



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Use of market authorisation evidence from comparable overseas regulators for medical devices (including IVDs)

To abridge TGA conformity assessments and
for ARTG inclusion applications

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Introduction

The Therapeutic Goods Administration (TGA) recognises and relies on a range of marketing approvals of medical devices, including IVD medical devices, where the device has been:

- assessed by a body that has been designated by a comparable overseas authority; or
- approved by a comparable overseas regulator.

This guidance

This document gives an overview of the specific comparable overseas regulator assessments and approvals that applicants:

- can use to support abridged assessment of an application for a TGA conformity assessment certificate
- must provide with applications for inclusion of medical devices (including IVDs) in the ARTG.

Please note

These arrangements are prescribed by the following instruments:

- [Therapeutic Goods \(Overseas Regulators\) Determination 2022](#)
- [Therapeutic Goods \(Medical Devices—Information that Must Accompany Application for Inclusion\) Amendment Determination \(No. 3\) 2024](#)

In case of any inconsistencies between instruments (including future amendments) and this guidance, the instruments are in force and should be followed.



Overseas evidence that can be considered

The TGA will consider the following specific evidence and documentation issued by comparable overseas regulators:

- Certificates issued by Notified Bodies under the medical device regulatory frameworks of the European Union ([Medical Device Directives 93/42/EEC and 90/385/EEC](#), [IVD Directive 98/79/EC](#), [Medical Device Regulation](#), or [IVD Regulation](#))
- Premarket approval and 510K decisions of the United States Food and Drug Administration (FDA)
- Approvals and medical device licences issued by Health Canada
- Pre-market approvals or certification from Japan (issued by the Ministry of Health, Labour and Welfare (MHLW), Pharmaceutical and Medical Devices Agency (PMDA))
- Registrations or approvals of the Singapore Health Sciences Authority (HSA)
- ISO 13485 certificates issued by a certification body that is also a Notified Body designated under the IVDD 98/79/EC, submitted with an EU Declaration of Conformity made by the manufacturer before 26 May 2022 under Annex III of IVDD 98/79/EC (for Class 2 IVD applications submitted before 26 May 2027 and Class 3 IVD applications submitted before 26 May 2026).
- ISO 13485 certificates issued by a body that is accredited by a signatory to the Multilateral Recognition Arrangement of the International Accreditation Forum (IAF MLA) submitted with an EU Declaration of Conformity made by the manufacturer before 26 May 2022 under Annex III of IVDD 98/79/EC (for Class 2 IVD applications submitted before 26 May 2027 and Class 3 IVD applications submitted before 26 May 2026).

- Certificates issued by Approved Bodies under the United Kingdom Medical Device Regulations 2002 ([Council Directive 93/42/EEC concerning medical devices](#), [Council Directive relating to active implantable medical devices 90/385/EEC](#), [Directive 98/79/EC on in vitro medical devices](#))
- Certificates and reports issued under the Medical Device Single Audit Program (MDSAP).



For MDSAP certificates and audit reports to be considered, the Australian regulatory requirements must have been covered in the audits, and certificates must show that the manufacturer has been assessed and found to comply with the relevant aspects of the *Therapeutic Goods (Medical Devices) Regulations 2002*

The documentation should be issued by a comparable overseas regulator for the same medical device or medical device group you are applying for. The device must:

- have the same design, intended purpose and user
- be intended for the same indications.

Table 1 and Table 2 in this guidance specify what documentation can be used for what purpose:

- [Table 1 – Documents to abridge TGA conformity assessment](#)
- [Table 2 – Information needed for ARTG inclusion applications](#)

Application requirements

Reduced assessment fees for medical devices

The TGA may reduce assessment fees for application audit assessments and conformity assessments in some cases. Please see: [Reduction of assessment fees for medical devices](#) for information about the eligibility requirements and procedures.

How to use this section

The requirements are divided into two parts:

- [Part A – Abridgement of TGA conformity assessment applications](#)
- [Part B – Applications for ARTG inclusion](#)

Part A – Abridged TGA conformity assessment

Evidence of conformity assessment needs to demonstrate that a manufacturer's quality management system meets certain regulatory requirements, and that their devices comply with the relevant essential principles. An acceptable comparable overseas regulator audit report or product evaluation report may contain information that will help to demonstrate that these requirements are met.

For the possible abridgement of a TGA conformity assessment application, you may provide certain documents from specified overseas assessment bodies. The TGA may be able to reduce the amount of assessment that it must undertake on the application.

Requirements when relying on overseas approvals or assessments

[Table 1](#) outlines the documents that can be provided against the relevant conformity assessment procedures. This includes MDSAP reports, which can be considered when assessing a conformity assessment application.

How to use Table 1

Example A – Initial application for TGA conformity assessment certificate using overseas initial audit evidence

An application for a:

- Part 1 Full Quality Management System (QMS) certificate for a manufacturer of medical devices requires:
 - a Design and Production QMS assessment
 - that the manufacturer has an EU Medical Device Directive (MDD) Full Quality Assurance (FQA) audit report (issued by an EU notified body or UK approved body)
 - that the FQA audit report is an initial audit report that covers the same manufacturing sites and device categories as your application.

TGA Conformity Assessment Procedure		Comparable Overseas Regulator / Assessment Body evidence which can be provided for abridgement			
		Product Assessment	Initial Audit	Surveillance Audit (Annual)	Re-audit (new certification cycle)
Part 1 – Full QMS	1.3		<ul style="list-style-type: none"> • EU MDD/IVDD/AIMDD Full Quality Assurance (FQA) Audit Report • EU MDR/IVDR Quality Management System Audit Report • MDSAP³ Audit Report 	<ul style="list-style-type: none"> • MDSAP² Audit Report or • EU MDD/IVDD/AIMDD FQA Audit Report or • EU MDR/IVDR Audit Report <p>Accepted in place of a TGA surveillance assessment (with a satisfactory audit scope and in the absence of safety signals)</p> <p>Considered along with a Re-audit for the purposes of TGA recertification (5 year cycle)</p>	<ul style="list-style-type: none"> • MDSAP² Audit Report or • EU MDD/IVDD/AIMDD FQA Audit Report or • EU MDR/IVDR Audit Report <p>Accepted in place of a TGA surveillance assessment (with a satisfactory audit scope and in the absence of safety signals)</p>
	Design and Production QMS Assessment (Initial, and Recertification)				

You may provide the FQA audit report to the TGA with the supporting documentation for the application.

If a sufficiently detailed report is provided, then we may be able reduce the assessment by undertaking a desk assessment of the QMS instead of an on-site audit.

Example B – Initial application for TGA conformity assessment certificate using overseas re-audit evidence

An application for a:

- Part 1 Full Quality Management System (QMS) certificate for a manufacturer of medical devices requires:
 - a Design and Production QMS assessment
 - that the manufacturer has an EU Medical Device Directive (MDD) Full Quality Assurance (FQA) audit report (issued by an EU notified body or UK approved body)
 - That the FQA audit report is a recertification audit report (re-audit) that covers the same manufacturing sites and device categories as your application.

TGA Conformity Assessment Procedure		Comparable Overseas Regulator / Assessment Body evidence which can be provided for abridgement			
		Product Assessment	Initial Audit	Surveillance Audit (Annual)	Re-audit (new certification cycle)
Part 1 – Full QMS	1.3 Design and Production QMS Assessment (Initial, and Recertification)		<ul style="list-style-type: none"> EU MDD/IVDD/AIMDD Full Quality Assurance (FQA) Audit Report EU MDR/IVDR Quality Management System Audit Report MDSAP³ Audit Report 	<ul style="list-style-type: none"> MDSAP² Audit Report or EU MDD/IVDD/AIMDD FQA Audit Report or EU MDR/IVDR Audit Report <p>Accepted in place of a TGA surveillance assessment (with a satisfactory audit scope and in the absence of safety signals)</p> <p>Considered along with a Re-audit for the purposes of TGA recertification (<u>5 year</u> cycle)</p>	<ul style="list-style-type: none"> MDSAP² Audit Report or EU MDD/IVDD/AIMDD FQA Audit Report or EU MDR/IVDR Audit Report <p>Accepted in place of a TGA surveillance assessment (with a satisfactory audit scope and in the absence of safety signals)</p>

You may provide the FQA audit report (re-audit) to the TGA with the supporting documentation for the application.

If a sufficiently detailed report is provided, then we may be able reduce the assessment by undertaking a desk assessment of the QMS instead of an on-site audit.

Example C – Assessing substantial change to a TGA Production QMS Certificate

You have a current TGA Part 4 Production QMS certificate and:

- have applied for the assessment of a substantial change
- the manufacturer has an MDSAP Audit Report for a surveillance audit that includes assessment of the change.

TGA Conformity Assessment Procedure		Comparable Overseas Regulator / Assessment Body evidence which can be provided for abridgement			
		Product Assessment	Initial Audit	Surveillance Audit (Annual)	Re-audit (new certification cycle)
Part 4 – Production QMS	4.5 Assessment of changes to Production QMS			<ul style="list-style-type: none"> EU MDD FQA Audit Report or EU MDR/IVDR Audit Report or MDSAP Audit Report <p>Considered for the purposes of abridging TGA's assessment of the change.</p>	<ul style="list-style-type: none"> EU MDD FQA Audit Report or EU MDR/IVDR Audit Report or MDSAP Audit Report <p>Considered for the purposes of abridging TGA's assessment of the change.</p>

You may provide the audit report to the TGA with the supporting documentation for the application.

If the report is sufficiently detailed and the change has been assessed as satisfactory by the assessment body, then we may be able to abridge the assessment of the change.

Part B – Applications for ARTG inclusion

Any application for inclusion of a medical device in the ARTG must include certain information as required in the application form. Also, certain information must accompany the application to pass *preliminary assessment*. If an application does not pass *preliminary assessment*, it will be refused.

The [Therapeutic Goods \(Medical Devices—Information that Must Accompany Application for Inclusion\) Determination 2018](#) (as amended) sets out what documentation must be provided with an application for inclusion to pass preliminary assessment. This information is summarised in [Table 2](#).

Depending on the category and classification of a medical device, sponsors can choose certain documents from comparable overseas regulators or assessment bodies to meet the requirements for:

- Manufacturer Evidence (must be submitted, assessed and accepted before you apply for your device to be included in the ARTG), and
- evidence of product assessment (must be attached to your application for ARTG inclusion).

All information that accompanies an application for inclusion in the ARTG must be either:

- in English; or
- if it is not in English – be accompanied by a certified translation into English.

Please note:

Applications for ARTG inclusion of certain medical devices, including IVDs, supported by certain comparable overseas regulator or assessment body approvals, must be selected for audit (refer to [Regulation 5.3](#)).

The TGA may also select any other application for inclusion of a medical device in the ARTG for non-mandatory audit, for example, where there are known issues with the performance or the use of the device in question.

The level of audit assessment may depend on the category or class of the medical device, and the comparable overseas regulator evidence provided with the application.



Sponsors can ask for reduced audit assessment fees if the audit can be abridged (including, for example, requests to abridge assessments from Level 2 to Level 1 audit if appropriate). In such cases sponsors need to provide brief justifications supporting their requests for the TGA delegate to consider.

The [guidance on requests for abridged assessment](#) is available on the TGA website.

We have provided [some examples](#) on the TGA website on the expected level of audit assessment for different devices with different conformity assessment documents.



Requirements when relying on overseas approvals or assessments

[Table 2](#) provides a list of the documents that are required for different classes of medical devices.

How to use Table 2

Please review the list of *conformity assessment documents* provided in Table 2 for your class of medical device.

The categories of documents included as the *Manufacturer Evidence* and the *Evidence of product assessment* attached with your ARTG inclusion application, must appear in the same line in Table 2.



Example A – Class Is medical device

If you apply for inclusion in the ARTG of a Class I medical device intended to be supplied sterile (Class Is), and the manufacturer provided you with a copy of their Certificate issued by one of the

European Notified Bodies, or by a UK approved body, under EU MDD 93/42/EEC, the following documents will be required.

Manufacturer Evidence

The Certificate issued under either Annex II.3 or Annex V must be submitted as your Manufacturer Evidence (Certificate issued under Annex IV or Annex VI is not appropriate evidence for Class Is medical devices).

Device Classification	Regulators / Approvals		Manufacturer Evidence (QMS Certificate)
Class Is or Im (supplied in a sterile state or with measuring function) (Regulation 3.9(2) and 3.9(3))	EU	EU MDD 93/42/EEC ⁴	<ul style="list-style-type: none"> Annex II.3, or Annex IV (specific batches are included on the certificate) (not applicable for Class Is), or Annex V, or Annex VI ('metrology aspects' or equivalent wording) (not applicable for Class Is)

Documentation that must be provided with the application for inclusion of your medical device in ARTG

The next part of the table lists the documentation that you must provide with the application for ARTG inclusion of your medical device.

In this case, there is no additional information which needs to be provided.

Example B – Class IIb medical device

If you apply for inclusion of a Class IIb medical device in the ARTG, and the manufacturer holds a MDSAP Certificate for their quality management system (QMS) and product approvals from FDA or Health Canada, you will be required to submit these documents as specified below.

Manufacturer Evidence

The MDSAP Certificate issued to the manufacturer of the device must be submitted as Manufacturer Evidence.



Please note

The MDSAP certificate must be issued to the manufacturer stated on the labelling and instructions for use as the manufacturer of the kind of device for which you submitted your application for inclusion in the ARTG.

Device Classification	Regulators / Approvals		Manufacturer Evidence (QMS Certificate)
Class IIb (Regulation 3.7)	Health Canada	MDR SOR/98-282 ²	<ul style="list-style-type: none"> MDSAP Certificate
	FDA	DeNovo ³	<ul style="list-style-type: none"> MDSAP Certificate
		Premarket Notification - 510(k)	
		Premarket Approval (PMA)	<ul style="list-style-type: none"> MDSAP Certificate (or PMA)

Evidence of product assessment that must be provided with the application for inclusion of your medical device in ARTG

In this case, the documentation that you must provide with the application for ARTG inclusion of your medical device must include the following:

From

- **Health Canada:** Medical device licence Class III,
- or**
- **US FDA:** De Novo Decision Summary, or 510(k) Summary, or Premarket Approval (PMA).

Device Classification	Regulators / Approvals		Documentation that must be provided with the application (Evidence of product assessment)
Class IIb (Regulation 3.7)	Health Canada	MDR SOR/98-282 ^b	Medical device licence Class III
	FDA	DeNovo ^d	De Novo Decision Summary
		Premarket Notification - 510(k)	510(k) – Summary
		Premarket Approval (PMA)	PMA

Please note



Applications for ARTG inclusion of Class IIb devices may be selected for a non-mandatory application audit. The TGA encourages applicants to have and be able to provide the relevant supporting documentation which underpins approvals of these devices. Applicants should also have available clinical evidence to support the device’s intended purpose and claims and be able to provide that to the TGA on request.

Example C – Class 3 IVD medical device

If you apply for ARTG inclusion of a Class 3 IVD medical device in the ARTG and the manufacturer provided you with a copy of their certification issued by one of the European Notified Bodies under EU IVD [Regulation \(EU\) 2017/746](#) , the following documents will be required.

Manufacturer Evidence

The certification issued under Annex IX, Chapter 1 or Annex XI excluding section 5, must be submitted as your Manufacturer Evidence.

Device Classification	Regulators / Approvals		Manufacturer Evidence (QMS Certificate)	Documentation that must be provided with the application (Evidence of product assessment)
Class 3 IVD (Regulation 3.7A)	TGA	CAC – MD Regulations Schedule 3 ⁴	Part 1 – Full Quality Assurance (excluding clause 1.6 Design Examination)	N/A
			Part 4 – Production Quality Assurance	Part 2 – Type Examination
	EU	IVDD 98/79/EC in vitro diagnostic medical devices ¹³	Annex IV.3	N/A
			Annex VII	Annex V – Type Examination
		EU IVD regulations ¹⁴	Annex IX (QMS) Chapter I	Assessment of the technical documentation as specified in Section 4 of Annex IX for at least one representative device per generic device group. Annex IX, Chapter II (at least one representative device per group). For self-testing and near-patient testing: Assessment of Technical documentation set out in Section 5.1. For companion diagnostics: Assessment of Technical Documentation set out in section 5.2
			Annex XI (Production Quality Assurance) except Section 5	Annex X –Type Examination

Evidence of product assessment that must be provided with the application for inclusion of your medical device in ARTG

If you provide a certification issued under Annex IX, Chapter 1 of EU IVDR, you must also provide evidence of product assessment under Annex IX Section 4, and for self-tests and companion diagnostics there is additional requirements under Annex IX, Section 5.1 and 5.2, respectively depending on the device.

Device Classification	Regulators / Approvals		Manufacturer Evidence (QMS Certificate)	Documentation that must be provided with the application (Evidence of product assessment)
Class 3 IVD (Regulation 3.7A)	TGA	CAC – MD Regulations Schedule 3 ⁴	Part 1 – Full Quality Assurance (excluding clause 1.6 Design Examination)	N/A
			Part 4 – Production Quality Assurance	Part 2 – Type Examination
	EU	IVDD 98/79/EC in vitro diagnostic medical devices ¹³	Annex IV.3	N/A
			Annex VII	Annex V – Type Examination
		EU IVD regulations ¹⁴	Annex IX (QMS) Chapter I	Assessment of the technical documentation as specified in Section 4 of Annex IX for at least one representative device per generic device group. Annex IX, Chapter II (at least one representative device per group). For self-testing and near-patient testing: Assessment of Technical documentation set out in Section 5.1. For companion diagnostics: Assessment of Technical Documentation set out in section 5.2
			Annex XI (Production Quality Assurance) except Section 5	Annex X –Type Examination

Examples of product evidence can be the Performance Assessment Evaluation Report (PEAR), Technical Documentation Assessment Report (TDAR) provided by the notified bodies. For Class 3 devices, the PEAR and TDAR can be attached to the application for inclusion to facilitate preliminary assessment.

It is encouraged that applicants submit the instruction for use (IFU) of the device as part of the inclusion application, as this item can also help expedite the preliminary assessment.

Table 1: Documents to abridge TGA conformity assessment

For TGA-Issued Conformity Assessment Certificates

TGA Conformity Assessment Procedure		Comparable Overseas Regulator / Assessment Body evidence which can be provided for abridgement			
		Product Assessment	Initial Audit	Surveillance Audit (Annual)	Re-audit (new certification cycle)
Part 1 – Full QMS The TGA must certify the design and the full QMS as a “single decision maker” for the Part 1 CA procedure	1.3 Design and Production QMS Assessment (Initial, and Recertification)		MDSAP audit report or EU MDD/IVDD/AIMDD Full Quality Assurance (FQA) audit report or EU MDR/IVDR Quality Management System audit report or UK MDD/IVDD/AIMDD full quality assurance (UKCA) audit report issued by a UK approved body	MDSAP audit report or EU MDD/IVDD/AIMDD FQA audit report or EU MDR/IVDR audit report or UK MDD/IVDD/AIMDD full quality assurance (UKCA) audit report issued by a UK approved body Accepted in place of a TGA surveillance assessment (with a satisfactory audit scope and in the absence of safety signals) Considered along with a Re-audit for the purposes of TGA recertification (5 year cycle)	MDSAP audit report or EU MDD/IVDD/AIMDD FQA audit report or EU MDR/IVDR audit report or UK MDD/IVDD/AIMDD full quality assurance (UKCA) audit report issued by a UK approved body Accepted in place of a TGA surveillance assessment (with a satisfactory audit scope and in the absence of safety signals)
	1.5 Assessment of changes to the Design and Production QMS			MDSAP audit report or EU MDD/IVDD/AIMDD FQA audit report or EU MDR/IVDR audit report or UK MDD/IVDD/AIMDD full quality assurance (UKCA) audit report issued by a UK approved body Considered for the purposes of abridging TGA’s assessment of the change.	MDSAP audit report or EU MDD/IVDD/AIMDD FQA audit report or EU MDR/IVDR audit report or UK MDD/IVDD/AIMDD full quality assurance (UKCA) audit report issued by a UK approved body Considered for the purposes of abridging TGA’s assessment of the change.
	1.6 Examination of the design	PMA (US FDA) MDL (Health Canada) Product Certification (PMDA) EU MDD/AIMDD Annex II.4 report EU MDR/IVDR Annex IX – EU technical documentation report UK MDR 2002 Council Directive 93/42/EEC Annex II.4 report UK MDR 2002 Council Directive 90/385/EEC Annex 2.4 report EU IVDD Annex IV.4 report UK MDR 2002 Directive 98/79/EC Annex IV.4 report			

TGA Conformity Assessment Procedure		Comparable Overseas Regulator / Assessment Body evidence which can be provided for abridgement			
		Product Assessment	Initial Audit	Surveillance Audit (Annual)	Re-audit (new certification cycle)
Part 2 – Type Examination	2.3 Examination of the Type	EU MDD Annex III report EU MDR/IVDR Annex X – EU type-examination report			
	2.4 Examination of changes to the Type	UK MDR 2002 Council Directive 93/42/EEC Annex III report EU IVDD Annex V report UK MDR 2002 Directive 98/79/EC Annex V report EU AIMDD Annex 3 report UK MDR 2002 Council Directive 90/385/EEC Annex 3 report			
Part 3 – Verification	3.3 100% or Batch Verification				
Part 4 – Production QMS	4.3 Production QMS Assessment		EU MDD/IVDD/AIMDD Full Quality Assurance (FQA) or Production Quality Assurance (PQA) audit report or EU MDR/IVDR Quality Management System audit report or UK MDD/IVDD/AIMDD (UKCA) quality management system audit report issued by a UK approved body or MDSAP audit report	EU MDD/IVDD/AIMDD FQA audit report or EU MDD PQA audit report or EU MDR/IVDR audit report or UK MDD/IVDD/AIMDD (UKCA) quality management system audit report issued by a UK approved body or MDSAP audit report Accepted in place of a TGA surveillance assessment (with a satisfactory audit scope and in the absence of safety signals) Considered along with a Re-audit for the purposes of TGA recertification (5 year cycle)	EU MDD/IVDD/AIMDD FQA audit report or EU MDD PQA audit report or EU MDR/IVDR audit report or UK MDD/IVDD/AIMDD (UKCA) quality management audit report issued by a UK approved body or MDSAP audit report Accepted in place of a TGA surveillance assessment (with a satisfactory audit scope and in the absence of safety signals)
	4.5 Assessment of changes to Production QMS			EU MDD FQA audit report or EU MDR/IVDR audit report or UK MDD/IVDD/AIMDD (UKCA) quality management system audit report issued by a UK approved body or MDSAP audit report Considered for the purposes of abridging TGA's assessment of the change.	EU MDD FQA audit report or EU MDR/IVDR audit report or UK MDD/IVDD/AIMDD (UKCA) quality management system audit report issued by a UK approved body or MDSAP audit report Considered for the purposes of abridging TGA's assessment of the change.
Part 5 – Product QMS	5.3 Product QMS Assessment				
	5.5 Assessment of changes to Product QMS				

Notes on use of MDSAP evidence:

1. MDSAP Certificates are issued to **Manufacturers**, those legal entities that take responsibility for design, production, packaging and labelling etc. before placing on the market under their own name.
2. MDSAP Reports are prepared for medical device organisations (**Sites**), including the sites of the manufacturer, that are audited. A site is variously defined in Brazilian, Japanese and US regulations as a location that undertakes specific types of activities related to the manufacture of a medical device. (that is, a step-in manufacture of a medical device).
3. An MDSAP report may relate to a **Site that is within the scope of a Manufacturer's QMS**, or may relate to a **Supplier** to a Manufacturer. The TGA expects that a manufacturer is responsible for all aspects of the QMS related to their device. An MDSAP Report shall similarly account for all aspects of the Manufacturer's QMS.
4. The TGA can only use certificates and reports that relate to **Manufacturers**.
5. If a manufacturer chooses to apply a CA procedure for a higher class of medical device, the criteria for accepting MDSAP reports or certification applies as if the device was classified at that higher class.
6. MDSAP reports must contain evidence of the extent to which requirements have been fulfilled; in particular, for critical processes that will determine whether a product complies with the Essential Principles. The Australian regulatory requirements must have been covered in the audits, and certificates must show that the manufacturer has been assessed and found to comply with the relevant aspects of the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Table 2: Information needed for ARTG inclusion applications

Device Classification	Regulators / Approvals	Manufacturer Evidence (QMS Certificate)	Documentation that must be provided with the application (Evidence of product assessment)
Medical Devices (not including IVDs)			
Class I non-sterile, non-measuring (Regulation 3.9(1))	TGA	Declaration of conformity made under clause 6.6 of Schedule 3 of MD Regulations	N/A
Class I Procedure Pack or System Regulation 3.10(1)9d) or (e) whatever is relevant	TGA	Declaration of conformity made under clause 7.5 of Schedule 3 of MD Regulations	N/A
Class I Export only	TGA	N/A	N/A
Class Is or Im (supplied in a sterile state or with measuring function) (Regulation 3.9(2) and 3.9(3))	TGA	CAC – MD Regulations Schedule 3 ¹	N/A
	EU	EU MDD 93/42/EEC ²	

¹ TGA conformity assessment certificate issued under Schedule 3 of the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

² EC Certificate issued under [Council Directive 93/42/EEC of 14 June 1993 concerning medical devices](#)

Device Classification	Regulators / Approvals		Manufacturer Evidence (QMS Certificate)	Documentation that must be provided with the application (Evidence of product assessment)
		EU 90/385/EEC (AIMDD) for AIMD ³	Annex 2.3, or Annex 4 (for non-sterile devices where specific batches are included on the certificate), or Annex 5	
		EU MDR ⁴	Limited to establishing and maintaining sterility; or conformity with metrological requirements; or aspects related to reuse of the device: Annex IX, Chapter I (QMS) Annex XI (Product Conformity Verification), Part A	
	UK	UK MDR 2002 under applied directive 93/42 ⁵ (MDD)	Annex II.3, or Annex IV (specific batches are included on the certificate) (not applicable for Class Is), or Annex V, or Annex VI ('metrology aspects' or equivalent wording) (not applicable for Class Is)	N/A
		UK MDR 2002 under applied directive 90/385 ⁶ (AIMDD)	Annex 2.3, or Annex 4 (for non-sterile devices where specific batches are included on the certificate), or Annex 5	N/A
	MDSAP		MDAP Certificate	
Class IIa (Regulation 3.8)	TGA	CAC – MD Regulations Schedule 3 ¹	Part 1 – Full Quality Assurance (excluding clause 1.6 Design Examination), or Part 3 – Verification (for non-sterile devices), or Part 4 – Production Quality Assurance, or Part 5 – Product Quality Assurance (for non-sterile devices)	N/A
	EU	EU MDD 93/42/EEC ²	Annex II.3, or Annex IV (for non-sterile devices where specific batches are included on the certificate), or Annex V, or Annex VI (for non-sterile devices)	N/A

³ EC Certificate issued under [Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices](#)

⁴ EC Certificate issued under [Regulation \(EU\) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices](#), amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

⁵ UK Certificate issued under [Council Directive 93/42/EEC of 14 June 1993](#) (Medical Devices Directive) as adopted from the EU

⁶ UK Certificate issued under [Council Directive 90/385/EEC of 20 June 1990](#) (AIMD Directive) as adopted from the EU

Device Classification	Regulators / Approvals		Manufacturer Evidence (QMS Certificate)	Documentation that must be provided with the application (Evidence of product assessment)
		EU 90/385/EEC (AIMDD) for AIMD ³	Annex 2.3, or Annex 4 (for non-sterile devices where specific batches are included on the certificate), or Annex 5	N/A
		EU MDR ⁴	Annex IX, Chapter I (QMS), or Production quality assurance certificate issued under Part A of Annex XI, or Product verification certificate issued under Part B of Annex XI (for non-sterile devices)	N/A
	UK	UK MDR 2002 under applied directive 93/42 ⁵ (MDD)	Annex II.3, or Annex IV (for non-sterile devices where specific batches are included on the certificate), or Annex V, or Annex VI (for non-sterile devices)	N/A
		UK MDR 2002 under applied directive 90/385 ⁶ (AIMDD)	Annex 2.3, or Annex 4 (for non-sterile devices where specific batches are included on the certificate), or Annex 5	N/A
	Japan	Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency	QMS certificate, or MDSAP Certificate	Pre-market certificate
	Health Canada	MDR SOR/98-282 ⁷	MDSAP Certificate	Medical device licence Class II
	FDA	DeNovo	MDSAP Certificate	De Novo Decision Summary
		Premarket Notification – 510(k)	MDSAP Certificate	510(k) - Summary
		Exempted from 510(K) requirements		Evidence of 510(K) exemption (a statement that includes the device name or description, regulation number and submission type under United States Food and Drug Administration requirements)

⁷ Certificate or licence issued under the [Canadian Medical Devices Regulations \(SOR/98-282\)](#)

Device Classification	Regulators / Approvals		Manufacturer Evidence (QMS Certificate)	Documentation that must be provided with the application (Evidence of product assessment)
	Singapore	Health Sciences Authority	Extract from, or copy of, the entry in the Singapore Register of Health Products as a Class B medical device	N/A
Class IIb (Regulation 3.7)	TGA	CAC - MD Regulations Schedule 3 ¹	Part 1 – Full Quality Assurance (excluding clause 1.6 Design Examination)	N/A
			Part 3 – Verification (for non-sterile devices), or Part 4 – Production Quality Assurance, or Part 5 – Product Quality Assurance (for non-sterile devices)	Part 2 – Type Examination
	EU	EU MDD 93/42/EEC ²	Annex II.3	N/A
			Annex IV (for non-sterile devices where specific batches are included on the certificate), or Annex V, or Annex VI (for non-sterile devices)	Annex III – Type Examination
			Annex 2.3	N/A
			Annex IX, Chapter I (QMS)	For a relevant implantable medical device ⁸ —an EU technical documentation assessment certificate issued under Chapter II of Annex IX of the EU medical devices regulation
	UK	UK MDR 2002 under applied directive 93/42 ⁵ (MDD)	Annex II.3	N/A
			Annex IV (for non-sterile devices where specific batches are included on the certificate), or Annex V, or Annex VI (for non-sterile devices)	Annex III – Type Examination
		UK MDR 2002 under applied directive 90/385 ³ (AIMDD)	Annex 2.3	N/A

⁸ **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.

Device Classification	Regulators / Approvals		Manufacturer Evidence (QMS Certificate)	Documentation that must be provided with the application (Evidence of product assessment)
	Japan	Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency	QMS certificate, or MDSAP Certificate	Pre-market certificate
	Health Canada	MDR SOR/98-282 ⁷	MDSAP Certificate	Medical device licence Class III
	FDA	DeNovo	MDSAP Certificate	De Novo Decision Summary
		Premarket Notification - 510(k)		510(k) – Summary
		Premarket Approval (PMA)	MDSAP Certificate (or PMA)	PMA
Singapore	Health Sciences Authority (HSA)	Extract from, or copy of, the entry in the Singapore Register of Health Products as a Class C medical device	N/A	
Class III (Regulation 3.6)	TGA	CAC – MD Regulations Schedule 3 ¹	Part 1 – Full Quality Assurance (excluding clause 1.6 Design Examination)	Part 1 – clause 1.6 Design Examination
			Part 3 – Verification (for non-sterile devices), or Part 4 – Production Quality Assurance	Part 2 – Type Examination
	EU	EU MDD 93/42/EEC ² for Class III	Annex II.3	Annex II.4 – Design Examination
			Annex IV (for non-sterile devices where specific batches are included on the certificate), or Annex V	Annex III – Type Examination
		EU 90/385/EEC ³ (AIMDD) for AIMD	Annex 2.3	Annex 2.4 – Design Examination
			Annex 4 (for non-sterile devices where specific batches are included on the certificate), or Annex 5	Annex 3
		EU MDR ⁴	Annex IX (QMS)	Annex IX (Assessment of Technical Documentation)

Device Classification	Regulators / Approvals		Manufacturer Evidence (QMS Certificate)	Documentation that must be provided with the application (Evidence of product assessment)
			Annex XI (Product Conformity Verification)	Annex X – Type Examination
	UK	UK MDR 2002 under applied directive 93/42 ⁵ (MDD)	Annex II.3	Annex II.4 – Design Examination
			Annex IV (for non-sterile devices where specific batches are included on the certificate), or Annex V	Annex III – Type Examination
		UK MDR 2002 under applied directive 90/385 ³ (AIMDD)	Annex 2.3	Annex 2.4 – Design Examination
			Annex 4 (for non-sterile devices where specific batches are included on the certificate), or Annex 5	Annex 3
	Japan	Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency	QMS certificate, or MDSAP Certificate	Pre-market approval certificate
	Health Canada	MDR SOR/98-282 ⁷	MDSAP Certificate	Medical device licence Class IV
	FDA	Premarket Approval (PMA)	MDSAP Certificate (or PMA)	PMA
		Premarket notification	MDSAP Certificate	510(K) Clearance
	Singapore	Health Sciences Authority (HSA)	Extract from, or copy of, the entry in the Singapore Register of Health Products as a Class D medical device	
Procedure Pack or System (other than Class I) Regulation 3.10(1)(d) or (e) whatever is relevant	TGA ⁹	DOC	Declaration of conformity made under Clause 7.5 of Schedule 3 of MD Regulations	Evidence of the appropriate conformity assessment procedures applied to each medical device in the system/pack

⁹ The declaration of conformity is made by the manufacturer and is not assessed by the TGA. However, sponsors must ensure that the declaration is made in accordance with the Australian requirements (Clause 7.5 of Schedule 3 of the *Therapeutic Goods (Medical Device) Regulations 2002*)

Device Classification	Regulators / Approvals	Manufacturer Evidence (QMS Certificate)	Documentation that must be provided with the application* (Evidence of product assessment)	
IVD				
Class 1 IVD and Class 1 IVD Export only (Regulation 3.9A)	TGA	N/A	N/A	
Class 2 IVD (Regulation 3.8A)	TGA	CAC – MD Regulations Schedule 3 ¹	Part 1 – Full Quality Assurance (excluding clause 1.6 Design Examination), or Part 4 – Production Quality Assurance	
	EU	IVDD 98/79/EC ¹⁰ in vitro diagnostic medical devices	For an application submitted before 1 January 2030, Certification issued under Annex IV.3, or Certification issued under Annex VII <i>Note - The sponsor may also need to provide evidence that the manufacturer meets the EU IVDR extension eligibility conditions if using EU notified body evidence</i>	
		EU IVD regulations ¹¹	Annex IX, Chapter I	For self-testing and near-patient testing: Assessment of Technical Documentation set out in Section 5.1 of Annex IX
	FDA	Premarket Notification – 510(k)	MDSAP Certificate	510(k) Summary
	UK	UK MDR 2002 under applied directive 98/79 ¹² (IVDD)	Certification issued under Annex IV.3, or Certification issued under Annex VII	N/A
	Health Canada		MDSAP Certificate	Class II medical device license
	Singapore	Health Sciences Authority (HSA)	Extract from, or copy of, the entry in the Singapore Register of Health Products as a Class B IVD	N/A
	MDSAP		MDSAP Certificate	N/A
	PMDA (Japan)		MDSAP Certificate	For self-testing and near-patient testing: Pre-market certification under PMDA

¹⁰ EC Certificate issued under [Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices](#)

¹¹ Certificates issued under [Regulation \(EU\) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU](#). To assist with preliminary assessment of the applications it is recommended to submit the PEAR/TDAR issued by the notified body.

¹² UK Certificate issued under [Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998](#) (IVD Directive) as adopted from the EU

Device Classification	Regulators / Approvals		Manufacturer Evidence (QMS Certificate)	Documentation that must be provided with the application* (Evidence of product assessment)
			QMS certificate for the purposes of the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) Act	Pre-market approval under PMDA
	ISO 13485		For Class 2 IVD applications submitted before 26 May 2027, we will accept ISO 13485 certificates issued by a certification body that is also a Notified Body designated under the IVD Directive 98/79/EC (IVDD), if the manufacturer <u>also</u> has a signed EU declaration of conformity issued under Annex III of the IVDD before 26 May 2022.	N/A
	ISO 13485		For Class 2 IVD applications submitted before 26 May 2027, we will accept ISO 13485 certificates issued by a certification body accredited by a signatory to the Multilateral Recognition Arrangement of the International Accreditation Forum (IAF MLA), if the manufacturer <u>also</u> has a signed EU declaration of conformity issued under Annex III of the IVD Directive 98/79/EC (IVDD) before 26 May 2022	N/A
Class 3 IVD (Regulation 3.7A)	TGA	CAC – MD Regulations Schedule 3 ¹	Part 1 – Full Quality Assurance (excluding clause 1.6 Design Examination)	N/A
			Part 4 – Production Quality Assurance	Part 2 – Type Examination
	EU	IVDD 98/79/EC in vitro diagnostic medical devices ¹⁰	For an application submitted before 1 January 2029, Certification issued under Annex IV.3	N/A
			For an application submitted before 1 January 2029, Certification issued under Annex VII <i>Note - The sponsor may also need to provide evidence that the manufacturer meets the EU IVDR extension eligibility conditions if using EU notified body evidence</i>	Annex V – Type Examination
		EU IVD regulation ¹¹	Annex IX (QMS) Chapter I	Assessment of the technical documentation as specified in Section 4 of Annex IX for at least one representative device per generic device group. For self-testing and near-patient testing: Assessment of Technical documentation set out in Section 5.1; For companion diagnostics: Assessment of Technical Documentation set out in Section 5.2
			Annex XI (Production Quality Assurance) except Section 5	Annex X –Type Examination
	UK	UK MDR 2002 under applied directive 98/79 ¹² (IVDD)	Certification issued under Annex IV.3	N/A
			Certification issued under Annex VII	Annex V – Type Examination
FDA	Premarket Notification - 510(k)	MDSAP Certificate	510(k) Summary	

Device Classification	Regulators / Approvals		Manufacturer Evidence (QMS Certificate)	Documentation that must be provided with the application* (Evidence of product assessment)
		Premarket Approval (PMA) under 515 of the US FDC Act	MDSAP Certificate (or PMA)	PMA
	Health Canada		MDSAP Certificate	Medical device licence Class III
	Singapore	Health Sciences Authority (HSA)	Extract from, or copy of, the entry in the Singapore Register of Health Products as a Class C IVD	N/A
	MDSAP		MDSAP Certificate	N/A
	PMDA (Japan)		MDSAP Certificate or QMS certificate for the purposes of the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) Act	For self-testing and point of care testing: Pre-market certification under PMDA or Pre-market approval under PMDA
	ISO 13485		For Class 3 IVD applications submitted before 26 May 2026, we will accept ISO 13485 certificates issued by a certification body that is also a Notified Body designated under the IVD Directive 98/79/EC (IVDD), if the manufacturer <u>also</u> has a signed EU declaration of conformity issued under Annex III of the IVDD before 26 May 2022.	EU declaration of conformity issued under Annex III of the IVD Directive (IVDD) 98/79/EC before May 2022
	ISO 13485		For class 3 IVD applications submitted before 26 May 2026, we will accept ISO 13485 certificates issued by a certification body accredited by a signatory to the Multilateral Recognition Arrangement of the International Accreditation Forum (IAF MLA), if the manufacturer <u>also</u> has a signed EU declaration of conformity issued under Annex III of the IVD Directive 98/79/EC (IVDD) before 26 May 2022.	EU declaration of conformity issued under Annex III of the IVD Directive (IVDD) 98/79/EC before May 2022
Class 4 IVD (Regulation 3.6A)	TGA	CAC – MD Regulations Schedule 3 ¹	Part 1 – Full Quality Assurance (excluding clause 1.6 Design Examination)	Part 1 - clause 1.6 Design Examination
			Part 4 – Production Quality Assurance	Part 2 - Type Examination
	EU	IVDD 98/79/EC in vitro diagnostic medical devices ¹⁰	For an application submitted before 1 January 2028, Certification issued under Annex IV.3	Annex IV – Design examination
			For an application submitted before 1 January 2028, Certification issued under Annex VII <i>Note - The sponsor may also need to provide evidence that the manufacturer meets the EU IVDR extension eligibility conditions if using EU notified body evidence</i>	Annex V - Type Examination
		EU IVD regulations ¹¹	Annex IX (QMS) Chapter I	Annex IX (QMS) Chapter II – Design examination
			Annex XI (Production Quality Assurance) except Section 5	Annex X -Type Examination

Device Classification	Regulators / Approvals		Manufacturer Evidence (QMS Certificate)	Documentation that must be provided with the application* (Evidence of product assessment)
	UK	UK MDR 2002 under applied directive 98/79 ¹² (IVDD)	Certification issued under Annex IV.3	Annex IV – Design examination
			Certification issued under Annex VII	Annex V - Type Examination
	FDA		Premarket approval under 515 of the US FDC Act	Premarket approval under section 515 of the US FDC Act
	Health Canada		MDSAP Certificate	Medical Device class IV license
	Singapore		An extract of the Singapore Register of Health Products as a Class D IVD	N/A
	PMDA (Japan)		MDSAP certificate Or QMS certificate from the Pharmaceuticals and Medical Devices Agency (PMDA)	Pre-market approval under PMDA
Class 4 In-House IVD (Regulation 3.6B)	TGA	CAC – MD Regulations Schedule 3 ¹	Part 1 – Full Quality Assurance (excluding clause 1.6 Design Examination)	Part 1 - clause 1.6 Design Examination
			Part 6B – GMP licence	N/A
			Part 6B – NATA accreditation	

*For inclusion applications of higher risk IVDs such as class 3, class 4, self-tests and Point of Care tests, it is encouraged that applicants submit the instructions for use (IFU) of the device, as this item can also help expedite the preliminary assessment

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch, Therapeutic Goods Administration	20/08/2018
V1.1	Clarification of acceptable ISO 13485 certificates for IVD medical devices	Medical Devices Branch, Therapeutic Goods Administration	26/11/2018
V1.2	Further clarification on acceptable ISO 13485:2016 certificates for IVD medical devices. Removal of requirement for attachment of Health Canada Medical licence listing for applications for Class 2 and Class 3 IVD medical devices (to pass <i>preliminary assessment</i>). Removal of CMDCAS reference for medical devices (that is, non-IVD medical devices)	Medical Devices Branch, Therapeutic Goods Administration	May 2019
V1.3	Insertion of links to legislative instruments and related notations	Medical Devices Branch, Therapeutic Goods Administration	July 2019
V1.4	Amendments to reflect changes to application process and requirements for inclusion of Class I non-sterile, non-measuring devices	Medical Devices Authorisation and Surveillance Branches, Therapeutic Goods Administration	October 2020
V1.5	Amendments to reflect the repeal of <i>Therapeutic Goods (Medical Devices) Regulations 2002</i> , Regulation 4.1 (requirement for TGA conformity assessment for medical devices containing medicines or materials of animal, microbial, recombinant or human origin, or Class 4 IVDs	Medical Devices Authorisation and Surveillance Branches, Therapeutic Goods Administration	September 2021
V1.6	Amendments to reflect the extended acceptance of ISO13485 certificates as manufacturer evidence for IVD applications in line with EU IVDR (2017/746)	Medical Devices Authorisation and Surveillance Branches, Therapeutic Goods Administration	May 2022
V1.7	Amendments to include Singapore HSA as a comparable overseas regulator	Medical Devices Authorisation and Surveillance Branches, Therapeutic Goods Administration	September 2022

Version	Description of change	Author	Effective date
V1.8	Amendments to clarify the requirements for EUMDR	Medical Devices Authorisation and Surveillance Branches, Therapeutic Goods Administration	May 2023
V1.9	Corrections, and to reflect end of acceptance of most ISO 13485 certificates for IVDS	Medical Devices Authorisation and Surveillance Branches, Therapeutic Goods Administration	June 2023
V1.10	Amendments to reflect the Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Class IIa and Class IIb) Determination 2023	Medical Devices Authorisation and Surveillance Branches, Therapeutic Goods Administration	November 2023
V2.0	Amendments to reflect recent updates to the Determination as part of changes to Regulation 5.3 on 1 July 2024 and the TGA strategy to manage further extension to the EU IVDR transition timelines.	Medical Devices Authorisation Branch, Therapeutic Goods Administration	January 2025
V2.1	Amended to reflect inclusion of UK approved bodies as comparable overseas regulators	Medical Devices Authorisation Branch, Therapeutic Goods Administration	May 2026

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