

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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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