Therapeutic Goods (Medical Devices—Donor Screening) (COVID-19 Emergency) Exemption 2023

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

Dated 15 March 2023

Professor Brendan Murphy AC
Secretary
Department of Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Donor Screening) (COVID-19 Emergency) Exemption 2023*.

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.	15 March 2023

Note: This table relates only to the provisions of this instrument as originally made.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 subsection 3(1) of the Act, including the following:

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

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 Regulations.

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.

Regulations means 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 the suitability of a person for donating blood, blood components, blood products, cells, tissues or organs, or any other derivatives of these products, of human origin for transfusion or transplantation.

SARS-CoV-2 means severe acute respiratory syndrome coronavirus 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) The 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 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 30 June 2024.

6 Conditions

The exemption in section 5 is subject to all of the following conditions:

(a) the relevant kinds of medical devices must only be manufactured or supplied by an accredited pathology laboratory;

(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;

(c) where requested by the Secretary, the laboratory mentioned in paragraph (a) must make the records mentioned in paragraph (b) available to the Secretary.

Note 1: A person may commit an offence or contravene a civil penalty provision by breaching a condition of the exemption (see sections 41MNB and 41MNC of the Act).

Note 2: A person may also contravene a civil penalty provision for making misrepresentations about medical devices (see section 41MND of the Act).

Note 3: There are other provisions in the Act that apply to medical devices 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 4: Regulation 6A.1 and Schedule 3A of the Regulations set out arrangements for the disposal of unused emergency medical devices for the purposes of section 41GY of the Act.