



# **Therapeutic Goods (Medical Devices—Excluded Purposes) Amendment (COVID-19 Rapid Antigen IVD Medical Devices for Self-Testing) Specification 2021**

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

Dated 29 September 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—Excluded Purposes) Amendment (COVID-19 Rapid Antigen IVD Medical Devices for Self-Testing) Specification 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	1 October 2021.	1 October 2021

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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## Schedule 1—Amendments

### *Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020*

#### 1 Section 4

Insert:

*Class 1 IVD medical device* has the same meaning as in the Regulations.

*SARS-CoV-2*, or severe acute respiratory syndrome coronavirus 2, means the virus that causes coronavirus disease (COVID-19).

Note: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the name given by the International Committee on Taxonomy of Viruses to the virus that causes coronavirus disease (COVID-19).

*serious disease* has the same meaning as in the Regulations.

#### 2 After section 4

Insert:

#### 4A Excluded purposes—Class 1 IVD medical devices

- (1) This section applies in relation to medical devices that are:
  - (a) IVD medical devices for self-testing; and
  - (b) Class 1 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 1A of Schedule 1 are specified for the purposes of paragraph 41FD(ia) and subsection 41FF(1A) of the Act.

#### 3 Before Part 1 of Schedule 1

Insert:

### **Part 1A—Class 1 IVD medical devices**

Note: See section 4A.

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#### Excluded purposes

Column 1	Column 2
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Item	Purposes
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1	testing specimens from the human body in relation to a serious disease, other than to: <ol style="list-style-type: none"><li>(a) test for the presence of, or exposure to, any of the following pathogenic organisms or transmissible agents:<ol style="list-style-type: none"><li>(i) chlamydia trachomatis;</li><li>(ii) hepatitis B virus;</li><li>(iii) hepatitis C virus;</li></ol></li></ol>
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2 *Therapeutic Goods (Medical Devices—Excluded Purposes) Amendment (COVID-19 Rapid Antigen IVD Medical Devices for Self-Testing) Specification 2021*

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**Excluded purposes****Column 1**    **Column 2**

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**Item**        **Purposes**

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- (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; or
  - (c) in relation to a device supplied on or after 1 November 2021—test for the presence of SARS-CoV-2 antigens
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**4 Part 2 of Schedule 1 (at the end of the cell at table item 1, column 2)**

Add:

- ; or (c) in relation to a device supplied on or after 1 November 2021—test for the presence of SARS-CoV-2 antigens