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

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

Contents

1 Name

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Note: This table relates only to the provisions of this instrument as originally made.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

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

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.

IVD medical device has the same meaning as in the Regulations.

Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

relevant kinds of medical devices means medical devices that are IVD medical devices used for the diagnosis, confirmatory testing, prevention, monitoring, treatment or alleviation of 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 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:

(i) imported, manufactured or supplied by, or on behalf of, an accredited pathology laboratory; or

(ii) imported or manufactured by another person for supply to an accredited pathology laboratory; and

(b) the laboratory mentioned in subparagraph (a)(i) or the person mentioned in subparagraph (a)(ii) must keep records in relation to such importation, manufacture and supply of the relevant kinds of medical devices for which that laboratory or person is responsible; and

(c) on request from the Secretary, the laboratory mentioned in subparagraph (a)(i) or the person mentioned in subparagraph (a)(ii) 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 Regulations set out arrangements for the disposal of unused emergency medical devices for the purposes of section 41GY of the Act.

7 Repeals

Each instrument that is specified in Schedule 1 to this instrument is repealed as set out in the applicable items in that Schedule.

Schedule 1—Repeals

Therapeutic Goods (Medical Devices—Novel Coronavirus) (Emergency) Exemption 2020

1 The whole of the instrument

Repeal the instrument