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

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

Dated 29 August 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—Stakeholder Testing) (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	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made.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(5AB) 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) manufacturer, of a medical device;
(e) medical device;
(f) overseas regulator conformity assessment document;
(g) Secretary;
(h) sponsor.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

ANZHPR members means the following members of the Australia and New Zealand Health Procurement Roundtable:

(a) Finance and Business Intelligence, Canberra Health Services, ACT Government;

(b) New Zealand Health Partnerships, Te Whatu Ora, Health New Zealand;
(c) Pharmac, New Zealand Government;
(d) Procurement and Supply Chain Management, Department of Health and Wellbeing, SA Health, Government of South Australia;
(e) Procurement Advisory Services, Tasmania Health Service, Tasmania Government;
(f) Procurement and Supply Health Support Services, Government of Western Australia;
(g) Procurement, HealthShare Victoria;
(h) Strategic Contracting & Infrastructure, System Support Services, Department of Health, Northern Territory Government;
(i) Strategic Procurement, HealthShare, NSW Government;
(j) Strategic Procurement, Supply Chain Surety Division, Queensland Health, Queensland Government.

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 immediately before 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 immediately before 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 immediately before the commencement of this instrument.

health professional has the same meaning as in the Medical Devices Regulations.

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 Notification Form, 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 immediately before the commencement of this instrument.

RegTech members means the following members of the Regulatory and Technical Consultative Forum:

(a) Assistive Technology Suppliers Australia (ATSA);
(b) Association of Therapeutic Goods Consultants;
(c) AusBiotech;
(d) Australian Dental Industry Association of Australia (ADIA);
(e) Australian Medical Manufacturers & Distributors Association (AMMDA);
(f) Consumer Healthcare Products (CHP) Australia;
(g) Medical Technology Association of Australia (MTAA);
(h) Optical Distributors & Manufacturers Association (ODMA);
(i) Pathology Technology Australia (PTA).

relevant kind of medical device means a kind of medical device 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

For subsection 61(5AA) of the Act, in relation to each item, the kinds of therapeutic goods information specified in column 2 of the table in Schedule 1 may be released to the kinds of persons and bodies specified in column 3, for the purposes specified in column 4 of that table.

Note: Under subsection 61(5AA) of the Act, the Secretary may release to a person, body or authority that is specified, or is of a kind specified, under subsection 61(5AB), specified kinds of therapeutic goods information for a specified purpose.

Schedule 1—Therapeutic goods information

Note: See section 5.

Therapeutic goods information that may be released			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kinds of information**	**Persons or bodies**	**Purpose**
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) contact details for enquiries; (b) the device number; (c) the date of effect of the EU MDR certificate; (d) 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; and the following dates: (e) the date the online notification form is submitted; (f) the date of release of the information by the TGA	the following persons and bodies: (a) health professionals; (b) private hospitals, public hospitals in States and Territories, and other healthcare facilities; (c) sponsors of medical devices (and persons authorised to act on behalf of such sponsors); (d) patients; (e) RegTech members; (f) ANZHPR members	to obtain feedback in relation to the usefulness, suitability and presentation of the information mentioned in column 2 as a means of notifying health professionals, other stakeholders and the public of changes relating to medical devices in Australia that are being implemented as part of the transition of relevant kinds of medical devices