



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

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I, Hongxia Jin, as delegate of the Secretary of the Department of Health, make the following determination.

Dated 5 October 2018

(Signed by)

Hongxia Jin  
Acting Assistant Secretary  
Medical Devices Branch  
Health Products Regulation Group  
Department of Health

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## Contents

1 Name.....	1
2 Commencement .....	1
3 Authority.....	1
4 Definitions .....	1
5 Kind of information—medical devices other than IVD medical devices.....	4
6 Kind of information—IVD medical devices.....	6
7 Kind of information—medical devices used for a special purpose that are a system or procedure pack .....	7
8 Alternative kinds of information.....	8
9 Classes of medical device for which accompanying information is not determined.....	9
10 Form of information—all medical devices .....	9
<b>Schedule 1— Medical devices other than IVD medical devices</b>	<b>10</b>
<b>Part 1—Class I medical devices</b>	<b>10</b>
<b>Part 2—Class IIa medical devices</b>	<b>14</b>
<b>Part 3—Class IIb medical devices</b>	<b>19</b>
<b>Part 4—Class III medical devices</b>	<b>23</b>
<b>Part 5—Class AIMD medical devices</b>	<b>27</b>
<b>Schedule 2—IVD medical devices</b>	<b>31</b>
<b>Part 1—Class 2 IVD medical devices</b>	<b>31</b>
<b>Part 2—Class 3 IVD medical devices</b>	<b>33</b>
<b>Part 3—Class 4 IVD medical devices</b>	<b>35</b>
<b>Part 4—Class 4 in-house IVD medical devices</b>	<b>36</b>
<b>Schedule 3—Medical devices used for a special purpose that are a system or procedure pack</b>	<b>37</b>
<b>Part 1—All medical devices used for a special purpose that are a system or procedure pack</b>	<b>37</b>
<b>Part 2—Medical devices used for a special purpose that are a system or procedure pack that are intended to be supplied in a sterile state</b>	<b>38</b>



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## 1 Name

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

## 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
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 subsections 41FDB(7) and 41FDB(8) of the Act.

## 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*.

*active implantable medical device* or *AIMD* has the same meaning as in the Regulations.

*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.

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**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.

**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 2 IVD medical device** means a medical device that is classified under the Regulations as a Class 2 IVD medical device, other than a medical device used for a special purpose.

**Class 3 IVD medical device** means a medical device that is classified under the Regulations as a Class 3 IVD medical device, other than a medical device used for a special purpose.

**Class 4 IVD medical device** means a medical device that is classified under the Regulations as a Class 4 IVD medical device, other than a medical device used for a special purpose.

**Class 4 in-house IVD medical device** means a medical device that is classified, under the Regulations as a Class 4 in-house IVD medical device, other than a medical device used for a special purpose.

**Class I medical device** means a medical device that is classified, under the Regulations, as a Class I medical device, other than a medical device used for a special purpose.

**Class IIa medical device** means a medical device that is classified under the Regulations as a Class IIa medical device, other than a medical device used for a special purpose.

**Class IIb medical device** means a medical device that is classified under the Regulations as a Class IIb medical device, other than a medical device used for a special purpose.

**Class III medical device** means a medical device that is classified under the Regulations as a Class III medical device, other than a medical device used for a special purpose.

**Class AIMD medical device** means a medical device that is classified under the Regulations as a Class AIMD medical device, other than a medical device used for a special purpose.

**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.

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**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 immediately before the commencement of this instrument.

**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.

**in-house IVD medical device** 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.

**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 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.

**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 auditing organisation** means an organisation authorised to perform audits under the Medical Device Single Audit Program by the Regulatory Authority Council, in relation to that program, comprising the Australian Therapeutic Goods Administration, the United States Food and Drug Administration, the Brazilian Agência Nacional de Vigilância Sanitária, Health Canada, and 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*.

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

**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*

- (1) Subject to section 8, an application for a Class I 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 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) 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 IIa medical devices*

- (3) Subject to section 8, 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.



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*Class IIb medical devices*

- (5) Subject to section 8, an application for a Class IIb 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 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) Subject to section 8, 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; 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.
- (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.

*Class AIMD medical devices*

- (9) Subject to section 8, an application for a Class AIMD 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 5 of Schedule 1, 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.

(10) To avoid doubt:

- (a) an application may be accompanied by more than one document referred to in paragraph (9)(a), and its corresponding certificate or other document of product assessment referred to in paragraph (9)(b) (if any);
- (b) a document which accompanies the application in accordance with subsection (9) must relate to the kind of device to which the application relates.

## **6 Kind of information—IVD medical devices**

### *Class 2 IVD medical devices*

- (1) Subject to section 8, 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.
- (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) Subject to section 8, 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
  - (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);

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- (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) Subject to section 8, 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.
- (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) Subject to section 8, 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
  - (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.

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

- (1) An application for a medical device used for a special purpose that is a system or procedure pack, other than a system or procedure pack that is classified under the Regulations as:

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- (a) a class I medical device that does not have a measuring function and that the manufacturer intends to be supplied in a non-sterile state; or
  - (b) a class 1 IVD medical device;

must be accompanied by the following kind of information:

- (c) 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 1 of Schedule 3, which is issued or recognised by the regulatory authority in column 2 of that item; and
- (d) 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 subsection (2) must relate to the kind of device to which the application relates.

## **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 instead 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.

*IVD medical devices*

- (2) An application for an IVD medical device may instead 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.

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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) a Class I medical device that:
  - (i) the manufacturer intends to be supplied in a non-sterile state; and
  - (ii) does not have a measuring function;
- (b) a medical device that is intended by the manufacturer to be for export only;
- (c) a Class 1 IVD medical device;
- (d) an in-house IVD medical device other than a Class 4 in-house IVD medical device.

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

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	<p>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:</p> <ul style="list-style-type: none"> <li>(a) for a medical device that the manufacturer intends to be supplied in a sterile state (whether or not it has a measuring function): <ul style="list-style-type: none"> <li>(i) Part 1 (full quality assurance procedures), excluding clause 1.6 of that Part; or</li> <li>(ii) Part 4 (production quality assurance procedures);</li> </ul> </li> <li>(b) for a medical device that has a measuring function (and that the manufacturer intends to be supplied in a non-sterile state): <ul style="list-style-type: none"> <li>(i) Part 1 (full quality assurance procedures), excluding clause 1.6 of that Part;</li> <li>(ii) Part 3 (verification procedures);</li> <li>(iii) Part 4 (production quality assurance procedures); or</li> <li>(iv) Part 5 (product quality assurance procedures)</li> </ul> </li> </ul>	
2	a notified body within the meaning of Council Directive	<ul style="list-style-type: none"> <li>(a) for a medical device that the manufacturer intends to be supplied in a sterile state</li> </ul>	

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
	93/42/EEC	<p>(whether or not it has a measuring function), either of the following:</p> <ul style="list-style-type: none"> <li>(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</li> <li>(ii) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC;</li> </ul> <p>(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:</p> <ul style="list-style-type: none"> <li>(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;</li> <li>(ii) an EC verification certificate issued under Annex IV of Council Directive 93/42/EEC;</li> <li>(iii) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC; or</li> <li>(iv) a product quality assurance certificate or other document issued under Annex VI of Council Directive 93/42/EEC</li> </ul>	

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
3	a notified body within the meaning of Council Directive 90/385/EEC	<p>(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:</p> <p>(i) a complete quality assurance system certificate or other document issued under section 3 of Annex 2 of Council Directive 90/385/EEC; or</p> <p>(ii) an assurance of production quality certificate or other document issued under Annex 5 of Council Directive 90/385/EEC;</p> <p>(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:</p> <p>(i) a complete quality assurance system certificate or other document issued under section 3 of Annex 2 of Council Directive 90/385/EEC;</p> <p>(ii) an EC verification certificate issued under Annex 4 of Council Directive 90/385/EEC; or</p> <p>(iii) an assurance of production quality certificate or other document issued under Annex 5 of Council Directive 90/385/EEC</p>	
4	a notified body within the meaning of the EU medical	for a medical device that the manufacturer intends to be supplied in a sterile state and/or	



<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
	devices regulation	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 auditing organisation	for a medical device that the manufacturer intends to be supplied in a sterile state and/or that has a measuring function— a MDSAP certificate	

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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	<p>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:</p> <p>(a) for a medical device that the manufacturer intends to be supplied in a sterile state:</p> <p>(i) Part 1 (full quality assurance procedures), excluding clause 1.6 of that Part; or</p> <p>(ii) Part 4 (production quality assurance procedures);</p> <p>(b) for a medical device that the manufacturer intends to be supplied in a non-sterile state:</p> <p>(i) Part 1 (full quality assurance procedures), excluding clause 1.6 of that Part;</p> <p>(ii) Part 3 (verification procedures);</p> <p>(iii) Part 4 (production quality assurance procedures); or</p> <p>(iv) Part 5 (product quality assurance procedures)</p>	
2	a notified body within the meaning of Council Directive 93/42/EEC	<p>(a) for a medical device that the manufacturer intends to be supplied in a sterile state, either of the following:</p> <p>(i) a full quality assurance system certificate or other document issued under Annex II of Council Directive 93/42/EEC, excluding</p>	

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
		<p>section 4 of that Part; or</p> <p>(ii) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC;</p> <p>(b) for a medical device that the manufacturer intends to be supplied in a non-sterile state, one of the following:</p> <p>(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;</p> <p>(ii) an EC verification certificate issued under Annex IV of Council Directive 93/42/EEC;</p> <p>(iii) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC; or</p> <p>(iv) a product quality assurance certificate or other document issued under Annex VI of Council Directive 93/42/EEC</p>	
3	a notified body within the meaning of Council Directive 90/385/EEC	<p>(a) for a medical device that the manufacturer intends to be supplied in a sterile state, either of the following:</p> <p>(i) a complete quality assurance system certificate or other document issued under section 3 of Annex 2 of Council Directive 90/385/EEC; or</p> <p>(ii) an assurance of</p>	

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

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
		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	either of the following: (a) a MDSAP certificate; or (b) for an application submitted before 1 January 2019— a quality management system certificate for the purposes of the Canadian medical devices regulations	a Class II 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 granting a request for classification under section 513 of the US

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
			FDC Act (a De Novo classification request)

## Part 3—Class IIb medical devices

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer’s quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
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 Directive 93/42/EEC	(a) for a medical device that the manufacturer intends to be supplied in a sterile state: (i) a production quality assurance certificate or other document issued	an EC type-examination certificate issued under Annex III of Council Directive 93/42/EEC

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
		<p>under Annex V of Council Directive 93/42/EEC;</p> <p>(b) for a medical device that the manufacturer intends to be supplied in a non-sterile state, one of the following:</p> <p>(i) an EC verification certificate issued under Annex IV of Council Directive 93/42/EEC;</p> <p>(ii) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC; or</p> <p>(iii) a product quality assurance certificate or other document issued under Annex VI of Council Directive 93/42/EEC</p>	
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	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 of the EU medical devices regulation	<p>(a) for a medical device that the manufacturer intends to be 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</p>	an EU type-examination certificate issued under Annex X of the EU medical devices regulation



<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
		<p>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>	
8	Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency	<p>either of the following:</p> <p>(a) a MDSAP certificate; or</p> <p>(b) a quality management system certificate for the purposes of the Japanese PMD Act</p>	<p>either of the following:</p> <p>(a) a pre-market certification issued under the Japanese PMD Act; or</p> <p>(b) a pre-market approval issued under the Japanese PMD Act</p>
9	Health Canada	<p>either of the following:</p> <p>(a) a MDSAP certificate; or</p> <p>(b) for an application submitted before 1 January 2019—a quality management system certificate for the purposes of the Canadian medical devices regulations</p>	a Class III medical device licence issued under the Canadian medical devices regulations
10	United States Food and Drug Administration	a MDSAP certificate	<p>one of the following:</p> <p>(a) a determination of substantial equivalence made with respect to a notification submitted under section 510(k) of the US FDC Act;</p> <p>(b) an order granting a request for classification under</p>

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer’s quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
11	United States Food and Drug Administration	an order approving an application for premarket approval under section 515 of the US FDC Act	<p>section 513 of the US FDC Act (a De Novo classification request); or</p> <p>(c) an order approving an application for premarket approval under section 515 of the US FDC Act</p>

## Part 4—Class III medical devices

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
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: <ul style="list-style-type: none"> <li>(a) for a medical device that the manufacturer intends to be supplied in a sterile state: <ul style="list-style-type: none"> <li>(i) Part 4 (production quality assurance procedures);</li> </ul> </li> <li>(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"> <li>(i) Part 3 (verification procedures); or</li> <li>(ii) Part 4 (production quality assurance procedures)</li> </ul> </li> </ul>	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"> <li>(i) a production quality assurance certificate or</li> </ul>	an EC type-examination certificate issued under Annex III of Council Directive 93/42/EEC

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
		<p>other document issued under Annex V of Council Directive 93/42/EEC;</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) an EC verification certificate issued under Annex IV of Council Directive 93/42/EEC; or</p> <p>(ii) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC</p>	
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	<p>(a) for a medical device that the manufacturer intends to be supplied in a sterile state:</p> <p>(i) an assurance of production quality certificate or other document issued under Annex 5 of Council Directive 90/385/EEC;</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) an EC verification certificate issued under Annex 4 of Council Directive 90/385/EEC; or</p> <p>(ii) an assurance of production quality certificate or other</p>	an EC type-examination certificate issued under Annex 3 of Council Directive 90/385/EEC

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
		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
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	either of the following: (a) a MDSAP certificate; or	a Class IV medical device licence issued under the

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
		(b) for an application submitted before 1 January 2019—a quality management system certificate for the purposes of the Canadian medical devices regulations	Canadian medical devices regulations
11	United States Food and Drug Administration	a MDSAP certificate	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	

## Part 5—Class AIMD medical devices

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer’s quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
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: <ul style="list-style-type: none"> <li>(a) for a medical device that the manufacturer intends to be supplied in a sterile state: <ul style="list-style-type: none"> <li>(i) Part 4 (production quality assurance procedures)</li> </ul> </li> <li>(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"> <li>(i) Part 3 (verification procedures); or</li> <li>(ii) Part 4 (production quality assurance procedures)</li> </ul> </li> </ul>	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"> <li>(i) a production quality assurance certificate or</li> </ul>	an EC type-examination certificate issued under Annex III of Council Directive 93/42/EEC

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
		<p>other document issued under Annex V of Council Directive 93/42/EEC;</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) an EC verification certificate issued under Annex IV of Council Directive 93/42/EEC; or</p> <p>(ii) a production quality assurance certificate or other document issued under Annex V of Council Directive 93/42/EEC</p>	
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	<p>(a) for a medical device that the manufacturer intends to be supplied in a sterile state:</p> <p>(i) an assurance of production quality certificate or other document issued under Annex 5 of Council Directive 90/385/EEC;</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) an EC verification certificate issued under Annex 4 of Council Directive 90/385/EEC; or</p> <p>(ii) an assurance of production quality certificate or other document issued under</p>	an EC type-examination certificate issued under Annex 3 of Council Directive 90/385/EEC



<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
		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
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	either of the following: (a) a MDSAP certificate; or (b) for an application submitted before 1 January 2019—a	a Class IV medical device licence issued under the Canadian medical devices regulations

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
		quality management system certificate for the purposes of the Canadian medical devices regulations	
11	United States Food and Drug Administration	a MDSAP certificate	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	

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## Schedule 2—IVD medical devices

Note: See section 6.

### Part 1—Class 2 IVD medical devices

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
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	either 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; or (b) a production quality assurance certificate or other document issued under Annex VII of Directive 98/79/EC	
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	
4	Health Canada	either of the following: (a) a MDSAP certificate; or (b) for an application submitted before 1 January 2019—a quality management system certificate for the purposes of the Canadian medical devices regulations	a Class II medical device licence issued under the Canadian medical devices regulations

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
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 auditing organisation	a MDSAP certificate	

## Part 2—Class 3 IVD medical devices

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
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	a full quality assurance system certificate or other document issued under section 3 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	
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
7	Health Canada	either of the following: (a) a MDSAP certificate; or (b) for an application submitted before 1 January 2019—a quality management system	a Class III medical device licence issued under the Canadian medical devices regulations

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
		certificate for the purposes of 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	
10	recognised auditing organisation	a MDSAP certificate	

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## Part 3—Class 4 IVD medical devices

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer’s quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
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)

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## Part 4—Class 4 in-house IVD medical devices

<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document or other evidence relating to manufacturer’s quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
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 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

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<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Declaration of conformity in relation to the system or procedure pack</b>	<b>Column 4 Conformity assessment document in relation to each medical device</b>
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—Medical devices used for a special purpose that are a system or procedure pack that are intended to be supplied in a sterile state

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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
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;	
4	a notified body within the meaning	either of the following: (a) an EU quality management	

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<b>Column 1 Item</b>	<b>Column 2 Regulatory authority</b>	<b>Column 3 Conformity assessment document relating to manufacturer's quality management system</b>	<b>Column 4 Conformity assessment document relating to product assessment</b>
	of the EU medical devices regulation	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 auditing organisation	a MDSAP certificate	