Therapeutic Goods (Transition to EU Medical Devices Regulation) (Information) Specification 2022

I, Tracey Duffy, as delegate of the Minister for Health and Aged Care, make the following specification.

Dated 28 November 2022

Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Transition to EU Medical Devices Regulation) (Information) Specification 2022*.

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	5 December 2022.	5 December 2022

Note: This table relates only to the provisions of this instrument as originally made.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 subsection 61(5D) 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) device number;
(b) included in the Register;
(c) kind, in relation to a medical device;
(d) medical device;
(e) overseas regulator conformity assessment document;
(f) Secretary;
(g) sponsor.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

Council Directive 90/385/EEC means *Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)* of the Council of the European Communities, as in force or existing at the commencement of this instrument.

Council Directive 93/42/EEC means *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices* of the Council of the European Communities, as in force or existing at the commencement of this instrument.

EU MDD certificate means an overseas regulator conformity assessment document that is issued by a notified body under Council Directive 93/42/EEC or Council Directive 90/385/EEC.

EU MDR certificate means an overseas regulator conformity assessment document that is issued by a notified body under the EU medical devices regulation.

EU medical devices regulation means *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices*, as in force or existing at the commencement of this instrument.

GMDN Agency means the not-for-profit organisation, registered in the United Kingdom, responsible for the Global Medical Device Nomenclature system.

GMDN code, or Global Medical Device Nomenclature code, means the 5-digit numeric code assigned to all medical devices under the Global Medical Device Nomenclature system maintained by the GMDN Agency.

GS1 means the not-for-profit standards organisation known as GS1 that has its headquarters in Belgium.

GTIN, or Global Trade Item Number, means the GS1 identification key used to identify trade items.

Note: A GTIN comprises a GS1 company prefix, an item reference and a check digit.

instructions for use has the same meaning as in the Medical Devices Regulations.

intended purpose has the same meaning as in the Medical Devices Regulations.

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

notified body means a body that has been designated by a member state of the European Union, and notified to the European Commission, to assess the conformity of medical devices, including in vitro diagnostic medical devices and active implantable medical devices.

online notification form means the online form *Form: Sponsor notification for medical devices transitioning from the EU MDD to the EU MDR*, which relates to the provision of information about a relevant kind of medical device and its transition, accessed via the TGA – Citizen Space website at https://consultations.tga.gov.au/tga/ef19f496/, as in force or existing at the commencement of this instrument.

relevant kind of medical device means a kind of medical device that is included in the Register and for which certification of the matter referred to in paragraph 41FD(f) of the Act is based on an EU MDD certificate.

Therapeutic Goods Administration, or ***TGA***, means that part of the Department known as the Therapeutic Goods Administration.

therapeutic goods information has the meaning given by subsection 61(1) of the Act.

transition, in relation to a relevant kind of medical device, means transition from an EU MDD certificate to an EU MDR certificate that applies to the kind of device.

5 Release of therapeutic goods information

The kinds of therapeutic goods information set out in the table in Schedule 1 are specified for the purposes of subsection 61(5C) of the Act.

Note: Kinds of therapeutic goods information specified under subsection 61(5D) of the Act may be released by the Secretary to the public under subsection 61(5C) of the Act.

6 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Therapeutic goods information

Note: See section 5.

Specified kinds of therapeutic goods information	
Column 1	**Column 2**
Item	**Kinds of Information**
1	the following information provided by a sponsor (or a person authorised to act on behalf of a sponsor) in the online notification form in relation to the transition of a relevant kind of medical device, as applicable: (a) the manufacturer's name; (b) the sponsor's name; (c) contact details for enquiries; (d) the name of the kind of medical device affected by the transition; (e) the device number; (f) the GMDN code; (g) the GTIN; (h) the intended purpose; (i) the date of effect of the EU MDR certificate; (j) details of changes in relation to any of the following matters relating to the kind of medical device as a result of the transition (that is, details under the EU MDD certificate, details under the EU MDR certificate and products affected): (i) indications in the instructions for use; (ii) class of persons for which the device is suitable; (iii) intended purpose; (iv) functional description; (v) addition of a warning for a novel or newly identified safety issue or contraindication; (vi) addition of adverse event information that would change patient management recommendations
2	the following dates in relation to the information mentioned in item 1: (a) the date the online notification form is submitted; (b) the date of release of that information by the TGA

Schedule 2—Repeals

Note: See section 6.

Therapeutic Goods (Transition to EU Medical Devices Regulation—Stakeholder Testing) (Information) Specification 2022

1 The whole of the instrument

Repeal the instrument