



Therapeutic Goods (Medical Devices— Ventilators) (COVID-19 Emergency) Exemption 2020

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

Dated 8 April 2020

Caroline Edwards
Acting Secretary
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Ventilators) (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.	8 April 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Note: This table relates only to the provisions of this instrument as originally made.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*.

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. On 18 March 2020, the Australian Government declared a human biosecurity emergency in Australia under the *Biosecurity Act 2015*.

minimum technical requirements means the required features specified in the document, *Ventilator for COVID-19 use in Australia* (version 1.0) published by the Therapeutic Goods Administration on 7 April 2020, as in force or existing at the commencement of this instrument.

Note: The document is available at www.tga.gov.au.

specified kind of medical device means a medical device that is a ventilator manufactured in Australia in accordance with the minimum technical requirements.

Therapeutic Goods Administration has the same meaning as in the *Therapeutic Goods Regulations 1990*.

5 Exemption

- (1) A specified kind of medical device is 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 actual 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 specified kind of medical device must be manufactured by a person (the ***relevant manufacturer***) for supply to a hospital in a state or territory (the ***hospital***); and
- (b) prior to supply of the specified kind of medical device to the hospital, the relevant manufacturer must:
 - (i) provide to the Therapeutic Goods Administration a set of documents comprising copies of the test procedure, test results and risk analysis undertaken by the relevant manufacturer in relation to the specified kind of medical device, and a declaration that the specified kind of medical device has been manufactured in accordance with the minimum technical requirements; and
 - (ii) obtain written permission from the Therapeutic Goods Administration that, following consideration of the set of documents mentioned in subparagraph (i), the supply of the specified kind of medical device to the hospital may proceed;

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- (c) within the relevant period of time mentioned in paragraph (d)—the relevant manufacturer must provide to the Therapeutic Goods Administration information relating to:
- (i) any malfunction or deterioration in the characteristics or performance of the specified kind of medical device that might lead to a serious threat to public health, or to the death of a patient or user of the device, or to a serious deterioration in his or her state of health; or
 - (ii) any technical or medical reason for the malfunction or deterioration mentioned in subparagraph (i) that has led the relevant manufacturer to take steps to recall the specified kind of medical device;
- (d) the relevant period of time for providing the information mentioned in paragraph (c) is:
- (i) in relation to information that represents a serious threat to public health—48 hours after the relevant manufacturer becomes aware of the information; or
 - (ii) in relation to all other information—10 days after the relevant manufacturer becomes aware of the information;
- (e) the relevant manufacturer must keep records in relation to the manufacture and supply of the specified kind of medical device; and
- (f) on request from the Therapeutic Goods Administration, the relevant manufacturer must make the records mentioned in paragraph (e) available to the Therapeutic Goods Administration; and
- (g) the relevant manufacturer must allow a person authorised by the Therapeutic Goods Administration:
- (i) to enter, at any reasonable time, any premises at which the relevant manufacturer deals with the specified kind of medical device; and
 - (ii) while on those premises, to inspect those premises and the specified kind of medical device, and to examine, take measurements of, conduct tests on, or require tests to be conducted on the specified kind of medical device; and
- (h) on request from the Therapeutic Goods Administration, the relevant manufacturer must provide a representative sample of the specified kind of medical device to the Therapeutic Goods Administration for examination as to compliance with the minimum technical requirements.

Note 1: There are offences and civil penalty provisions in relation to goods exempt under section 41GS, including:

- (a) sections 41MNB and 41MNC (offences and civil penalties for breaching a condition of exemption); and
- (b) section 41MND (civil penalty for making misrepresentations).

Note 2: There are other provisions in the Act that apply to goods exempt under section 41GS, including:

- (a) section 41JCA (requirement to provide information to the Secretary); and
- (b) section 46A (provision enabling search of premises).

Note 3: 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.