



Therapeutic Goods (Medical Devices—Novel Coronavirus) (Emergency) Exemption 2020

I, Glenys Beauchamp, as delegate of the Minister for Health, make the following exemption.

Dated 31 January 2020

Glenys Beauchamp
Secretary
Department of Health

Contents

1 Name.....	1
2 Commencement.....	1
3 Authority.....	1
4 Definitions.....	1
5 Exemption.....	2
6 Conditions.....	2

1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Novel Coronavirus) (Emergency) Exemption 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 this instrument is made.	31 January 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Note: This table relates only to the provisions of this instrument as originally made.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 41GS of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:

- (a) conformity assessment certificate;
- (b) conformity assessment procedures;
- (c) essential principles;
- (d) medical device;
- (e) Register; and
- (f) Secretary.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

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

novel coronavirus means the disease known as novel coronavirus (2019-nCoV) infection, first identified in Wuhan, Hubei Province, China in 2019.

relevant kinds of medical devices means kinds of medical devices that are used for the diagnosis, confirmatory testing, prevention, monitoring, treatment or alleviation of novel coronavirus.

5 Exemption

- (1) Relevant kinds of medical devices are exempt from:
- (a) Division 1 of Part 4-2 of the Act (essential principals); and
 - (b) Division 1 of Part 4-3 of the Act (conformity assessment procedures); and
 - (c) Part 4-4 of the Act (conformity assessment certificates); and
 - (d) Part 4-5 of the Act (including medical devices in the Register);
- when imported, exported, manufactured or supplied to deal with the threat to public health caused by the novel coronavirus emergency.

Note: Under subsection 41GS(2)(b) of the Act, the Minister may make an exemption under subsection 41GS(1) only if satisfied that, in the national interest, the exemption should be made so that the devices can be made available urgently in Australia in order to deal with an actual threat to public health caused by an emergency that has occurred.

Period of exemption

- (2) This exemption comes into force on the commencement of this instrument and remains in force until 31 January 2021.

6 Conditions

This exemption is subject to the following conditions:

- (a) relevant kinds of medical devices must only be imported, exported, manufactured or supplied by a laboratory that is a state or territory member of the Public Health Laboratory Network; and
- (b) a laboratory mentioned in paragraph (a) must keep records in relation to the importation, exportation, manufacture and supply of the relevant kinds of medical devices; and
- (c) on request from the Secretary, the laboratory must make the records mentioned in paragraph (b) available to the Secretary.

Note: Regulation 6A.1 and Schedule 3A of the Medical Devices Regulations set out arrangements for the disposal of unused emergency medical devices for the purposes of section 41GY of the Act.