



# **Therapeutic Goods (Medical Devices—Face Masks and Other Articles) (COVID-19 Emergency) Exemption 2020**

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I, Caroline Edwards, as delegate of the Minister for Health, make the following exemption.

Dated 22 March 2020

Caroline Edwards  
Acting Secretary  
Department of Health

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## 1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Face Masks and Other Articles) (COVID-19 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.	

Note: This table relates only to the provisions of this instrument as originally made.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*.

**COVID-19 emergency** means the public health emergency caused by the outbreak of the disease known as coronavirus disease (COVID-19).

Note: The World Health Organization declared the outbreak of COVID-19, formerly novel coronavirus (2019 nCoV), a Public Health Emergency of International Concern on 30 January 2020, and subsequently characterised the outbreak as a pandemic on 11 March 2020.

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*relevant kinds of medical devices* means medical devices that are disposable face masks, disposable gloves, disposable gowns, and protective eye wear in the form of goggles, glasses or visors, which are designed to be worn by individuals to prevent the transmission of organisms.

## 5 Exemption

- (1) Relevant kinds of medical devices are exempt from:
- (a) Division 1 of Part 4-2 of the Act (essential principles); 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);
- in order to deal with the threat to public health caused by the COVID-19 emergency.

Note: Under paragraph 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) the relevant kinds of medical devices must only be imported, exported, manufactured or supplied by a person under a contract between the person and the Australian Government Department of Health, or another agency of the Commonwealth acting on behalf of Australian Government Department of Health, for that purpose; and
- (b) the person 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 person mentioned in paragraph (a) must make the records mentioned in paragraph (b) available to the Secretary.

Note 1: There are offences and civil penalty provisions related to the breach of a condition: see Division 3A of Part 4-11 of the Act.

Note 2: Regulation 6A.1 and Schedule 3A of the *Therapeutic Goods (Medical Devices) Regulations 2002* set out arrangements for the disposal of unused emergency medical devices for the purposes of section 41GY of the Act.