



Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020

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

Dated 4 September 2020

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

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<i>Therapeutic Goods (Excluded purposes) Specification 2010</i>	<i>4</i>

1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 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	1 October 2020.	1 October 2020

Note: This table relates only to the provisions of this instrument as originally made.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 41BEA 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) State.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

Class 2 IVD medical device has the same meaning as in the Regulations.

Class 3 IVD medical device has the same meaning as in the Regulations.

Class 4 IVD medical device has the same meaning as in the Regulations.

government health screening program means a health screening program that is conducted, approved or funded by the Commonwealth or a State.

Note: *State* is defined in subsection 3(1) of the Act as including the Australian Capital Territory and the Northern Territory.

IVD medical device for self-testing has the same meaning as in the Regulations.

Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

5 Excluded purposes—Class 2 IVD medical devices

- (1) This section applies in relation to medical devices that are:
 - (a) IVD medical devices for self-testing; and
 - (b) Class 2 IVD medical devices; and
 - (c) not intended exclusively for export; and
 - (d) not intended to be used exclusively for testing as part of a government health screening program.
- (2) The purposes mentioned in Part 1 of Schedule 1 are specified for the purposes of paragraph 41FD(ia) and subsection 41FF(1A) of the Act.

6 Excluded purposes—Class 3 and 4 IVD medical devices

- (1) This section applies in relation to medical devices that are:
 - (a) IVD medical devices for self-testing; and
 - (b) Class 3 IVD medical devices or Class 4 IVD medical devices; and
 - (c) not intended to be used exclusively for testing to monitor a disease or condition that has been diagnosed by a suitably qualified health professional; and
 - (d) not intended exclusively for export; and
 - (e) not intended to be used exclusively for testing as part of a government health screening program.
- (2) The purposes mentioned in Part 2 of Schedule 1 are specified for the purposes of paragraph 41FD(ia) and subsection 41FF(1A) of the Act.

7 Repeals

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

Schedule 1—Excluded purposes

Part 1—Class 2 IVD medical devices

Note: See section 5.

Excluded purposes

Column 1 Column 2

Item Purposes

1 testing for faecal occult blood

Part 2—Class 3 and 4 IVD medical devices

Note: See section 6.

Excluded purposes

Column 1 Column 2

Item Purposes

1 testing specimens from the human body, other than to:

- (a) test for the presence of, or exposure to any of the following pathogenic organisms or transmissible agents:
 - (i) chlamydia trachomatis;
 - (ii) hepatitis B virus;
 - (iii) hepatitis C virus;
 - (iv) herpes simplex virus type 1 and 2;
 - (v) human immunodeficiency virus type 1 and type 2;
 - (vi) seasonal influenza virus;
 - (vii) neisseria gonorrhoea;
 - (viii) treponema pallidum (syphilis); or
- (b) diagnose, aid in diagnosis of, indicate the presence of, or test for the presence of markers that are precursors to, any of the following diseases or conditions, other than by genetic testing:
 - (i) diabetes;
 - (ii) kidney disease;
 - (iii) cardiovascular disease

Schedule 2—Repeals

Note: See section 7.

Therapeutic Goods (Excluded purposes) Specification 2010

1 The whole of the instrument

Repeal the instrument.