



Therapeutic Goods (Excluded Goods) Amendment (Personalised Medical Devices) Determination 2021

I, John Skerritt, as delegate of the Minister for Health and Aged Care, make the following determination.

Dated 20 August 2021

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

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1 Name

This instrument is the *Therapeutic Goods (Excluded Goods) Amendment (Personalised Medical Devices) Determination 2021*.

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Note: This table relates only to the provisions of this instrument as originally made.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 section 7AA 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 (Excluded Goods) Determination 2018

1 Section 4 (definition of AS/NSZ 2604:2012)

Omit “AS/NSZ”, substitute “AS/NZS”.

2 Schedule 1 (after table item 1)

Insert:

- 1A anatomical models that are intended by the manufacturer to be used for educational or record-keeping purposes

3 Schedule 1 (after table item 2A)

Insert:

- 2B cosmetic finishing components for orthoses and prostheses
-

- 2C craniofacial prostheses that are:
(a) spectacle-retained; or
(b) adhesive-retained

4 Schedule 1 (after table item 3)

Insert:

- 3AA dental impression trays

5 Schedule 1 (after table item 7)

Insert:

- 7AA ear moulds that are intended by the manufacturer to anchor hearing aids

6 Schedule 1 (after table item 10)

Insert:

- 10A medicament trays that are intended by the manufacturer to hold medicaments

7 Schedule 1 (after table item 11)

Insert:

- 11A mouthguards intended by the manufacturer to be used to protect teeth from external forces including, but not limited to, mouthguards used in contact sports
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- 11B ocular prostheses intended by the manufacturer to be used for cosmetic purposes
-

- 11C physical impressions of anatomy, and models cast from such impressions

8 Schedule 1 (after table item 12)

Insert:

- 12A spectacle frames
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