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

made under subsections 41FDB(7) and 41FDB(8) of the

Therapeutic Goods Act 1989

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About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* that shows the text of the law as amended and in force on 1 December 2025 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018*.

3 Authority

This instrument is made under subsections 41FDB(7) and 41FDB(8) 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 document;
(c) conformity assessment procedures;
(d) included in the Register;
(e) kind, in relation to a medical device;
(f) medical device;
(g) system or procedure pack.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

application means an application to the Secretary for a kind of medical device to be included in the Register under section 41FC of the Act.

applied Directive 90/385 has the meaning given to "Directive 90/385" in regulation 2(1) of the UK Regulations, and a reference to an Annex in applied Directive 90/385 is to be construed in accordance with regulation 2(1A) of the UK Regulations.

applied Directive 93/42 has the meaning given to "Directive 93/42" in regulation 2(1) of the UK Regulations, and a reference to an Annex in applied Directive 93/42 is to be construed in accordance with regulation 2(1A) of the UK Regulations.

applied Directive 98/79 has the meaning given to "Directive 98/79" in regulation 2(1) of the UK Regulations, and a reference to an Annex in applied Directive 98/79 is to be construed in accordance with regulation 2(1A) of the UK Regulations.

Canadian medical devices regulations means the Medical Devices Regulations (SOR/98-282) made under the *Food and Drugs Act* of Canada, as in force immediately before the commencement of this instrument.

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certified translation means a translation that contains a statement, dated and signed by a person, to the effect that the translation is a true and complete translation of the accompanying document.

Class 1 IVD medical device has the same meaning as in the Regulations.

Class 2 IVD medical device has the same meaning as in the Regulations.

Class 3 IVD medical device has the same meaning as in the Regulations.

Class 4 IVD medical device has the same meaning as in the Regulations.

Class 4 in-house IVD medical device has the same meaning as in the Regulations.

Class I medical device has the same meaning as in the Regulations.

Class IIa medical device has the same meaning as in the Regulations.

Class IIb medical device has the same meaning as in the Regulations.

Class III medical device has the same meaning as in the Regulations.

clinical evaluation report means a report prepared by a manufacturer detailing the assessment and analysis of clinical data to verify the safety and performance of a medical device when used as intended by the manufacturer.

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 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 immediately before the commencement of this instrument.

Directive 98/79/EC means *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices*, as in force immediately before the commencement of this instrument.

EU IVD regulation means *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices*, as in force on 1 December 2024.

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 immediately before the commencement of this instrument.

generic device group has the same meaning as in the EU IVD regulation.

IAF accredited conformity assessment body means a body that is accredited to undertake certification for compliance with ISO 13485 by an accreditation body

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member that is a signatory to the Multilateral Recognition Arrangement of the International Accreditation Forum, Inc., otherwise known as the IAF MLA.

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

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

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

ISO 13485 means International Standard ISO 13485:2016 *Medical devices—Quality management systems—Requirements for regulatory purposes,* issued by the International Organization for Standardization in March 2016, as in force or existing immediately before the commencement of this instrument.

Note: ISO 13485 is published at: https://www.iso.org.

IVD companion diagnostic has the same meaning as in the Regulations.

IVD medical device, or in vitro diagnostic medical device, has the same meaning as in the Regulations.

IVD medical device for self-testing has the same meaning as in the Regulations.

Japanese PMD Act means *The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices* of Japan, as in force immediately before the commencement of this instrument.

manufacturing licence has the same meaning as in the Regulations.

MDSAP certificate means a certification document issued by a recognised or authorised auditing organisation, following the completion of an audit of a manufacturer's quality management system.

measuring function has the same meaning as in the Regulations.

medical device used for a special purpose has the same meaning as in the Regulations.

NATA has the same meaning as in the Regulations.

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.

point of care testing has the same meaning as in the Regulations.

quality management system certificate means a certificate that is issued following an assessment of a manufacturer's quality management system, but does not include a MDSAP certificate.

recognised or authorised auditing organisation means an organisation that is recognised or authorised to perform audits under the Medical Device Single

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Audit Program by the Regulatory Authority Council in relation to that program, comprising Australia's Therapeutic Goods Administration, the United States Food and Drug Administration, Brazil's Agência Nacional de Vigilância Sanitária, Health Canada, Japan's Ministry of Health, Labour and Welfare and the Japanese Pharmaceuticals and Medical Devices Agency.

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

relevant implantable medical device means an implantable medical device other than a medical device:

(a) mentioned in paragraphs 13A.1(1)(b) or (ba) of Schedule 1 to the Regulations; or

(b) to which subclause 13A.1(2) of Schedule 1 to the Regulations applies.

Note: Medical devices mentioned in paragraph 13A.1(1)(b) of Schedule 1 to the Regulations include, for example, sutures, staples, dental fillings and dental braces. The medical devices mentioned in paragraph 13A.1(1)(ba) of Schedule 1 to the Regulations are medical devices that are intended by the manufacturer to be for export only.

Singapore Health Products Act means the Health Products Act 2007 of Singapore as in force on 1 July 2022.

Singapore Register of Health Products means the Register of Health Products kept and maintained by the Health Sciences Authority of Singapore under section 34 of the Singapore Health Products Act.

Therapeutic Goods Administration means that part of the Department known as the Therapeutic Goods Administration.

UK approved body has the meaning given to "approved body" in regulation A45 of the UK Regulations.

UK Regulations means the Medical Devices Regulations 2002 (SI 2002/618), as in force in England, Wales and Scotland on 1 December 2025.

Note: The UK Regulations could in 2025 be viewed on the UK legislation website (www.legislation.gov.uk).

US FDC Act means the *Federal Food, Drug, and Cosmetic Act* of the United States, as in force immediately before the commencement of this instrument.

5 Kind of information—medical devices other than IVD medical devices

Class I medical devices

(1A) An application for a Class I medical device that the manufacturer intends to be supplied in a non-sterile state and that does not have a measuring function must be accompanied by the following kind of information:

(a) a declaration of conformity that relates to the manufacturer's quality management system specified in column 3 of an item in the table in Division 1 of Part 1 of Schedule 1, which is recognised by the regulatory authority in column 2 of that item; and

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(b) a conformity assessment document in relation to the medical device specified for that item in column 4 (if any), which is issued or recognised by the regulatory authority in column 2 of that item.

(1) An application for a Class I medical device that the manufacturer intends to be supplied in a sterile state or that has a measuring function 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 1 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.

(2) To avoid doubt:

(a) for the purpose of subsection (1), an application may be accompanied by more than one document referred to in paragraph (1)(a), and its corresponding certificate or other document of product assessment referred to in paragraph (1)(b) (if any);

(b) a document which accompanies an application in accordance with subsection (1) or (1A) must relate to the kind of device to which the application relates.

Class IIa medical devices

(3) An application for a Class IIa 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 Part 2 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.

(4) To avoid doubt:

(a) an application may be accompanied by more than one document referred to in paragraph (3)(a), and its corresponding certificate or other document of product assessment referred to in paragraph (3)(b) (if any);

(b) a document which accompanies the application in accordance with subsection (3) must relate to the kind of device to which the application relates.

Class IIb medical devices

(5) An application for a Class IIb medical device must be accompanied by the following kind of information:

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(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 Part 3 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.

(6) To avoid doubt:

(a) an application may be accompanied by more than one document referred to in paragraph (5)(a), and its corresponding certificate or other document of product assessment referred to in paragraph (5)(b) (if any);

(b) a document which accompanies the application in accordance with subsection (5) must relate to the kind of device to which the application relates.

Class III medical devices

(7) An application for a Class III 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 Part 4 of Schedule 1, which is issued or recognised by the regulatory authority in column 2 of that item;

(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;

(c) if the application is not accompanied by a conformity assessment certificate issued by the TGA—a clinical evaluation report and the instructions for use.

(8) To avoid doubt:

(a) an application may be accompanied by more than one document referred to in paragraph (7)(a), and its corresponding certificate or other document of product assessment referred to in paragraph (7)(b) (if any);

(b) a document which accompanies the application in accordance with subsection (7) must relate to the kind of device to which the application relates.

Application of this section

(11) This section does not apply to any of the following:

(a) a medical device used for a special purpose;

(b) a medical device that is intended by the manufacturer to be for export only.

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6 Kind of information—IVD medical devices

Class 1 IVD medical devices

(1A) An application for a Class 1 IVD medical device must be accompanied by the following kind of information:

(a) a declaration of conformity that relates to the manufacturer's quality management system specified in column 3 of an item in the table in Part 1A of Schedule 2, which is recognised by the regulatory authority in column 2 of that item; and

(b) a conformity assessment document in relation to the medical device specified for that item in column 4 (if any), which is issued or recognised by the regulatory authority in column 2 of that item.

(1B) To avoid doubt, a document which accompanies the application in accordance with subsection (1A) must relate to the kind of device to which the application relates.

Class 2 IVD medical devices

(1) An application for a Class 2 IVD 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 Part 1 of Schedule 2, 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; and

(c) if the application is accompanied by the information specified in item 2 or 2B in the table in Part 1 of Schedule 2—evidence to demonstrate compliance with Article 110(3c) of the EU IVD regulation.

(2) To avoid doubt:

(a) an application may be accompanied by more than one document referred to in paragraph (1)(a), and its corresponding certificate or other document of product assessment referred to in paragraph (1)(b) (if any);

(b) a document which accompanies the application in accordance with subsection (1) must relate to the kind of device to which the application relates.

Class 3 IVD medical devices

(3) An application for a Class 3 IVD 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 Part 2 of Schedule 2, which is issued or recognised by the regulatory authority in column 2 of that item; and

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(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; and

(c) if the application is accompanied by the information specified in item 3, 3B or 4 in the table in Part 2 of Schedule 2—evidence to demonstrate compliance with Article 110(3c) of the EU IVD regulation.

(4) To avoid doubt:

(a) an application may be accompanied by more than one document referred to in paragraph (3)(a), and its corresponding certificate or other document of product assessment referred to in paragraph (3)(b) (if any);

(b) a document which accompanies the application in accordance with subsection (3) must relate to the kind of device to which the application relates.

Class 4 IVD medical devices

(5) An application for a Class 4 IVD 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 Part 3 of Schedule 2, 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; and

(c) if the application is accompanied by the information specified in item 3 or 4 in the table in Part 3 of Schedule 2—evidence to demonstrate compliance with Article 110(3c) of the EU IVD regulation.

(6) To avoid doubt:

(a) an application may be accompanied by more than one document referred to in paragraph (5)(a), and its corresponding certificate or other document of product assessment referred to in paragraph (5)(b) (if any);

(b) a document which accompanies the application in accordance with subsection (5) must relate to the kind of device to which the application relates.

Class 4 in-house IVD medical devices

(7) An application for a Class 4 in-house IVD medical device must be accompanied by the following kind of information:

(a) a conformity assessment document or other evidence that relates to the manufacturer's quality management system specified in column 3 of an item in the table in Part 4 of Schedule 2, which is issued or recognised by the regulatory authority in column 2 of that item; and

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(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.

(8) To avoid doubt:

(a) an application may be accompanied by more than one document referred to in paragraph (7)(a), and its corresponding certificate or other document of product assessment referred to in paragraph (7)(b) (if any);

(b) a document which accompanies the application in accordance with subsection (7) must relate to the kind of device to which the application relates.

Application of this section

(9) This section does not apply to any of the following:

(a) a medical device used for a special purpose;

(b) a medical device that is intended by the manufacturer to be for export only.

6A Kind of information—medical devices intended for export only

(1) An application for a medical device that is intended by the manufacturer to be for export only, including an IVD medical device, must be accompanied by the following kind of information:

(a) a declaration of conformity that relates to the manufacturer's quality management system specified in column 3 of an item in the table in Schedule 2A, which is recognised by the regulatory authority in column 2 of that item; and

(b) a conformity assessment document in relation to the medical device specified for that item in column 4 (if any), which is issued or recognised by the regulatory authority in column 2 of that item.

(2) To avoid doubt, a document which accompanies the application in accordance with this section must relate to the kind of device to which the application relates.

Application of this section

(3) This section does not apply to a medical device used for a special purpose.

7 Kind of information—medical devices used for a special purpose that are a system or procedure pack

(1A) An application for a medical device used for a special purpose that is a system or procedure pack and:

(a) classified under the Regulations as a Class I medical device that:

(i) does not have a measuring function; and

(ii) the manufacturer intends to be supplied in a non-sterile state; or

(b) classified under the Regulations as a Class 1 IVD medical device; or

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(c) intended by the manufacturer to be for export only;

must be accompanied by the following kind of information:

(d) a declaration of conformity that relates to the manufacturer's quality management system specified in column 3 of an item in the table in Division 1 of Part 1 of Schedule 3, which is recognised by the regulatory authority in column 2 of that item; and

(e) a conformity assessment document in relation to each medical device contained in the system or procedure pack specified for that item in column 4 (if any), which is issued or recognised by the regulatory authority in column 2 of that item.

(1) An application for a medical device used for a special purpose that is a system or procedure pack, other than a medical device that is mentioned in subsection (1A), must be accompanied by the following kind of information:

(a) a declaration of conformity that relates to the manufacturer's quality management system specified in column 3 of an item in the table in Division 2 of Part 1 of Schedule 3, which is recognised by the regulatory authority in column 2 of that item; and

(b) a conformity assessment document in relation to each medical device contained in the system or procedure pack specified for that item in column 4 (if any), which is issued or recognised by the regulatory authority in column 2 of that item.

Additional information required where the manufacturer intends the medical device used for a special purpose to be supplied in a sterile state

(2) An application for a medical device to which subsection (1) applies, and which the manufacturer intends to be supplied in a sterile state, must also 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 Part 2 of Schedule 3, 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.

(3) To avoid doubt:

(a) an application may be accompanied by more than one document referred to in paragraph (2)(a), and its corresponding certificate or other document of product assessment referred to in paragraph (2)(b) (if any);

(b) a document which accompanies the application in accordance with this section must relate to the kind of device to which the application relates.

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8 Alternative kinds of information

Medical devices other than IVD medical devices

(1) An application for a medical device other than an IVD medical device may be accompanied by the kind of information determined under section 5 that relates to an application for a kind of medical device that is classified at a higher level than the medical device concerned, rather than the kind of information determined for that class of medical device under that section.

IVD medical devices

(2) An application for an IVD medical device may be accompanied by the kind of information determined under section 6 that relates to an application for a kind of medical device that is classified at a higher level than the medical device concerned, rather than the kind of information determined for that class of medical device under that section.

Note: The kind of information determined under sections 5 and 6 relate to the minimum conformity assessment procedures that the manufacturer must apply to a kind of device of that classification.

9 Classes of medical device for which accompanying information is not determined

To avoid doubt, no kind of information is determined for the purposes of subsection 41FDB(7) for an application in relation to a medical device in one of the following classifications:

(a) an in-house IVD medical device other than a Class 4 in-house IVD medical device;

(b) a medical device used for a special purpose that is not a system or procedure pack.

Note: In effect, this means that no information must accompany applications in relation to these classifications.

10 Form of information—all medical devices

All information that accompanies an application in accordance with section 5, 6 or 7 must be:

(a) legible; and

(b) either of the following:

(i) in English; or

(ii) if it is not in English—be accompanied by a certified translation into English.

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Schedule 1—Medical devices other than IVD medical devices

Note: See section 5.

Part 1—Class I medical devices

Division 1—Class I medical devices that are intended to be supplied in a non-sterile state and do not have a measuring function

Column 1 Item	Column 2 Regulatory authority	Column 3 Declaration of conformity in relation to the medical device	Column 4 Conformity assessment document relating to the medical device
1	Therapeutic Goods Administration	a declaration of conformity made by the manufacturer under clause 6.6 of Schedule 3 to the Regulations	

Division 2—Class I medical devices that are intended to be supplied in a sterile state or have a measuring function

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 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: (a) for a medical device that the manufacturer intends to be supplied in a sterile state (whether or not it has a measuring function): (i) Part 1 (full quality assurance procedures), excluding clause 1.6 of that Part; or	

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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
		(ii) Part 4 (production quality assurance procedures); (b) for a medical device that has a measuring function (and that the manufacturer intends to be supplied in a non-sterile state): (i) Part 1 (full quality assurance procedures), excluding clause 1.6 of that Part; (ii) Part 3 (verification procedures); (iii) Part 4 (production quality assurance procedures); or (iv) Part 5 (product quality assurance procedures)	
2	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 (whether or not it has a measuring function), either of the following: (i) a full quality assurance system certificate or other document issued under Annex II of Council Directive 93/42/EEC, excluding section 4 of that Part; or (ii) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC; (b) for a medical device that has a measuring function (and that the manufacturer intends to be supplied in a	

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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
		non-sterile state), one of the following: (i) a full quality assurance system certificate or other document issued under Annex II of Council Directive 93/42/EEC, excluding section 4 of that Part; (ii) an EC verification certificate issued under Annex IV of Council Directive 93/42/EEC; (iii) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC; or (iv) a product quality assurance certificate or other document issued under Annex VI of Council Directive 93/42/EEC	
3	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 (whether or not it has a measuring function), either of the following: (i) a complete quality assurance system certificate or other document issued under section 3 of Annex 2 of Council Directive 90/385/EEC; or (ii) an assurance of production quality certificate or other document issued under	

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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
		Annex 5 of Council Directive 90/385/EEC; (b) for a medical device that has a measuring function (and that the manufacturer intends to be supplied in a non-sterile state), one of the following: (i) a complete quality assurance system certificate or other document issued under section 3 of Annex 2 of Council Directive 90/385/EEC; (ii) an EC verification certificate issued under Annex 4 of Council Directive 90/385/EEC; or (iii) an assurance of production quality certificate or other document issued under Annex 5 of Council Directive 90/385/EEC	
4	a notified body within the meaning of the EU medical devices regulation	for a medical device that the manufacturer intends to be supplied in a sterile state and/or that has a measuring function, either of the following: (a) an EU quality management system certificate issued under Chapter I of Annex IX of the EU medical devices regulation; or (b) a production quality assurance certificate issued under Part A of Annex XI of the EU medical devices regulation	
5	recognised or authorised auditing organisation	for a medical device that the manufacturer intends to be supplied in a sterile state and/or	

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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
		that has a measuring function— a MDSAP certificate	
6	a UK approved body	(a) for a medical device that the manufacturer intends to be supplied in a sterile state (whether or not it has a measuring function)—either of the following: (i) a complete quality assurance system certificate or other document issued under section 3 of Annex 2 in applied Directive 90/385; (ii) an assurance of production quality certificate or other document issued under Annex 5 in applied Directive 90/385; (b) for a medical device that has a measuring function (and that the manufacturer intends to be supplied in a non-sterile state)—one of the following: (i) a complete quality assurance system certificate or other document issued under section 3 of Annex 2 in applied Directive 90/385; (ii) a verification certificate of conformity issued under Annex 4 in applied Directive 90/385; (iii) an assurance of production quality certificate or other document issued under Annex 5 in applied Directive 90/385	

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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
7	a UK approved body	(a) for a medical device that the manufacturer intends to be supplied in a sterile state (whether or not it has a measuring function)—either of the following: (i) a full quality assurance system certificate or other document issued under Annex II in applied Directive 93/42, excluding section 4 of that Annex; (ii) a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42; (b) for a medical device that has a measuring function (and that the manufacturer intends to be supplied in a non-sterile state)—one of the following: (i) a full quality assurance system certificate or other document issued under Annex II in applied Directive 93/42, excluding section 4 of that Annex; (ii) a verification certificate of conformity issued under Annex IV in applied Directive 93/42; (iii) a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42; (iv) a product quality assurance certificate or other document issued	

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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
		under Annex VI in applied Directive 93/42	

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Part 2—Class IIa 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 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: (a) for a medical device that the manufacturer intends to be supplied in a sterile state: (i) Part 1 (full quality assurance procedures), excluding clause 1.6 of that Part; or (ii) Part 4 (production quality assurance procedures); (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state: (i) Part 1 (full quality assurance procedures), excluding clause 1.6 of that Part; (ii) Part 3 (verification procedures); (iii)Part 4 (production quality assurance procedures); or (iv)Part 5 (product quality assurance procedures)	
2	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, either of the following: (i) a full quality assurance system certificate or other document issued under Annex II of	

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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
		Council Directive 93/42/EEC, excluding section 4 of that Part; or (ii) 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, one of the following: (i) a full quality assurance system certificate or other document issued under Annex II of Council Directive 93/42/EEC, excluding section 4 of that Part; (ii) an EC verification certificate issued under Annex IV of Council Directive 93/42/EEC; (iii) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC; or (iv) a product quality assurance certificate or other document issued under Annex VI of Council Directive 93/42/EEC	
3	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, either of the following: (i) a complete quality assurance system certificate or other	

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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
		document issued under section 3 of Annex 2 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; (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state, one of the following: (i) a complete quality assurance system certificate or other document issued under section 3 of Annex 2 of Council Directive 90/385/EEC; (ii) an EC verification certificate issued under Annex 4 of Council Directive 90/385/EEC; or (iii) an assurance of production quality certificate or other document issued under Annex 5 of Council Directive 90/385/EEC	
4	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	
5	a notified body within the meaning of the EU medical devices regulation	(a) for a medical device that the manufacturer intends to be supplied in a sterile state: (i) a production quality assurance certificate issued under Part A of Annex XI of the EU	

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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
		medical devices regulation; (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state, either of the following: (i) a production quality assurance certificate issued under Part A of Annex XI of the EU medical devices regulation; or (ii) an EU product verification certificate issued under Part B of Annex XI of the EU medical devices regulation	
6	Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency	either of the following: (a) a MDSAP certificate; or (b) a quality management system certificate for the purposes of the Japanese PMD Act	either of the following: (a) a pre-market certification issued under the Japanese PMD Act; or (b) a pre-market approval issued under the Japanese PMD Act
7	Health Canada	a MDSAP certificate	a Class II medical device licence issued under the Canadian medical devices regulations
8	United States Food and Drug Administration	a MDSAP certificate	for medical devices that are not exempted, by the United States Food and Drug Administration, from section 510(k) requirements—either of the following: (a) a determination of substantial equivalence made with respect to a

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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
			notification submitted under section 510(k) of the US FDC Act; or (b) an order granting a request for classification under section 513 of the US FDC Act (a De Novo classification request)
8A	United States Food and Drug Administration	a MDSAP certificate	for medical devices that are exempted, by the United States Food and Drug Administration, from section 510(k) requirements—a statement that includes the device name or description, regulation number and submission type under United States Food and Drug Administration requirements
9	Health Sciences Authority of Singapore	an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class B medical device	
10	a UK approved body	(a) for a medical device that the manufacturer intends to be supplied in a sterile state—either of the following: (i) a full quality assurance system certificate or other document issued under Annex II in applied Directive 93/42, excluding section 4 of that Annex; (ii) a production quality assurance certificate or other document issued	

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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
		under Annex V in applied Directive 93/42; (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state—one of the following: (i) a full quality assurance system certificate or other document issued under Annex II in applied Directive 93/42, excluding section 4 of that Annex; (ii) a verification certificate of conformity issued under Annex IV in applied Directive 93/42; (iii) a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42; (iv) a product quality assurance certificate or other document issued under Annex VI in applied Directive 93/42	

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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
11	a UK approved body	(a) for a medical device that the manufacturer intends to be supplied in a sterile state—either of the following: (i) a complete quality assurance system certificate or other document issued under section 3 of Annex 2 in applied Directive 90/385; (ii) an assurance of production quality certificate or other document issued under Annex 5 in applied Directive 90/385; (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state—one of the following: (i) a complete quality assurance system certificate or other document issued under section 3 of Annex 2 in applied Directive 90/385; (ii) a verification certificate of conformity issued under Annex 4 in applied Directive 90/385; (iii) an assurance of production quality certificate or other document issued under Annex 5 in applied Directive 90/385	

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Part 3—Class IIb 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 Administration	a conformity assessment 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	
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: (a) for a medical device that the manufacturer intends to be supplied in a sterile state: (i) Part 4 (production quality assurance procedures); (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state: (i) Part 3 (verification procedures); (ii) Part 4 (production quality assurance procedures); or (iii) Part 5 (product 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 Part	
4	a notified body within the meaning of Council	(a) for a medical device that the manufacturer intends to be supplied in a sterile state:	an EC type-examination certificate issued under

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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
	Directive 93/42/EEC	(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, one of the following: (i) an EC verification certificate issued under Annex IV of Council Directive 93/42/EEC; (ii) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC; or (iii) a product quality assurance certificate or other document issued under Annex VI of Council Directive 93/42/EEC	Annex III 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	
6	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	for a relevant implantable medical device—an EU technical documentation assessment certificate issued under Chapter II of Annex IX of the EU medical devices regulation
7	a notified body within the meaning	(a) for a medical device that the manufacturer intends to be supplied in a sterile state:	an EU type-examination certificate issued under Annex X of the EU

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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	(i) a production quality assurance certificate issued under Part A of Annex XI of the EU medical devices regulation; (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state, either of the following: (i) a production quality assurance certificate issued under Part A of Annex XI of the EU medical devices regulation; or (ii) an EU product verification certificate issued under Part B of Annex XI of the EU medical devices regulation	medical devices regulation
8	Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency	either of the following: (a) a MDSAP certificate; or (b) a quality management system certificate for the purposes of the Japanese PMD Act	either of the following: (a) a pre-market certification issued under the Japanese PMD Act; or (b) a pre-market approval issued under the Japanese PMD Act
9	Health Canada	a MDSAP certificate	a Class III medical device licence issued under the Canadian medical devices regulations
10	United States Food and Drug Administration	a MDSAP certificate	one of the following: (a) a determination of substantial equivalence made with respect to a notification submitted under

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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
			section 510(k) of the US FDC Act; (b) an order granting a request for classification under section 513 of the US FDC Act (a De Novo classification request); or (c) an order approving an application for premarket approval under section 515 of the US FDC Act
11	United States Food and Drug Administration	an order approving an application for premarket approval under section 515 of the US FDC Act	
12	Health Sciences Authority of Singapore	an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class C medical device	
13	a UK approved body	a full quality assurance system certificate or other document issued under Annex II in applied Directive 93/42, excluding section 4 of that Annex	
14	a UK approved body	(a) for a medical device that the manufacturer intends to be supplied in a sterile state—a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42; (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state—one of the following: (i) a verification certificate of conformity issued under Annex IV in applied Directive 93/42;	

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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
		(ii) a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42; (iii) a product quality assurance certificate or other document issued under Annex VI in applied Directive 93/42	
15	a UK approved body	a complete quality assurance system certificate or other document issued under section 3 of Annex 2 in applied Directive 90/385	

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Part 4—Class III 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 Administration	a conformity assessment 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	a conformity assessment 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: (a) for a medical device that the manufacturer intends to be supplied in a sterile state: (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: (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	(a) for a medical device that the manufacturer intends to be supplied in a sterile state:	an EC type-examination certificate issued under

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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
	Directive 93/42/EEC	(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: (i) an EC verification 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	Annex III 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	an EC type-examination certificate issued under Annex 3 of Council Directive 90/385/EEC

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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
		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	
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 of the EU medical devices regulation	(a) for a medical device that the manufacturer intends to be supplied in a sterile state: (i) a production quality assurance certificate issued under Part A of Annex XI of the EU medical devices regulation; (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state, either of the following: (i) a production quality assurance certificate issued under Part A of Annex XI of the EU medical devices regulation; or (ii) an EU product verification certificate issued under Part B of Annex XI of the EU medical devices regulation	an EU type-examination certificate issued under Annex X of the EU medical devices regulation

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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
9	Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency	either of the following: (a) a MDSAP certificate; or (b) a quality management system certificate for the purposes of the Japanese PMD Act	a pre-market approval issued under the Japanese PMD Act
10	Health Canada	a MDSAP certificate	a Class IV medical device licence issued under the Canadian medical devices regulations
11	United States Food and Drug Administration	a MDSAP certificate	one of the following: (a) a determination of substantial equivalence made with respect to a notification submitted under section 510(k) of the US FDC Act; (b) an order approving an application for premarket approval under section 515 of the US FDC Act
12	United States Food and Drug Administration	an order approving an application for premarket approval under section 515 of the US FDC Act	
13	Health Sciences Authority of Singapore	an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class D medical device	
14	a UK approved body	a full quality assurance system certificate or other document issued under Annex II in applied Directive 93/42, excluding section 4 of that Annex	a design examination certificate issued under section 4 of Annex II in applied Directive 93/42

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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
15	a UK approved body	(a) for a medical device that the manufacturer intends to be supplied in a sterile state—a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42; (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state—either of the following: (i) a verification certificate of conformity issued under Annex IV in applied Directive 93/42; (ii) a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42	a type-examination certificate issued under Annex III in applied Directive 93/42
16	a UK approved body	a complete quality assurance system certificate or other document issued under section 3 of Annex 2 in applied Directive 90/385	a design examination certificate issued under section 4 of Annex 2 in applied Directive 90/385
17	a UK approved body	(a) for a medical device that the manufacturer intends to be supplied in a sterile state—an assurance of production quality certificate or other document issued under Annex 5 in applied Directive 90/385; (b) for a medical device that the manufacturer intends to be supplied in a non-sterile state—either of the following: (i) a verification certificate of conformity issued	a type-examination certificate issued under Annex 3 in applied Directive 90/385

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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
		under Annex 4 in applied Directive 90/385; (ii) an assurance of production quality certificate or other document issued under Annex 5 in applied Directive 90/385	

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Schedule 2—IVD medical devices

Note: See section 6.

Part 1A—Class 1 IVD medical devices

Column 1 Item	Column 2 Regulatory authority	Column 3 Declaration of conformity in relation to the medical device	Column 4 Conformity assessment document relating to the medical device
1	Therapeutic Goods Administration	a declaration of conformity made by the manufacturer under clause 6.6 of Schedule 3 to the Regulations	

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Part 1—Class 2 IVD 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 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: (a) Part 1 (full quality assurance procedures), excluding clause 1.6 of that Part; or (b) Part 4 (production quality assurance procedures)	
2	a notified body within the meaning of Directive 98/79/EC	for an application submitted before 1 January 2030—one of the following: (a) a full quality assurance system certificate or other document issued under section 3 of Annex IV of Directive 98/79/EC; (b) a production quality assurance certificate or other document issued under Annex VII of Directive 98/79/EC	
2A	a notified body within the meaning of Directive 98/79/EC	for an application submitted before 26 May 2027—a document certifying compliance with ISO 13485	an EU declaration of conformity made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022
2B	a notified body within the meaning of Directive 98/79/EC	for an application submitted before 1 January 2030—an EU declaration of conformity made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022	
3	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	for an IVD medical device for self-testing or an IVD medical device for point of care testing—an

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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
			assessment of technical documentation referred to in section 5.1 of Annex IX of the EU IVD regulation
4	Health Canada	a MDSAP certificate	a Class II medical device licence issued under the Canadian medical devices regulations
5	United States Food and Drug Administration	a MDSAP certificate	a determination of substantial equivalence made with respect to a notification submitted under section 510(k) of the US FDC Act
6	recognised or authorised auditing organisation	a MDSAP certificate	
8	an IAF accredited conformity assessment body	for an application submitted before 26 May 2027—a document certifying compliance with ISO 13485	an EU declaration of conformity made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022
9	Health Sciences Authority of Singapore	an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class B IVD	
10	Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency	either of the following: (a) a MDSAP certificate; or (b) a quality management system certificate for the purposes of the Japanese PMD Act	for an IVD medical device for self-testing or an IVD medical device for point of care testing—one or more of the following: (a) a pre-market certification issued under the Japanese PMD Act; (b) a pre-market approval issued under the Japanese PMD Act

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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
11	a UK approved body	either of the following: (a) a full quality assurance system certificate or other document issued under section 3 of Annex IV in applied Directive 98/79; (b) a production quality assurance certificate or other document issued under Annex VII in applied Directive 98/79	

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Part 2—Class 3 IVD 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 Administration	a conformity assessment 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)	
2	Therapeutic Goods Administration	a conformity assessment certificate issued under the Act that covers the conformity assessment procedures set out in Part 4 of Schedule 3 to the Regulations (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 Directive 98/79/EC	for an application submitted before 1 January 2029—a full quality assurance system certificate or other document issued under section 3 of Annex IV of Directive 98/79/EC	
3A	a notified body within the meaning of Directive 98/79/EC	for an application submitted before 26 May 2026—a document certifying compliance with ISO 13485	an EU declaration of conformity made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022
3B	a notified body within the meaning of Directive 98/79/EC	for an application submitted before 1 January 2029—an EU declaration of conformity made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022	
4	a notified body within the meaning of Directive 98/79/EC	for an application submitted before 1 January 2029—a production quality assurance certificate or other document issued under Annex VII of Directive 98/79/EC	for an application submitted before 1 January 2029—an EC type-examination certificate issued under

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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
			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	one of the following: (a) for an IVD medical device for self-testing or an IVD medical device for point of care testing—an assessment of technical documentation set out in section 5.1 of Annex IX of the EU IVD regulation; or (b) for an IVD companion diagnostic—an assessment of technical documentation set out in section 5.2 of Annex IX of the EU IVD regulation; or (c) for other IVD medical devices—the assessment of technical documentation as set out in section 4 of Annex IX of the EU IVD regulation for at least one representative device in a generic device group
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, excluding section 5 of that Annex	an EU type-examination certificate issued under Annex X of the EU IVD regulation

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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
7	Health Canada	a MDSAP certificate	a Class III medical device licence issued under the Canadian medical devices regulations
8	United States Food and Drug Administration	a MDSAP certificate	either of the following: (a) a determination of substantial equivalence made with respect to a notification submitted under section 510(k) of the US FDC Act; or (b) an order approving an application for premarket approval under section 515 of the US FDC Act
9	United States Food and Drug Administration	an order approving an application for premarket approval under section 515 of the US FDC Act	an order approving an application for premarket approval under section 515 of the US FDC Act
10	recognised or authorised auditing organisation	a MDSAP certificate	
12	an IAF accredited conformity assessment body	for an application submitted before 26 May 2026—a document certifying compliance with ISO 13485	an EU declaration of conformity made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022
13	Health Sciences Authority of Singapore	an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class C IVD	
14	Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency	either of the following: (a) a MDSAP certificate; or (b) a quality management system certificate for the purposes of the Japanese PMD Act	for an IVD medical device for self-testing or an IVD medical device for point of care testing—either of the following: (a) a pre-market certification issued under the Japanese PMD Act; or

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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
			(b) a pre-market approval issued under the Japanese PMD Act
15	a UK approved body	a full quality assurance system certificate or other document issued under section 3 of Annex IV in applied Directive 98/79	
16	a UK approved body	a production quality assurance certificate or other document issued under Annex VII in applied Directive 98/79	a type-examination certificate issued under Annex V in applied Directive 98/79

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Part 3—Class 4 IVD 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 Administration	a conformity assessment 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	a conformity assessment 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 Part 4 of Schedule 3 to the Regulations (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 Directive 98/79/EC	for an application submitted before 1 January 2028—a full quality assurance system certificate or other document issued under section 3 of Annex IV of Directive 98/79/EC	for an application submitted before 1 January 2028—an EC design-examination certificate issued under Annex IV of Directive 98/79/EC
4	a notified body within the meaning of Directive 98/79/EC	for an application submitted before 1 January 2028—a production quality assurance certificate or other document issued under Annex VII of Directive 98/79/ EC	for an application submitted before 1 January 2028— 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

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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
7	Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency	either of the following: (a) a MDSAP certificate; or (b) a quality management system certificate for the purposes of the Japanese PMD Act	a pre-market approval issued under the Japanese PMD Act
8	United States Food and Drug Administration	an order approving an application for premarket approval under section 515 of the US FDC Act	an order approving an application for premarket approval under section 515 of the US FDC Act
9	Health Canada	a MDSAP certificate	a Class IV medical device licence issued under Canadian medical device regulations
10	Health Sciences Authority of Singapore	an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class D IVD	
11	a UK approved body	a full quality assurance system certificate or other document issued under section 3 of Annex IV in applied Directive 98/79	a design-examination certificate issued under Annex IV in applied Directive 98/79
12	a UK approved body	a production quality assurance certificate or other document issued under Annex VII in applied Directive 98/79	a type-examination certificate issued under Annex V in applied Directive 98/79

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Part 4—Class 4 in-house IVD medical devices

Column 1 Item	Column 2 Regulatory authority	Column 3 Conformity assessment document or other evidence relating to manufacturer's quality management system	Column 4 Conformity assessment document relating to product assessment
1	Therapeutic Goods Administration	a conformity assessment 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	a conformity assessment 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 manufacturing licence referred to in subparagraph 6B.3(2)(a)(ii) of Schedule 3 to the Regulations	
3	Therapeutic Goods Administration	a certificate of accreditation issued by NATA of the kind referred to in subparagraph 6B.3(2)(b)(i) of Schedule 3 to the Regulations	

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Schedule 2A—Medical devices intended for export only

Note: See section 6A.

Column 1 Item	Column 2 Regulatory authority	Column 3 Declaration of conformity in relation to the medical device	Column 4 Conformity assessment document relating to the medical device
1	Therapeutic Goods Administration	a declaration of conformity made by the manufacturer under clause 6.6 of Schedule 3 to the Regulations	

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Schedule 3—Medical devices used for a special purpose that are a system or procedure pack

Note: See section 7.

Part 1—All medical devices used for a special purpose that are a system or procedure pack

Division 1—System or procedure packs that are Class I medical devices intended to be supplied in a non-sterile state and that do not have a measuring function, Class 1 IVD medical devices, or intended for export only

Column 1 Item	Column 2 Regulatory authority	Column 3 Declaration of conformity in relation to the system or procedures pack	Column 4 Conformity assessment document in relation to each medical device
1	Therapeutic Goods Administration	a declaration of conformity made by the manufacturer under clause 7.5 of Schedule 3 to the Regulations	

Division 2—System or procedure packs that are not Class I medical devices intended to be supplied in a non-sterile state and that do not have a measuring function, not Class 1 IVD medical devices, or not intended for export only

Column 1 Item	Column 2 Regulatory authority	Column 3 Declaration of conformity in relation to the system or procedure pack	Column 4 Conformity assessment document in relation to each medical device
1	Therapeutic Goods Administration	a declaration of conformity made by the manufacturer under clause 7.5 of Schedule 3 to the Regulations	a conformity assessment document in relation to each medical device contained in the system or procedure pack

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Part 2—System or procedure packs that are intended to be supplied in a sterile state and that are not Class 1 IVD medical devices, or not intended for export only

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 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: (a) Part 1 (full quality assurance procedures), excluding clause 1.6 of that Part; or (b) Part 4 (production quality assurance procedures)	
2	a notified body within the meaning of Council Directive 93/42/EEC	either of the following: (a) a full quality assurance system certificate or other document issued under Annex II of Council Directive 93/42/EEC, excluding section 4 of that Part; or (b) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC;	
3	a notified body within the meaning of Council Directive 90/385/EEC	either of the following: (a) a complete quality assurance system certificate or other document issued under section 3 of Annex 2 of Council Directive 90/385/EEC; or (b) an assurance of production quality certificate or other document issued under Annex 5 of Council Directive 90/385/EEC;	

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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
4	a notified body within the meaning of the EU medical devices regulation	either of the following: (a) an EU quality management system certificate issued under Chapter I of Annex IX of the EU medical devices regulation; or (b) a production quality assurance certificate issued under Part A of Annex XI of the EU medical devices regulation	
5	recognised or authorised auditing organisation	a MDSAP certificate	
6	a UK approved body	either of the following: (a) a full quality assurance system certificate or other document issued under Annex II in applied Directive 93/42, excluding section 4 of that Annex; (b) a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42	
7	a UK approved body	either of the following: (a) a complete quality assurance system certificate or other document issued under section 3 of Annex 2 in applied Directive 90/385; (b) an assurance of production quality certificate or other document issued under Annex 5 in applied Directive 90/385	

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Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and "(md not incorp)" is added to the amendment history.

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Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

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Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018	9 Oct 2018 (F2018L01410)	10 Oct 2018	—
Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018	21 Dec 2018 (F2018L01822)	22 Dec 2018	—
Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2019	9 Apr 2019 (F2019L00589)	10 Apr 2019	—
Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (COVID-19 Measures—Class I Medical Devices) Determination 2020	28 Sep 2020 (F2020L01236)	1 Oct 2020	—
Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (COVID-19 Measures—Class 1 IVD Medical Devices) Determination 2020	3 Dec 2020 (F2020L01528)	4 Dec 2020	—
Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (COVID-19 Measures—Export Only and System or Procedure Packs) Determination 2021	14 May 2021 (F2021L00582)	19 May 2021	—
Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (Class III, Class AIMD and Class 4 IVD) Determination 2021	11 Aug 2021 (F2021L01091)	12 Aug 2021	—

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Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Consequential Amendments) Determination 2022	3 May 2022 (F2022L00669)	4 May 2022	—
Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (Singapore) Determination 2022	8 Sep 2022 (F2022L01189)	9 Sep 2022	—
Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Class IIa and Class IIb) Determination 2023	16 Oct 2023 (F2023L01382)	17 Oct 2023	—
Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination 2024	24 Jun 2024 (F2024L00760)	1 July 2024	—
Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination (No. 2) 2024	18 Oct 2024 (F2024L01328)	19 Oct 2024	—
Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination (No. 3) 2024	17 Dec 2024 (F2024L01674)	18 Dec 2024	—
Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination 2025	30 Oct 2025 (F2025L01322)	1 Dec 2025	—

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Endnote 4—Amendment history

Provision affected	How affected
s 2	rep LA s 48D
s 3	am F2019L00589
s 4	am F2018L01822; F2019L00589; F2020L01528; F2021L00582; F2021L01091; F2022L01189; F2023L01382; F2024L00760; F2024L01674; F2025L01322
s 5	am F2020L01236; F2021L00582; F2021L01091; F2024L00760; F2024L01328
s 6	am F2020L01236; F2020L01528; F2021L00582; F2024L01674
s 6A	ad F2021L00582
s 7	am F2020L01236; F2021L00582
s 8	am F2020L01236
s 9	am F2020L01236; F2020L01528
	rs F2021L00582
Schedule 1	
Part 1	
Part 1	am F2020L01236; F2025L01322
Part 2	
Part 2	am F2022L01189; F2023L01382; F2024L00760; F2024L01328; F2025L01322
Part 3	
Part 3	am F2022L01189; F2023L01382; F2024L00760; F2025L01322
Part 4	
Part 4	am F2024L01328; F2025L01322
Division 1	
Division 1 heading	ad F2021L01091
	rep F2024L00760
Division 1	am F2022L01189; F2024L00760
Division 2	
Division 2	ad F2021L01091
	rep F2024L00760
Part 5	
Division 1	
Division 1 heading	ad F2021L01091
	rep F2024L00760
Division 1	am F2022L01189
	rep F2024L00760
Division 2	
Division 2 heading	ad F2021L01091
	rep F2024L00760
Division 2	rep F2024L00760

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Provision affected	How affected
Schedule 2	
Part 1A	ad F2020L01528
Part 1	am F2018L01822; F2019L00589; F2022L00669; F2022L01189; F2024L00760; F2024L01674; F2025L01322
Part 2	am F2018L01822; F2019L00589; F2022L00669; F2022L01189; F2024L00760; F2024L01674; F2025L01322
Part 3	am F2021L01091; F2024L00760; F2024L01674; F2025L01322
Schedule 2A	
Schedule 2A	ad F2021L00582
Schedule 3	
Part 1	
Part 1	am F2020L01236
Division 1	
Division 1 heading	am F2021L00582
Division 2	
Division 2 heading	rs F2021L00582
Part 2	
Part 2 heading	rs F2021L00582
Part 2	am F2025L01322

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