Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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

For abridgement of TGA conformity assessments and as information required for applications for ARTG inclusion

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Contents

Introduction

One of the recommendations accepted by the Australian Government from the Expert Panel Review of Medicines and Medical Devices Regulation (the Review) was a better utilisation of marketing approvals of medical devices, including IVD medical devices, where the device has been:

- conformity assessed by a body that has been designated to undertake conformity assessments by a comparable overseas designating authority; or
- approved by a comparable overseas national regulatory authority.

Please note

The Australian Government also accepted the Review recommendation that TGA retain responsibility for making decisions regarding market authorisation of therapeutic goods in Australia.

The TGA will continue to assess applications for conformity assessment certificates for some devices and for the inclusion of medical devices in the Australian Register of Therapeutic Goods (ARTG).

This guidance

The purpose of this document is to provide an overview of how specific overseas assessments and approvals can be used by applicants for the purposes of supporting the basis for a possible abridged assessment of an application for a TGA conformity assessment certificate, or as the documentation required to be provided 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 2018*
- *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018*

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

Specific evidence and documentation, issued by specific overseas regulators and assessment bodies, will be considered by the TGA in relation to requests for abridgement of TGA conformity assessments or as the documentation required for applications for inclusion of medical devices in the ARTG:

- Certificates issued by Notified Bodies designated by the medical device regulators of European union member states, under the medical device regulatory frameworks of the European Union (Medical devices directives[1], IVD directive, Medical Device Regulation, or IVD Regulation)

[1] Council Directive 93/42/EEC (medical devices), Directive 90/385/EEC (AIMD), Directive 98/79/EC (IVD)

- Decisions of the United States Food and Drug Administration (FDA)
- Approvals and licences issued by Health Canada
- Pre-market approvals from Japan (issued by the Ministry of Health, Labour and Welfare (MHLW), Pharmaceutical and Medical Devices Agency (PMDA) or Registered Certified Body (RCB), which is applicable)
- Registrations of the Singapore Health Sciences Authority (HSA)
- Certificates and reports issued under the Medical Device Single Audit Program (MDSAP)*
- ISO 13485certificates issued by a certification body that is also a Notified Body designated under the IVDD 98/79/EC, along with 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 13485certificates issued by a body that is an accredited body that is a signatory to the Multilateral Recognition Arrangement of the International Accreditation Forum (IAF MLA) along with 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)

* For MDSAP certificates and audit reports to be considered, the Australian regulatory requirements must have been covered in the audit(s), 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 an overseas regulator or assessment body for the same medical device you are applying to have included in the ARTG. The device must:

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

Table1 and Table 2 in this guidance specify what documentation can be utilised for what purpose:

- Table 1 – Documents for abridgement of TGA conformity assessment
- Table 2 – Information that must accompany ARTG inclusion applications

Application requirements

Please note

Apart from the ability to use a broader range of overseas assessments and approvals in support of applications, there is no other change to existing regulatory requirements for the safety, quality, and performance of medical devices authorised for supply in Australia, and no change to the TGA's existing regulatory requirements and processes.

Reduction of assessment fees for medical devices

Guidance is available which outlines where assessment fees administered by the TGA can be reduced for both application audit assessments, and conformity assessments involving medical devices (including IVDs).

Please see: Reduction of assessment fees for medical devices which provides additional information about the eligibility requirements and procedures used by the TGA.

How to use this section

To best describe how specified overseas evidence should be used the application requirements are divided into two parts:

- Part A – Abridgement of TGA conformity assessment applications
- Part B – Applications for ARTG inclusion

Part A – Abridgement of 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 overseas audit report or product evaluation report may contain information that will help to demonstrate that these requirements are met.

For the possible abridgement of an assessment of a TGA conformity assessment application, you may provide certain documents from specified overseas assessment bodies to facilitate the TGA's overall conformity assessment evaluation process. This will result in the TGA being able to reduce the amount of assessment that it must undertake on a particular 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 also includes reference to MDSAP reports, which can also 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
  - 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 Design and Production QMS Assessment (Initial, and Recertification)		• EU MDD/IVDD/AIMDD Full Quality Assurance (FQA) Audit Report • EU MDR/IVDR Quality Management System Audit Report • MDSAP[3] Audit Report	• MDSAP[2] Audit Report or • EU MDD/IVDD/AIMDD FQA Audit Report or • EU MDR/IVDR 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)	• MDSAP[2] Audit Report or • EU MDD/IVDD/AIMDD FQA Audit Report or • EU MDR/IVDR Audit Report **Accepted** in place of a TGA surveillance assessment (with a satisfactory audit scope and in the absence of safety signals)

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
  - 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)		• EU MDD/IVDD/AIMDD Full Quality Assurance (FQA) Audit Report • EU MDR/IVDR Quality Management System Audit Report • MDSAP[3] Audit Report	• MDSAP[2] Audit Report or • EU MDD/IVDD/AIMDD FQA Audit Report or • EU MDR/IVDR 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)	• MDSAP[2] Audit Report or • EU MDD/IVDD/AIMDD FQA Audit Report or • EU MDR/IVDR Audit Report **Accepted** in place of a TGA surveillance assessment (with a satisfactory audit scope and in the absence of safety signals)

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			• EU MDD FQA Audit Report or • EU MDR/IVDR Audit Report 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 • MDSAP Audit Report **Considered** for the purposes of abridging TGA's assessment of the change.

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 in order to pass a *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 overseas regulators and/or assessment bodies which they will be required to provide with their applications to meet the requirements for:

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

Please note

Applications for ARTG inclusion of certain medical devices, including IVDs, 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 audit, for example, where there are concerns about the device or information provided in the application.

The Level of audit assessment may depend on the category and/or Class of a medical device, and the overseas evidence provided to the TGA in support of the application.

For an application for inclusion of an IVD medical device, the provision of suitable evidence of product assessment from a comparable overseas regulator may allow for abridgement of an assessment.

Sponsors can submit requests with their applications for a reduction of the 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 are required to provide brief justifications supporting their requests. TGA's delegate will decide whether such request is appropriate.

The guidance on requests for abridged assessment is available on the TGA website.

We have provided some examples on the TGA website on 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 to be accepted as the information approved to accompany the application.

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 EC Certificate issued by one of the European Notified Bodies under EU MDD 93/42/EEC, the following documents will be required.

Manufacturer Evidence

The EC Certificate issued under either Annex II.3 or Annex V must be submitted as your Manufacturer Evidence (EC 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]	• 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[8]	• MDSAP Certificate
	FDA	DeNovo[9]	• MDSAP Certificate
		Premarket Notification - 510(k)	
		Premarket Approval (PMA)	• MDSAP Certificate (or PMA)

Note: ISO 13485 issued by CMDCAS Recognised Registrar no longer accepted for medical devices.

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[8]	Medical device licence Class III
	FDA	DeNovo[9]	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 subjected to an application audit. As a result, the TGA encourages applicants to have and be able to provide the relevant supporting documentation which underpins these types of approvals. 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 should the application be selected for a non-mandatory audit

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 EC Certificate issued by one of the European Notified Bodies under IVDD 98/79/EC, the following documents will be required.

Manufacturer Evidence

The EC Certificate issued under either Annex IV.3 or Annex VII must be submitted as your Manufacturer Evidence.

Device Classification	Regulators / Approvals		Manufacturer Evidence *(QMS Certificate)*
Class 3 IVD (Regulation 3.7A)	EU	IVDD 98/79/EC in vitro diagnostic medical devices[13]	Annex IV.3
			Annex VII

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

If you provide an EC Certificate issued under Annex IV.3, there is no additional information which needs to be provided.

If you provide an EC Certificate issued under Annex VII, you will need to provide a Type Examination Certificate (issued under Annex V) with your application.

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)	EU	IVDD 98/79/EC in vitro diagnostic medical devices[13]	Annex IV.3	N/A
			Annex VII	Annex V – Type Examination

Table 1: Evidence that may be used for abridgement of TGA conformity assessment

For TGA-Issued Conformity Assessment Certificates[2]

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)**		• EU MDD/IVDD/AIMDD Full Quality Assurance (FQA) Audit Report • EU MDR/IVDR Quality Management System Audit Report • MDSAP[3] Audit Report	• MDSAP[2] Audit Report or • EU MDD/IVDD/AIMDD FQA Audit Report or • EU MDR/IVDR 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)	• MDSAP[2] Audit Report or • EU MDD/IVDD/AIMDD FQA Audit Report or • EU MDR/IVDR Audit Report **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[2] Audit Report or • EU MDD/IVDD/AIMDD FQA Audit Report or • EU MDR/IVDR Audit Report **Considered** for the purposes of abridging TGA's assessment of the change.	• MDSAP[2] Audit Report or • EU MDD/IVDD/AIMDD FQA Audit Report or • EU MDR/IVDR Audit Report **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 • EU IVDD Annex IV.4 Report			
Part 2 – Type Examination	**2.3** **Examination of the Type**	• EU MDD Annex III Report • EU MDR/IVDR Annex X – EU type-examination report • EU IVDD Annex V Report • EU AIMDD Annex 3 Report			
	2.4 **Examination of changes to the Type**				

[2] The TGA must certify the design and the full QMS as a "single decision maker" for the Part 1 CA procedure.
[3] To be acceptable, MDSAP reports are to 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 audit(s), 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*

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 3 – Verification	**3.3** **100% or Batch Verification**				
Part 4 – Production QMS	**4.3** **Production QMS Assessment**		• EU MDD/IVDD/AIMDD Full Quality Assurance or Production Quality Assurance (PQA) Audit Report • EU MDR/IVDR Quality Management System Audit Report • MDSAP Audit Report	• EU MDD/IVDD/AIMDD FQA Audit Report or • EU MDD PQA Audit Report or • EU MDR/IVDR Audit Report 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 • 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 • 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 • 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 site(s) 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 MD).
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's expectation is that a manufacturer is responsible for all aspects of a QMS related to their device. An MDSAP AO's 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.

Table 2: Information that must accompany ARTG inclusion applications for the purpose of passing *preliminary assessment*

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	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	N/A
Class I Export only	**TGA**	N/A	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[4]	• Part 1 – Full Quality Assurance (excluding clause 1.6 Design Examination), or • Part 3 – Verification (not applicable for Class Is), or • Part 4 – Production Quality Assurance, or • Part 5 – Product Quality Assurance (not applicable for Class Is)	N/A
	EU	EU MDD 93/42/EEC[5]	• 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)	
		EU 90/385/EEC (AIMDD) for AIMD[6]	• Annex 2.3, or • Annex 4 (for non-sterile devices where specific batches are included on the certificate), or • Annex 5	
		EU MDR[7]	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	
	MDSAP		MDSAP Certificate	

[4] TGA conformity assessment certificate issued under Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*
[5] EC Certificate issued under Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
[6] 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
[7] Certificates 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

Device Classification	Regulators / Approvals		Manufacturer Evidence *(QMS Certificate)*	Documentation that must be provided with the application *(Evidence of product assessment)*
Class IIa (Regulation 3.8)	**TGA**	CAC – MD Regulations Schedule 3[4]	• 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/EEC5	• 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
		EU 90/385/EEC (AIMDD) for AIMD[6]	• 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[7]	Annex IX, Chapter I (QMS)	Section 4, Annex IX (Assessment of Technical Documentation)
			Annexes II and III	Section 10 or Section 18 of Annex XI (one representative device per category)
	Japan	Ministry of Health, Labour and Welfare (MHLW)/PMDA	• QMS certificate, or • MDSAP Certificate	Pre-market certificate
	Health Canada	MDR SOR/98-282[8]	• MDSAP Certificate	Medical device licence Class II
	FDA	DeNovo	• MDSAP Certificate	De Novo Decision Summary
		Premarket Notification – 510(k)	• MDSAP Certificate	510(k) - Summary
	Singapore	Health Sciences Authority	• Extract from, or copy of, the entry in the Singapore Register oh Health Products as a Class B medical device	N/A
Class IIb (Regulation 3.7)	**TGA**	CAC - MD Regulations Schedule 3[4]	Part 1 – Full Quality Assurance (excluding clause 1.6 Design Examination)	N/A

[8] 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)*
			• 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[5]	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
		EU 90/385/EEC (AIMDD) for AIMD[6]	Annex 2.3	N/A
		EU MDR[7]	Annex IX, Chapter I (QMS)	Annex IX, Chapter II (Assessment of Technical Documentation) (based on a representative sample, BUT Class IIb implantable, for each device, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.
			Annex XI (Product Conformity Verification)	Annex X – Type Examination
	Japan	Ministry of Health, Labour and Welfare (MHLW)/PMDA	• QMS certificate, or • MDSAP Certificate	Pre-market certificate
	Health Canada	MDR SOR/98-282[8]	• 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

Device Classification	Regulators / Approvals		Manufacturer Evidence *(QMS Certificate)*	Documentation that must be provided with the application *(Evidence of product assessment)*
Class III and AIMD (Regulation 3.6) (except specified medical devices) [9]. These are medical devices that do not contain medicines or materials of animal, microbial, recombinant or human origin.	**TGA**	CAC – MD Regulations Schedule 3[4]	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[5] 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[6] (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[7]	Annex IX (QMS)	Annex IX (Assessment of Technical Documentation)
			Annex XI (Product Conformity Verification)	Annex X – Type Examination
	Japan	Ministry of Health, Labour and Welfare (MHLW)/PMDA	• QMS certificate, or • MDSAP Certificate	Pre-market approval certificate
	Health Canada	MDR SOR/98-282[8]	MDSAP Certificate	Medical device licence Class IV
	FDA	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 D medical device	
Class III and AIMD	**TGA**	CAC – MD Regulations Schedule 3[4]	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

[9] Manufacturers of some medical devices, other than IVD medical devices, that contain tissues of animal origin or microbial origin, or incorporating stable derivatives of human blood or human plasma, or incorporate, or are intended to incorporate a substance that, if used separately, might be considered to be a medicine, are 'specified medical devices' defined under s.4 Definitions of the *Therapeutic Goods (Medical Devices— Information that Must Accompany Application for Inclusion) Determination 2018*. Specific requirements apply for these medical devices – listed separately below.

Device Classification	Regulators / Approvals		Manufacturer Evidence *(QMS Certificate)*	Documentation that must be provided with the application *(Evidence of product assessment)*
(Regulation 3.6) (specified medical devices) [10] **These are medical devices that contain medicines or materials of animal, microbial, recombinant or human origin.**	**EU**	EU MDD 93/42/EEC[5] 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[6] (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[7]	Annex IX (QMS)	Annex IX (Assessment of Technical Documentation)
			Annex XI (Product Conformity Verification)	Annex X – Type Examination
Procedure Pack or System (other than Class I) Regulation 3.10(1)(d) or (e) whatever is relevant	**TGA**[11]	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

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[4]	• Part 1 – Full Quality Assurance (excluding clause 1.6 Design Examination), or • Part 4 – Production Quality Assurance	N/A
	EU	IVDD 98/79/EC[12] in vitro diagnostic medical devices	• Annex IV.3, or • Annex VII	N/A
		EU IVD regulations[13]	Annex IX, Chapter I	Annex IX, Sections 4.4 to 4.8 (based on representative sample) For self-testing and near-patient testing: Assessment of Technical Documentation set out in Section 5.1 of Annex IX

[10] Manufacturers of some medical devices, other than IVD medical devices, that contain tissues of animal origin or microbial origin, or incorporating stable derivatives of human blood or human plasma, or incorporate, or are intended to incorporate a substance that, if used separately, might be considered to be a medicine, are 'specified medical devices' defined under s.4 Definitions of the *Therapeutic Goods (Medical Devices— Information that Must Accompany Application for Inclusion) Determination 2018*. Specific requirements apply for these medical devices.

[11] 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*)

[12] 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

[13] 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

Device Classification	Regulators / Approvals		Manufacturer Evidence *(QMS Certificate)*	Documentation that must be provided with the application *(Evidence of product assessment)*
	FDA	Premarket Notification – 510(k)	MDSAP Certificate	510(k) Summary
	Health Canada		• MDSAP Certificate	N/A
	Singapore	Health Sciences Authority (HSA)	• Extract from, or copy of, the entry in the Singapore Register of Health Products as a Class B IVD	
	MDSAP		MDSAP Certificate	
	ISO 13485		• ISO 13485issued by a certification body that is also a Notified body designated under the IVDD 98/79/EC accepted for Class 2 IVD applications submitted before 26 May 2027 if the manufacturer also has a signed EU declaration of conformity issued under Annex III of the IVD Directive (IVDD) 98/79/EC before 26 May 2022	
	ISO 13485		• ISO 13485issued by a certification body that is a signatory to the Multilateral Recognition Arrangement of the International Accreditation Forum (IAF MLA) accepted for Class 2 IVD applications submitted before 26 May 2027 if the manufacturer <u>also</u> has a signed EU declaration of conformity issued under Annex III of the IVD Directive (IVDD) 98/79/EC before 26 May 2022	
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[12]	Annex IV.3	N/A
			Annex VII	Annex V – Type Examination
		EU IVD regulations13	Annex IX (QMS) Chapter I	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 Reg 5.2
			Annex XI (Production Quality Assurance) except Section 5	Annex X –Type Examination
	FDA	Premarket Notification - 510(k)	MDSAP Certificate	510(k) Summary
		Premarket Approval (PMA)	MDSAP Certificate (or PMA)	PMA
	Health Canada		• MDSAP Certificate	Medical device licence Class III

Device Classification	Regulators / Approvals		Manufacturer Evidence *(QMS Certificate)*	Documentation that must be provided with the application *(Evidence of product assessment)*
	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
	ISO 13485		• ISO 13485issued by a certification body that is also a Notified Body designated under the IVDD 98/79/EC accepted for Class 3 IVD applications submitted before 26 May 2026 if the manufacturer also has a signed EU declaration of conformity issued under Annex III of the IVD Directive (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		•	
			• ISO 13485issued by an accredited body that is a signatory to the Multilateral Recognition Arrangement of the International Accreditation Forum (IAF MLA) accepted for Class 3 IVD applications submitted before 26 May 2026 if the if the manufacturer also has a signed EU declaration of conformity issued under Annex III of the IVD Directive (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[4]	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[12]	Annex IV.3	Annex IV – Design examination
			Annex VII	Annex V - Type Examination
		EU IVD regulations	Annex IX (QMS) Chapter I	Annex IX (QMS) Chapter II – Design examination
			Annex XI (Production Quality Assurance) except Section 5	Annex X -Type Examination
Class 4 In-House IVD (Regulation 3.6B)	**TGA**	CAC – MD Regulations Schedule 3[4]	Part 1 – Full Quality Assurance (excluding clause 1.6 Design Examination)	Part 1 - clause 1.6 Design Examination
			Part 6B – GMP licence	
			Part 6B – NATA accreditation	

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 *preliminary assessment*). 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 *Therapeutic Goods (Medical Devices) Regulations 2002*, 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 (207/746)	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

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Reference/Publication #