



Therapeutic Goods (Restricted Representations— Government Health Campaigns) (COVID-19 Tests) Permission 2022

I, Nicole McLay, as delegate of the Secretary of the Department of Health, make the following permission.

Dated 31 January 2022

Nicole McLay
Assistant Secretary
Regulatory Compliance Branch
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Government Health Campaigns) (COVID-19 Tests) Permission 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 made.	1 February 2022

Note: This table relates only to the provisions of this instrument as originally made.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 42DK 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) advertise;
- (b) included in the Register;
- (c) State;
- (d) therapeutic goods.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

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

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

Commonwealth health campaign means a campaign about a public health matter that is conducted, approved, or funded by the Commonwealth.

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

restricted representation means a representation referred to in section 42DD of the Act.

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

specified goods means either of the following:

- (a) a COVID-19 Polymerase Chain Reaction (PCR) test that is
 - (i) included in the Register;
 - (ii) classified as a Class 3 IVD medical device;
- (b) a COVID-19 rapid antigen test kit that is:
 - (i) included in the Register; and
 - (ii) classified as a Class 3 IVD medical device; andmay (or may not) be supplied for use in conjunction with an instrument or analyser that is a Class 1 IVD medical device.

State health campaign means a campaign about a public health matter that is conducted, approved, or funded by a State.

5 Permission

For subsection 42DK(1) of the Act, in relation to each item mentioned in the table in Schedule 1, the representations specified in column 2 are permitted to be used in the advertisements specified in column 3, about the therapeutic goods specified in column 4, subject to the conditions (if any) specified in column 5.

Schedule 1—Permission: restricted representations

Note: See section 5.

Permitted use of restricted representations				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representations	Advertisements	Therapeutic goods	Conditions
1	a representation to the effect, expressly or by implication, that the therapeutic goods may be used to detect possible infection with SARS-CoV-2 (COVID-19), including a representation that is contained within the name of the goods	an advertisement about the therapeutic goods that is, or forms part of, a: (a) Commonwealth health campaign (b) State health campaign	specified goods	
