



Therapeutic Goods (Medical Devices— Information that Must Accompany Application for Inclusion) Amendment (Class III, Class AIMD and Class 4 IVD) Determination 2021

I, Tracey Duffy, as delegate of the Secretary of the Department of Health, make the following determination.

Dated 10 August 2021

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

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1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (Class III, Class AIMD and Class 4 IVD) Determination 2021*.

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Note: This table relates only to the provisions of this instrument as originally made.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 41FDB(7) of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018

1 Section 4

Insert:

specified medical device means any of the following:

- (a) a medical device, other than an IVD medical device, that contains tissues of animal origin that have been rendered non-viable (other than one that is intended to come into contact with intact skin only);
- (b) a medical device, other than an IVD medical device, that contains tissues, cells or substances of microbial or recombinant origin and is intended for use in or on the human body;
- (c) a medical device, other than an IVD medical device, incorporating stable derivatives of human blood or human plasma that are liable to act on the human body in a way that is ancillary to the device;
- (d) a medical device, other than an IVD medical device, that incorporates, or intended to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device.

2 Subsection 5(7)

After “Class III medical device”, insert “that is not a specified medical device”.

3 Paragraph 5(7)(a)

After “the table in”, insert “Division 1 of”.

4 After subsection 5(8)

Insert:

- (8A) An application for a Class III medical device that is a specified medical device must be accompanied by the following kind of information:
- (a) a conformity assessment document that relates to the manufacturer’s quality management system specified in column 3 of an item in the table in Division 2 of Part 4 of Schedule 1, which is issued or recognised by the regulatory authority in column 2 of that item; and
 - (b) a conformity assessment document that relates to product assessment specified for that item in column 4 (if any), which is issued or recognised by the regulatory authority in column 2 of that item.
- (8B) To avoid doubt:
- (a) an application may be accompanied by more than one document referred to in paragraph (8A)(a), and its corresponding certificate or other document of product assessment referred to in paragraph (8A)(b) (if any);

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- (b) a document which accompanies the application in accordance with subsection (8A) must relate to the kind of device to which the application relates.

5 Subsection 5(9)

After “Class AIMD medical device”, insert “that is not a specified medical device”.

6 Paragraph 5(9)(a)

After “the table in”, insert “Division 1 of”.

7 After subsection 5(10)

Insert:

- (10A) An application for a Class AIMD medical device that is a specified medical device must be accompanied by the following kind of information:
- (a) a conformity assessment document that relates to the manufacturer’s quality management system specified in column 3 of an item in the table in Division 2 of Part 5 of Schedule 1, which is issued or recognised by the regulatory authority in column 2 of that item; and
 - (b) a conformity assessment document that relates to product assessment specified for that item in column 4 (if any), which is issued or recognised by the regulatory authority in column 2 of that item.
- (10B) To avoid doubt:
- (a) an application may be accompanied by more than one document referred to in paragraph (10A)(a), and its corresponding certificate or other document of product assessment referred to in paragraph (10A)(b) (if any);
 - (b) a document which accompanies the application in accordance with subsection (10A) must relate to the kind of device to which the application relates.

8 After the heading to Part 4 of Schedule 1

Insert:

Division 1—Class III medical devices that are not specified medical devices

9 At the end of Part 4 of Schedule 1

Add:

Division 2—Class III medical devices that are specified medical devices

Column 1 Item	Column 2 Regulatory authority	Column 3 Conformity assessment document relating to manufacturer’s quality management system	Column 4 Conformity assessment document relating to product assessment
1	Therapeutic Goods	a conformity assessment	a conformity assessment

Column 1 Item	Column 2 Regulatory authority	Column 3 Conformity assessment document relating to manufacturer's quality management system	Column 4 Conformity assessment document relating to product assessment
	Administration	certificate issued under the Act that covers the conformity assessment procedures set out in Part 1 of Schedule 3 to the Regulations (full quality assurance procedures), excluding clause 1.6 of that Part	certificate issued under the Act that covers the conformity assessment procedures set out in clause 1.6 of Part 1 of Schedule 3 to the Regulations (examination of design)
2	Therapeutic Goods Administration	a conformity assessment certificate issued under the Act that covers the conformity assessment procedures set out in one of the following Parts of Schedule 3 to the Regulations: <ul style="list-style-type: none"> (a) for a medical device that the manufacturer intends to be supplied in a sterile state: <ul style="list-style-type: none"> (i) Part 4 (production quality assurance procedures); (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state, either of the following: <ul style="list-style-type: none"> (i) Part 3 (verification procedures); or (ii) Part 4 (production quality assurance procedures) 	a conformity assessment certificate issued under the Act that covers the conformity assessment procedures set out in Part 2 of Schedule 3 to the Regulations (type examination procedures)
3	a notified body within the meaning of Council Directive 93/42/EEC	a full quality assurance system certificate or other document issued under Annex II of Council Directive 93/42/EEC, excluding section 4 of that Annex	an EC design-examination certificate issued under section 4 of Annex II of Council Directive 93/42/EEC
4	a notified body within the meaning of Council Directive 93/42/EEC	(a) for a medical device that the manufacturer intends to be supplied in a sterile state: <ul style="list-style-type: none"> (i) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC; (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state, either of the following <ul style="list-style-type: none"> (i) an EC verification 	an EC type-examination certificate issued under Annex III of Council Directive 93/42/EEC

Column 1 Item	Column 2 Regulatory authority	Column 3 Conformity assessment document relating to manufacturer's quality management system	Column 4 Conformity assessment document relating to product assessment
		certificate issued under Annex IV of Council Directive 93/42/EEC; or (ii) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC	
5	a notified body within the meaning of Council Directive 90/385/EEC	a complete quality assurance system certificate or other document issued under section 3 of Annex 2 of Council Directive 90/385/EEC	an EC design examination certificate issued under section 4 of Annex 2 of Council Directive 90/385/EEC
6	a notified body within the meaning of Council Directive 90/385/EEC	(a) for a medical device that the manufacturer intends to be supplied in a sterile state: (i) an assurance of production quality certificate or other document issued under Annex 5 of Council Directive 90/385/EEC; (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state, either of the following: (i) an EC verification certificate issued under Annex 4 of Council Directive 90/385/EEC; or (ii) an assurance of production quality certificate or other document issued under Annex 5 of Council Directive 90/385/EEC	an EC type-examination certificate issued under Annex 3 of Council Directive 90/385/EEC
7	a notified body within the meaning of the EU medical devices regulation	an EU quality management system certificate issued under Chapter I of Annex IX of the EU medical devices regulation	an EU technical documentation assessment certificate issued under Chapter II of Annex IX of the EU medical devices regulation
8	a notified body within the meaning	(a) for a medical device that the manufacturer intends to be	an EU type-examination certificate issued under

Column 1 Item	Column 2 Regulatory authority	Column 3 Conformity assessment document relating to manufacturer's quality management system	Column 4 Conformity assessment document relating to product assessment
	of the EU medical devices regulation	<p>supplied in a sterile state:</p> <p>(i) a production quality assurance certificate issued under Part A of Annex XI of the EU medical devices regulation;</p> <p>(b) for a medical device that the manufacturer intends to be supplied in a non-sterile state, either of the following:</p> <p>(i) a production quality assurance certificate issued under Part A of Annex XI of the EU medical devices regulation; or</p> <p>(ii) an EU product verification certificate issued under Part B of Annex XI of the EU medical devices regulation</p>	Annex X of the EU medical devices regulation

10 After the heading to Part 5 of Schedule 1

Insert:

Division 1—Class AIMD medical devices that are not specified medical devices

11 At the end of Part 5 of Schedule 1

Add:

Division 2—Class AIMD medical devices that are specified medical devices

Column 1 Item	Column 2 Regulatory authority	Column 3 Conformity assessment document relating to manufacturer's quality management system	Column 4 Conformity assessment document relating to the product assessment
1	Therapeutic Goods	a conformity assessment	a conformity assessment

Column 1 Item	Column 2 Regulatory authority	Column 3 Conformity assessment document relating to manufacturer's quality management system	Column 4 Conformity assessment document relating to the product assessment
	Administration	certificate issued under the Act that covers the conformity assessment procedures set out in Part 1 of Schedule 3 to the Regulations (full quality assurance procedures), excluding clause 1.6 of that Part	certificate issued under the Act that covers the conformity assessment procedures set out in clause 1.6 of Part 1 of Schedule 3 to the Regulations (examination of design)
2	Therapeutic Goods Administration	a conformity assessment certificate issued under the Act that covers the conformity assessment procedures set out in one of the following Parts of Schedule 3 to the Regulations: <ul style="list-style-type: none"> (a) for a medical device that the manufacturer intends to be supplied in a sterile state: <ul style="list-style-type: none"> (i) Part 4 (production quality assurance procedures); (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state, either of the following: <ul style="list-style-type: none"> (i) Part 3 (verification procedures); or (ii) Part 4 (production quality assurance procedures) 	a conformity assessment certificate issued under the Act that covers the conformity assessment procedures set out in Part 2 of Schedule 3 to the Regulations (type examination procedures)
3	a notified body within the meaning of Council Directive 93/42/EEC	a full quality assurance system certificate or other document issued under Annex II of Council Directive 93/42/EEC, excluding section 4 of that Annex	an EC design-examination certificate issued under section 4 of Annex II of Council Directive 93/42/EEC
4	a notified body within the meaning of Council Directive 93/42/EEC	(a) for a medical device that the manufacturer intends to be supplied in a sterile state: <ul style="list-style-type: none"> (i) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC; (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state, either of the following <ul style="list-style-type: none"> (i) an EC verification 	an EC type-examination certificate issued under Annex III of Council Directive 93/42/EEC

Column 1 Item	Column 2 Regulatory authority	Column 3 Conformity assessment document relating to manufacturer's quality management system	Column 4 Conformity assessment document relating to the product assessment
		certificate issued under Annex IV of Council Directive 93/42/EEC; or (ii) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC	
5	a notified body within the meaning of Council Directive 90/385/EEC	a complete quality assurance system certificate or other document issued under section 3 of Annex 2 of Council Directive 90/385/EEC	an EC design examination certificate issued under section 4 of Annex 2 of Council Directive 90/385/EEC
6	a notified body within the meaning of Council Directive 90/385/EEC	(a) for a medical device that the manufacturer intends to be supplied in a sterile state: (i) an assurance of production quality certificate or other document issued under Annex 5 of Council Directive 90/385/EEC; (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state, either of the following: (i) an EC verification certificate issued under Annex 4 of Council Directive 90/385/EEC; or (ii) an assurance of production quality certificate or other document issued under Annex 5 of Council Directive 90/385/EEC	an EC type-examination certificate issued under Annex 3 of Council Directive 90/385/EEC
7	a notified body within the meaning of the EU medical devices regulation	an EU quality management system certificate issued under Chapter I of Annex IX of the EU medical devices regulation	an EU technical documentation assessment certificate issued under Chapter II of Annex IX of the EU medical devices regulation
8	a notified body within the meaning	(a) for a medical device that the manufacturer intends to be	an EU type-examination certificate issued under

8 *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (Class III, Class AIMD and Class 4 IVD) Determination 2021*

Column 1 Item	Column 2 Regulatory authority	Column 3 Conformity assessment document relating to manufacturer's quality management system	Column 4 Conformity assessment document relating to the product assessment
	of the EU medical devices regulation	<p>supplied in a sterile state:</p> <p>(i) a production quality assurance certificate issued under Part A of Annex XI of the EU medical devices regulation;</p> <p>(b) for a medical device that the manufacturer intends to be supplied in a non-sterile state, either of the following:</p> <p>(i) a production quality assurance certificate issued under Part A of Annex XI of the EU medical devices regulation; or</p> <p>(ii) an EU product verification certificate issued under Part B of Annex XI of the EU medical devices regulation</p>	Annex X of the EU medical devices regulation

12 Part 3 of Schedule 2 (at the end of the table)

Add:

3	a notified body within the meaning of Directive 98/79/EC	a full quality assurance system certificate or other document issued under section 3 of Annex IV of Directive 98/79/EC	an EC design-examination certificate issued under section 4 of Annex IV of Directive 98/79/EC
4	a notified body within the meaning of Directive 98/79/EC	a production quality assurance certificate or other document issued under Annex VII of Directive 98/79/EC	an EC type-examination certificate issued under Annex V of Directive 98/79/EC
5	a notified body within the meaning of the EU IVD regulation	an EU quality management system certificate issued under Chapter I of Annex IX of the EU IVD regulation	an EU design-examination certificate issued under Chapter II of Annex IX of the EU IVD regulation
6	a notified body within the meaning of the EU IVD regulation	an EU production quality assurance certificate issued under Annex XI of the EU IVD regulation	an EU type-examination certificate issued under Annex X of the EU IVD regulation

