Therapeutic Goods (Medical Devices—Donor Screening) (COVID-19 Emergency) Exemption 2021

I, Brendan Murphy, as delegate of the Minister for Health, make the following exemption.

Dated 7 October 2021

Dr Brendan Murphy
Secretary
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Donor Screening) (COVID-19 Emergency) Exemption 2021*.

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.	

Note: This table relates only to the provisions of this instrument as originally made.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

Class 4 in-house IVD medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

COVID-19 emergency means the public health emergency caused by the outbreak of the 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.

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 the suitability of a person 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) that causes the 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 2022.

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

(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.