



Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Borderline Products—COVID-19) Instrument 2021

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

Dated 26 July 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 (Medical Devices—Specified Articles) Amendment (Borderline Products—COVID-19) 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 5

After “appliances,”, insert “software, implants, reagents,”.

2 Schedule 1 (at the end of the table)

Add:

- | | |
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| 3 | bedding, clothing, towels and other articles made principally of fabric that are:
(a) intended, by the person under whose name the articles are or are to be supplied, to be used primarily on, or in close contact with, the human body; and
(b) represented expressly to be effective against the virus that causes coronavirus disease (COVID-19);
other than articles that are mattresses, household furnishings, furniture or articles specified in item 1 |
| 4 | substances that are intended, by the person under whose name the products are or are to be supplied, specifically to be used for disinfecting a medical device |
| 5 | substances that are intended, by the person under whose name the products are or are to be supplied, to be used only to clean a medical device (other than contact lenses) by means of physical action |
| 6 | substances that are intended, by the person under whose name the products are or are to be supplied, specifically to be used for disinfecting, cleaning, rinsing or hydrating contact lenses |