**EXPLANATORY STATEMENT**

*Therapeutic Goods Act 1989*

*Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Class IIa and Class IIb) Determination 2023*

The *Therapeutic Goods Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, performance and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act is administered by the Therapeutic Goods Administration (“the TGA”) within the Australian Government Department of Health and Aged Care.

Section 41FDB of the Act sets out preliminary assessment requirements in relation to an application to the Secretary for a kind of medical device to be included in the Australian Register of Therapeutic Goods (“the Register”). These include the requirements that an application be accompanied by information that is of a kind determined under subsection 41FDB(7), in a form determined under subsection 41FDB(8), for the relevant classification of medical device (subparagraphs 41FDB(2)(d)(i) and (ii) of the Act refer).

Relevantly, subsections 41FDB(7) and (8) of the Act provide that the Secretary may, by legislative instrument, determine a kind and form of information respectively for the purposes of an application mentioned in subparagraphs 41FDB(2)(d)(i) and (ii) of the Act in relation to medical devices of a particular classification.

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* (“the Principal Determination”) is made under subsections 41FDB(7) and (8) of the Act. The Principal Determination determines the kind and form of information that must accompany an application for kinds of medical devices of a particular classification to be included in the Register.

The kinds of information specified in the Principal Determination relate to the conformity assessment documents that are required to demonstrate that appropriate conformity assessment procedures have been applied by the manufacturer to its quality management system and kind of medical device. The conformity assessment documents include certificates and other documents which have been issued or recognised by the Secretary and, in the alternative, comparable overseas regulators as defined in section 41BIB of the Act.

Under the Principal Determination, an application for inclusion in the Register of a Class IIa or Class IIb medical device that is supported by an EU quality management system certificate issued by a notified body within the meaning of the *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices* (“the EU medical devices regulation”) under Annex IX of that Regulation, must be accompanied by an EU technical documentation assessment certificate issued under Chapter II of that Annex (item 4 in Part 2 of Schedule 1, and item 6 in Part 3 of Schedule 1, to the Principal Determination refer). However, on review of current practices, it has been identified that such a certificate is not issued for Class IIa or certain Class IIb medical devices in the EU.

Accordingly, the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Class IIa and Class IIb) Determination 2023* (“the Amendment Determination”) made under subsection 41FDB(7) of the Act, amends the Principal Determination to correct the unintended misalignment with current practice under the EU medical devices regulation, by:

* removing the requirement for Class IIa and certain Class IIb medical devices to provide such documentation; and
* clarifying that such an application for inclusion of a Class IIb relevant implantable medical device must be supported by an EU technical documentation assessment certificate issued under Chapter II of Annex IX of the EU medical devices regulation.

**Incorporation by reference**

The Amendment Determination specifies the kinds of information that may accompany an application for inclusion of certain medical devices in the Register by reference to the European Union regulation, *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices*, which sets out safety and performance requirements for medical devices for human use. This regulation is freely available from EUR-Lex at https://eur-lex.europa.eu/.

In accordance with section 14 of the *Legislation Act 2003* (“the Legislation Act”), this document is incorporated as in force or existing immediately before the commencement of the Principal Determination (as specified in the definition of this term in section 4 of the Principal Determination). This means that any subsequent changes to this document will not be automatically applied under the Principal Determination.

**Consultation**

The TGA consulted with industry stakeholders in relation to the proposed amendments at the Regulatory and Technical Consultative Forum for medical devices (“RegTech”) meetings held on 2 June 2022 and 28 July 2023. In September 2023, the TGA provided a further update on the proposed amendments to RegTech via the TGA’s regular email update. No concerns were raised.

RegTech is a forum of key industry bodies and associations that facilitates consultation between the TGA and the medical device industry. RegTech membership includes, for example, the Medical and Technology Association of Australia, the Australian Dental Industry Association, AusBiotech and Pathology Technology Australia.

The Office of Impact Analysis (at the time, the Office of Best Practice Regulation) advised that the amendments are minor and machinery in nature and therefore a Regulation Impact Statement is not required (OPBR Ref 21178).

Details of the Amendment Determination are set out in **Attachment A**.

The Amendment Determination is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Amendment Determination is a disallowable legislative instrumentfor the purposes of the Legislation Actand commences on the day after it is registered on the Federal Register of Legislation.

**Attachment A**

**Details of the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Class IIa and Class IIb) Determination 2023***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Class IIa and Class IIb) Determination 2023* (“the Amendment Determination”).

**Section 2 – Commencement**

This section provides that the Amendment Determination commences on the day after it is registered on the Federal Register of Legislation.

**Section 3 – Authority**

This section provides that the legislative authority for making the Amendment Determination is subsection 41FDB(7) of the *Therapeutic Goods Act 1989* (“the Act”)*.*

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. The Amendment Determination is made in accordance with that provision.

**Section 4 – Schedules**

This section provides that each instrument that is specified in a Schedule to the Amendment Determination is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Amendment Determination has effect according to its terms.

**Schedule 1 – Amendments**

This Schedule amends the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* (“the Principal Determination”).

Item 1 of this Schedule inserts definitions of ‘implantable medical device’ and ‘relevant implantable medical device’ in section 4 of the Principal Determination.

Implantable medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002* ("the MD Regulations").

Relevant implantable medical device means an implantable medical device other than a medical device that is:

* mentioned in paragraph 13A.1(1)(b) of Schedule 1 to the MD Regulations – this paragraph currently mentions a suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip, connector or other similar article; or
* mentioned in paragraph 13A.1(1)(ba) of Schedule 1 to the MD Regulations – this paragraph refers to medical devices that are intended by their manufacturer to be for export only; or
* a device to which subclause 13A.1(2) of Schedule 1 to the MD Regulations applies – this refers to medical devices that are, principally, intended by the manufacturer to be wholly, or mostly, absorbed by a patient’s body within 6 months of being implanted and that is for use as a filler, or for haemostasis, or for tissue approximation, or for the fixation of other medical devices within tissue.

Item 2 of this Schedule repeals the cell at column 4 of item 4 of the table in Part 2 of Schedule 1 to the Principal Determination with the effect of removing the requirement that an application for inclusion of a Class IIa medical device be accompanied by an EU technical documentation assessment certificate, issued under Chapter II of Annex IX of the EU medical devices regulation.

Item 3 of this Schedule repeals and substitutes the cell at column 4 of item 6 of the table in Part 3 of Schedule 1 to the Principal Determination, to determine that an application for a relevant implantable medical device must be accompanied by an EU technical documentation assessment certificate issued under chapter II of Annex IX of the EU medical devices regulation, where the application is accompanied by an EU quality management system certificate issued under Chapter I of that Annex (in accordance with column 3 of that item).

This has the effect that an application for inclusion in the Register of a Class IIb implantable medical device (other than a device that is, for example, a suture, staple or dental filling) that is supported by an EU quality management system certificate issued by a notified body within the meaning of the EU medical devices regulation under Annex IX of that Regulation, must be accompanied by an EU technical documentation assessment certificate issued under Chapter II of that Annex.

**Attachment B**

**Statement of Compatibility with Human Rights**

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

***Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Class IIa and Class IIb) Determination 2023***

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Overview of legislative instrument**

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* (“the Principal Determination”) is made under subsections 41FDB(7) and (8) of the Act. The Principal Determination determines the kind and form of information that must accompany an application for kinds of medical devices of a particular classification to be included in the Australian Register of Therapeutic Goods (“the Register”).

The kinds of information specified in the Principal Determination relate to the conformity assessment documents that are required to demonstrate that appropriate conformity assessment procedures have been applied by the manufacturer to its quality management system and kind of medical device. The conformity assessment documents include certificates and other documents which have been issued or recognised by the Secretary and, in the alternative, comparable overseas regulators as defined in section 41BIB of the Act.

Under the Principal Determination, an application for inclusion in the Register of a Class IIa or Class IIb medical device that is supported by an EU quality management system certificate issued by a notified body within the meaning of the *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices* (“the EU medical devices regulation”) under Annex IX of that Regulation, must be accompanied by an EU technical documentation assessment certificate issued under Chapter II of that Annex (item 4 in Part 2 of Schedule 1, and item 6 in Part 3 of Schedule 1, to the Principal Determination refer). However, on review of current practices, it has been identified that such a certificate is not issued for Class IIa or certain Class IIb medical devices in the EU.

Accordingly, the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Class IIa and Class IIb) Determination 2023* (“the Amendment Determination”) made under subsection 41FDB(7) of the Act, amends the Principal Determination to correct the unintended misalignment with current practice under the EU medical devices regulation, by:

* removing the requirement for Class IIa and certain Class IIb medical devices to provide such documentation; and
* clarifying that such an application for inclusion of a Class IIb relevant implantable medical device must be supported by an EU technical documentation assessment certificate issued under Chapter II of Annex IX of the EU medical devices regulation.

**Human rights implications**

The Amendment Determination engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (“ICESCR”).

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health. In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Amendment Determination takes positive steps to promote the right to health by ensuring there is appropriate documentary evidence accompanying an application for inclusion of a Class IIb medical device in the Register to enable the application to be processed by the Secretary of the Department of Health and Aged Care in an effective and timely manner. The information that must accompany an application for inclusion in the Register will assist in ensuring the safety and satisfactory performance of medical devices, as well as their timely availability, in Australia.

**Conclusion**

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.