



Therapeutic Goods (Medical Devices—Excluded Purposes) Amendment (COVID-19 Self-Testing) Specification 2022

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

Dated 25 October 2022

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

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1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Excluded Purposes) Amendment (COVID-19 Self-Testing) Specification 2022*.

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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020

1 Part 1A of Schedule 1 (table item 1, column 2, paragraph (c))

Repeal the paragraph, substitute:

(c) test for the presence of SARS-CoV-2 antigens or SARS-CoV-2 nucleic acid

2 Part 2 of Schedule 1 (table item 1, column 2, paragraph (c))

Repeal the paragraph, substitute:

(c) test for the presence of SARS-CoV-2 antigens or SARS-CoV-2 nucleic acid