectant has the same meaning as in the Regulations.

household grade disinfectant has the same meaning as in the Regulations.

Regulations means the *Therapeutic Goods Regulations 1990*.

sporicide has the same meaning as in the Regulations.

sterilant has the same meaning as in the Regulations.

tuberculocide has the same meaning as in the Regulations.

virucide has the same meaning as in the Regulations.

5 Articles that are not medical devices

For the purposes of the Act, the instruments, apparatus, appliances, software, implants, reagents, materials or other articles, or classes of instruments, apparatus, appliances, software, implants, reagents, materials or other articles, specified in Schedule 1 are not medical devices.

6 Repeals

Each instrument that is specified in Schedule 2 to this instrument is repealed as set out in the applicable items in that Schedule.

Schedule 1—Articles that are not medical devices

Note: See section 5.

Articles that are not medical devices	
Column 1	Column 2
Item	Articles or classes of articles
1	articles incorporating tissues, cells or substances of human origin, other than medical devices incorporating stable derivatives of either human blood or human plasma, that act on, or are likely to act on, the human body in a way that is ancillary to the device
2	articles incorporating viable tissues, cells or substances of animal origin
3	articles that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose)
4	chemical oxygen generators
5	hospital grade disinfectants or household grade disinfectants that are claimed to be sterilants, fungicides, sporicides, tuberculocides or virucides
6	in-vivo imaging agents injected, ingested, or otherwise instilled into the body
7	riboflavin products instilled into the eye that are used in the treatment of disorders of the eye which cause structural changes within the cornea Note: These riboflavin products are used with UV-A light illumination in order to achieve an alteration of the normal chemical process of crosslinking of collagen, with the purpose of making the cornea stronger and more stable.
8	topical applications intended to remove or neutralise chemical, biological or radiological agents used in chemical, biological or radiological warfare
9	unmedicated preparations for topical use for protecting against, or providing relief from, nappy rash symptoms by acting only as a barrier for the skin (whether or not the preparations also have a moisturising action)

Schedule 2—Repeals

Note: See section 6.

Therapeutic Goods (Articles that are not Medical Devices) Order No.2 of 2004

1 The whole of the instrument

Repeal the instrument.

Therapeutic Goods Information (Articles that are not Medical Devices) Order No.1 of 2010

2 The whole of the instrument

Repeal the instrument.

Therapeutic Goods (Articles that are not Medical Devices) Order No.1 2017

3 The whole of the instrument

Repeal the instrument.

Therapeutic Goods (Materials or Articles that are Not Medical Devices) Order 2019

4 The whole of the instrument

Repeal the instrument.