Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Personalised Medical Devices) Instrument 2021

I, John Skerritt, as delegate of the Secretary for the Department of Health, make the following instrument.

Dated 20 August 2021

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

Contents

1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Personalised Medical Devices) Instrument 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Note: This table relates only to the provisions of this instrument as originally made.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 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020

1 Section 4 (note)

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) health practitioner;

(b) manufacturer;

(c) medical device;

(d) supply.

Note 2: Other grammatical forms of a defined word have a corresponding meaning (see section 18A of the *Acts Interpretation Act 1901*), for example, ***manufacturer*** and ***manufacture***.

2 Section 4

Insert:

relevant practitioner means a health practitioner, or other person suitably trained or qualified who is acting on the instruction, or at the request, of a health practitioner.

3 Schedule 1 (after table item 3)

Insert:

3A	materials and other articles that are intended, by the person under whose name the articles are or are to be supplied, to be used by a relevant practitioner for the direct restoration of teeth, including but not limited to: (a) amalgam; (b) composite resins and respective bonding systems; (c) core build-up materials; (d) crown forms; (e) fibre or metal preformed posts; (f) fibre reinforcement materials; (g) fissure sealants; (h) glass ionomers; (i) liners and bases; (j) resin-modified glass ionomers; (k) temporary crown or bridge materials
3B	materials and articles that are intended, by the person under whose name the articles are or are to be supplied, to be used by a relevant practitioner for the indirect restoration of teeth, including but not limited to: (a) ceramic;

	(b) crown forms; (c) metal alloy; (d) temporary crown or bridge materials
3C	materials and other articles that are intended, by the person under whose name the articles are or are to be supplied, to be used by a relevant practitioner in the manufacture of externally-applied orthopaedic devices, including but not limited to: (a) fibreglass bandages used in the manufacture of splints or orthoses; (b) software; (c) thermoplastic sheeting used in the manufacture of splints or orthoses
3D	materials and other articles that are intended, by the person under whose name the articles are or are to be supplied, to be used by a relevant practitioner to manufacture non-implantable dental appliances, including but not limited to: (a) acrylic; (b) denture repair or reline materials; (c) metal alloy used in casting; (d) orthodontic components (such as bands, brackets, chains, elastics, ligature ties, separators and wire); (e) palate expanders; (f) preformed acrylic teeth; (g) preformed clasps; (h) software; (i) thermoplastic; (j) wrought wire used in the manufacture of clasps or retainers
3E	materials and other articles that are intended, by the person under whose name the articles are or are to be supplied, to be used by a relevant practitioner to obtain dental impressions