

Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020

I, Tracey Duffy, as delegate of the Secretary of the Department of Health, make the following instrument.

Dated 22 April 2020

Tracey Duffy

First Assistant Secretary

Medical Devices and Product Quality Division

Health Products Regulation Group

Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*.

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Note: This table relates only to the provisions of this instrument as originally made.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 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; and

(b) supply.

In this instrument:

***Act*** means the *Therapeutic Goods Act 1989*.

5 Classes of articles specified to be medical devices

The classes of instruments, apparatus, appliances, materials and other articles mentioned in Schedule 1 are specified to be medical devices for the purposes of paragraph 41BD(1)(ab) of the Act.

Note: The meaning of ***medical device*** in section 41BD of the Act includes any article that is included in a class of articles specified under subsection 41BD(2B).

6 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Specified classes of articles that are medical devices

Note: See section 5.

| Specified classes of articles | |
| --- | --- |
| Column 1 | Column 2 |
| Item | Specified class |
| 1 | articles that are non-sterile personal protective equipment or safety apparel (including but not limited to aprons, face masks, gloves, goggles, gowns and visors) intended, by the person under whose name the articles are or are to be supplied, to be used for the prevention of the transmission of disease between persons, including where that intention may be ascertained from the articles being represented as suitable for use in surgery, or clinical, medical or other health services |
| 2 | articles (whether used alone or in combination, and including the software necessary for their proper application) that:  (a) are intended by the person under whose name the articles are, or are to be, supplied to be used for the examination of a specimen derived from a human body for the purpose of:  (i) predicting the susceptibility or predisposition of persons to a disease or ailment; or  (ii) testing for pregnancy in persons; and  (b) do not achieve their principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in their function by such means |

Schedule 2—Repeals

Note: See section 6.

Therapeutic Goods (Articles that are Medical Devices) Specification 2014

1 The whole of the instrument

Repeal the instrument