



Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

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

This guidance explains how overseas assessments can support our medical device certification and registration processes.

Published 20 August 2018

Last updated 11 May 2026

Purpose

The purpose of this guidance is to provide an overview of how specific overseas assessments and approvals can be used by applicants for:

- supporting 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.

Legislation

[Therapeutic Goods \(Medical Devices\) Regulations 2002](#)


[Therapeutic Goods \(Overseas Regulators\) Determination 2018](#)


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

Guidance

This Guidance is presented as downloadable files because of its wide table format.

Downloads

 [Use of market authorisation evidence from comparable overseas regulators for medical devices \(including IVDs\)](#) [PDF, 592.22 KB]

 [Use of market authorisation evidence from comparable overseas regulators for medical devices \(including IVDs\)](#) [DOCX, 703.59 KB]

Page history

11 May 2026

Amended to reflect inclusion of UK approved bodies as comparable overseas regulators

23 January 2025

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.

13 November 2023

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.

1 June 2023

Corrections, and to reflect end of acceptance of most ISO 13485 certificates for IVDs.

1 May 2023

Amendments to clarify the requirements for EUMDR.

1 September 2022

Amendments to include Singapore HSA as a comparable overseas regulator.

1 May 2022

Amendments to reflect the extended acceptance of ISO13485 certificates as manufacturer evidence for IVD applications in line with EU IVDR (2017/746).

1 September 2021

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).

1 October 2020

Amendments to reflect changes to application process and requirements for inclusion of Class I non-sterile, non-measuring devices.

1 July 2019

Insertion of links to legislative instruments and related notations.

1 May 2019

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).

26 November 2018

Clarification of acceptable ISO 13485 certificates for IVD medical devices.

20 August 2018

Original publication.

This PDF was generated on 11 May 2026. Downloaded content may be out of date. For up-to-date information, always refer to the digital version:

<https://www.tga.gov.au/resources/guidance/use-market-authorisation-evidence-comparable-overseas-regulators-and-assessment-bodies-medical-devices-including-ivds>