



# **Therapeutic Goods (Medical Devices—Donor Screening) (COVID-19 Emergency) Exemption 2020**

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

Dated 25 June 2020

Caroline Edwards  
Acting Secretary  
Department of Health

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## 1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Donor Screening) (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. Sections 1 to 7 and anything in this instrument not elsewhere covered by this table	The day this instrument is made.	25 June 2020
2. Schedule 1	31 July 2020.	31 July 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Note: This table relates only to the provisions of this instrument as originally made.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 sections 41GS and 41GU 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:

**accredited pathology laboratory** has the same meaning as in the *Health Insurance Act 1973*.

**Act** means the *Therapeutic Goods Act 1989*.

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**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 coronavirus disease (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.

**IVD medical device** has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

**relevant kinds of medical devices** means kinds of medical devices that are Class 4 in-house IVD medical devices intended to be used to detect the presence of, or exposure to, SARS-CoV-2 for the purpose of assessing a person's suitability for donating blood, blood components, blood products, cells, tissues or organs or any derivatives of these products of human origin for transfusion or transplantation.

**SARS-CoV-2** means severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Note: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the name given by the International Committee on Taxonomy of Viruses to the virus that causes coronavirus disease (COVID 19).

## 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 section and remains in force until 30 June 2021.

## 6 Conditions

This exemption is subject to the following conditions:

- (a) the relevant kinds of medical devices must only be manufactured or supplied by an accredited pathology laboratory; and
- (b) the laboratory mentioned in paragraph (a) must keep records in relation to such manufacture and supply of the relevant kinds of medical devices for which that laboratory is responsible; and

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(c) on request from the Secretary, the laboratory 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 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.

## 7 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.

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## **Schedule 1—Repeals**

### ***Therapeutic Goods (Medical Devices—Accredited Pathology Laboratories) (COVID-19 Emergency) Exemption 2020***

#### **1 The whole of the instrument**

Repeal the instrument