



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Conformity assessment overview

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TGA Health Safety
Regulation



About the Therapeutic Goods Administration (TGA)


- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

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Conformity assessment overview

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What is conformity assessment of an IVD medical device?

A manufacturer must be able to demonstrate that both the in vitro diagnostic medical device (IVD) and the manufacturing processes used to make the IVD conform to the requirements of the therapeutic goods legislation.

The Australian requirements are set out in the:

- *Therapeutic Goods Act 1989* (the Act)
- *Therapeutic Goods (Medical Devices) Regulations 2002*.

Conformity assessment is the systematic and ongoing examination of evidence and procedures to ensure that an IVD and the manufacturing processes used to make the IVD comply with the Essential Principles and other requirements of the therapeutic goods legislation.

Conformity assessment:

- provides objective evidence of the:
 - safety
 - performance
 - benefits
 - risksfor a specific IVD; and
- enables regulatory bodies to ensure that products placed on the market conform to the applicable regulatory requirements.

The classification of an IVD determines the conformity assessment procedures a manufacturer can choose from to ensure that the device is adequately assessed. Higher classification devices must undergo more stringent conformity assessment procedures than lower classification devices.

There are several stages involved in the conformity assessment of an IVD:

Activity	Description	Who is responsible?
Conformity assessment procedures	<ul style="list-style-type: none">• How a manufacturer demonstrates that they have met the Essential Principles for a particular IVD• Manufacturers can choose the appropriate procedures to use to meet the regulatory requirements, depending on the classification of the IVD• Involves assessment of the manufacturer's quality management system and includes review of the:<ul style="list-style-type: none">– technical documentation for the design of the device– manufacturing processes used to make the device– risk analysis– clinical evidence– ongoing monitoring and vigilance procedures that will be in place once the device is available for supply	Manufacturer

Activity	Description	Who is responsible?
Issuing conformity assessment evidence ¹	<ul style="list-style-type: none"> • Conformity assessment evidence is the certificate issued by a conformity assessment body to demonstrate a manufacturer has been assessed (audited) and has an appropriate quality management system in place to manufacture the device • Assessment processes will vary according to the conformity assessment procedures selected by the manufacturer but may include: <ul style="list-style-type: none"> – confirmation that the conformity assessment procedures are appropriate for the classification of the device and have been applied correctly – examination of the documentation and procedures undertaken by the manufacturer – on-site audit of the manufacturing premises – examination of the design of high risk devices, possibly including performance testing – re-certification of conformity assessment evidence that is due to expire 	TGA or an acceptable conformity assessment body
Australian Declaration of Conformity (DoC)	<ul style="list-style-type: none"> • Once the manufacturer has obtained conformity assessment evidence, they must make a DoC to Australian requirements • The DoC declares that the device complies with: <ul style="list-style-type: none"> – the applicable provisions of the Essential Principles – the classification rules – an appropriate conformity assessment procedure • If requested, the TGA must be provided with a copy of the DoC. A copy of the DoC may also be required by the sponsor for submission to the TGA as part of an application for inclusion in the ARTG (see <i>Section – Including IVD medical devices in the ARTG</i>). • The DoC must be maintained and updated when appropriate 	Manufacturer

¹ Conformity assessment evidence is also known as Manufacturer's Evidence. The latter term is used when a sponsor submits their evidence to the TGA via eBusiness Services (eBS).

Activity	Description	Who is responsible?
Ongoing conformity assessment responsibilities	<ul style="list-style-type: none"> • Maintain appropriate records, including: <ul style="list-style-type: none"> – technical documentation – evidence that an appropriate conformity assessment procedure has been applied – the Australian DoC – details of any systematic reviews undertaken – details of any changes to the device and/or quality management system • Implement appropriate means to apply any necessary corrective action in relation to the design or production of a device • Notify the TGA and/or the sponsor as soon as practicable after becoming aware of information relating to any malfunction or adverse event • Systematically review information gained after the device is supplied in Australia <p><i>Please note: for more information on these requirements please see Section – Ongoing monitoring and vigilance</i></p> <ul style="list-style-type: none"> • Apply for re-certification prior to the expiry of existing conformity assessment certificate 	Manufacturer

The conformity assessment procedures have been modelled on those developed by the Global Harmonisation Task Force (GHTF), an international forum that was established to achieve greater uniformity between national medical device regulatory systems.

The GHTF principles of conformity assessment are also closely aligned with the relevant EU Directives. Although the Australian and EU conformity assessment procedures are similar, there are some important differences manufacturers must be aware of and accommodate, before completing an Australian Declaration of Conformity. For example, the manufacturers' quality management system must meet the requirements to notify the Secretary, as represented by the TGA, of certain matters, such as information relating to any malfunction or deterioration in the performance of an IVD that might lead to the death of a patient.

Conformity assessment evidence that demonstrates that the manufacturer's quality management system has been audited by an acceptable certification body needs to be registered as Manufacturer's Evidence with the TGA for all IVDs, except Class 1 IVDs and Class 1, 2 and 3 in-house IVDs. Further evidence of product assessment may also need to be provided to the TGA upon making an application for inclusion in the ARTG; e.g. where an ISO 13485 certificate is submitted as Manufacturer's Evidence and used to support an application for a Class 3 IVD.

For Class 1 IVDs (except Class 1 in-house IVDs), an Australian Declaration of Conformity and supporting evidence in a suitable technical file must be maintained by the manufacturer. This documentation must be provided to the TGA if requested.

In accordance with the legislation, for Class 2 and 3 IVDs manufactured outside Australia the TGA can accept assessments performed by conformity assessment bodies considered to have the appropriate authority and expertise. As the Australian, Canadian and the EU regulatory requirements are similar, the TGA has determined that ISO 13485 certificates and product licences issued for the purposes of the Canadian Medical Devices Regulations and certificates issued by EU Notified Bodies may be accepted as conformity assessment evidence for the supply of devices in Australia. The TGA has also determined that ISO 13485 certificates issued by some other recognised bodies may be accepted. There are IVDs that are exceptions to these determinations (*See following under heading **Types of conformity assessment evidence***).

Other regulatory authorities may sometimes issue conformity assessment evidence for products that are not regulated as IVDs in Australia. It should not be assumed that a product is an IVD because a certificate has been issued—the product must fit the Australian definition of an IVD medical device.

Once Manufacturer's Evidence has been accepted for Class 2, 3 and 4 IVDs and Class 4 in-house IVDs by the TGA, a sponsor can lodge an application to include an IVD medical device in the Australian Register of Therapeutic Goods (ARTG).

More detailed information on conformity assessment is available:

- ***Section – What a manufacturer needs to know about conformity assessment for IVDs***
- ***Section – What a sponsor needs to know about conformity assessment and manufacturer's evidence for IVDs***

Types of conformity assessment evidence

The TGA accepts the following certificates and licenses as conformity assessment evidence:

- a Conformity Assessment Certificate issued by the TGA – this is mandatory for some manufacturers and for IVDs in some risk classes (*see following under heading **Manufacturers who must have a TGA Conformity Assessment Certificate***)
- EC certificates issued by an EU Notified Body under the EU In Vitro Diagnostic Medical Device Directive (IVDD) 98/79/EC
- an ISO 13485 *Medical devices -- Quality management systems -- Requirements for regulatory purposes* certificate issued by:
 - a certification body that is also a Notified Body designated under the IVDD 98/79/EC
 - a CMDCAS (Canadian Medical Devices Conformity Assessment System) recognised Registrar
 - a certification body that is accredited by a signatory member of the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MRA) to undertake certification to ISO 13485
- for Class 3 IVDs that are supported by an ISO 13485 certificate, a Class III or IV Medical Device Active Licence Listing (MDALL) that is issued by Health Canada under the Canadian Medical Devices Regulations.

Since the EU does not have a risk based classification system and the Canadian risk based classification rules are not identical to those in Australia, the conformity assessment requirements may be different in Australia. The manufacturer may be required to obtain additional conformity assessment evidence. Where the manufacturer is not able to obtain the appropriate additional conformity assessment evidence from their conformity assessment body, they may need to obtain a TGA Conformity Assessment Certificate or undergo additional review upon making an application for entry on the ARTG. This particularly applies to Class 3 IVDs where both quality management certification and evidence of appropriate product review is required.

For more information please see:

- *Section – What a sponsor needs to know about conformity assessment and manufacturer's evidence for IVDs*
- *Section – Application audits of IVD medical device application*

Manufacturers who must have a TGA Conformity Assessment Certificate

Some manufacturers and IVDs in certain classes must have a TGA Conformity Assessment Certificate if they want to supply devices to the market in Australia, regardless of whether they have certificates or licences issued by an overseas body. These manufacturers and IVDs are:

- any manufacturer who manufactures a Class 4 IVD (including Class 4 in-house IVDs)
 - all manufacturers who manufacture IVDs in Australia except for manufacturers of the following²:
 - Class 1 IVDs
 - IVD systems and procedure packs for which the special conformity assessment procedures have been applied – for details see *Section – Systems and procedure packs*
 - devices supplied to individuals:
 - § as part of a clinical trial
 - § through the Special Access Scheme
 - § by Authorised Prescribers
 - § by personal importation
- For more information please see *Section – Access to unapproved medical devices in Australia*.
- exempt devices, including Class 1-3 in-house IVDs.

The TGA assessment will take into account any existing overseas conformity assessment evidence where it supports compliance with the Australian regulations.

What is the manufacturer responsible for?

The manufacturer of an IVD is the person who is responsible for the:

- design,
- production,
- packaging, and
- labelling

of the device before it is supplied under the person's name, whether they or another person acting on their behalf carries out those operations.

Manufacturers should have the appropriate processes in place to ensure compliance with the Essential Principles and conformity assessment procedures **before** they apply for a conformity assessment certificate.

Once a manufacturer obtains the necessary conformity assessment evidence, they need to ensure that their conformity assessment procedures are appropriately maintained and that the ongoing requirements are met (e.g. reporting adverse events, regular quality systems audits). For more information on these requirements please see *Section - Postmarket vigilance and monitoring*.

The manufacturer is responsible for obtaining the conformity assessment evidence and ensuring the information on the certificate remains current and valid.

² The TGA has sought comments on proposed changes to medical devices regulations including third party conformity assessments for Australian manufacturers. The consultation document can be found at <http://www.tga.gov.au/newsroom/consult-devices-reforms-101130.htm>.

The manufacturer must also make an Australian *Declaration of Conformity*. For more information on Declarations of Conformity please see **Section - What a manufacturer needs to know about conformity assessment for IVDs**.

The legislation requires that the TGA must be notified in writing by the appropriate legal representative, within 3 months of the event occurring, if the manufacturer:

- dies
- is declared bankrupt
- is a body corporate that is wound up.

An Australian manufacturer may also be the sponsor.

For more detailed information about the role and responsibilities of the IVD manufacturer please see **Section - What a manufacturer needs to know about conformity assessment for IVDs**.

What is the Australian sponsor responsible for?

The Australian sponsor is responsible for:

- having procedures in place, including a written agreement with the manufacturer, to obtain information from the manufacturer, when requested by the TGA
- ensuring that
 - they have available sufficient information to substantiate compliance with the Essential Principles or have procedures in place to ensure that such information can be obtained from the manufacturer within 20 working days
 - an appropriate conformity assessment procedure has been applied to the IVDs by the manufacturer
 - the manufacturer has appropriate conformity assessment evidence for the IVD
 - the conformity assessment evidence remains valid while the device is supplied in Australia
- obtaining a copy of the conformity assessment evidence from the manufacturer
- submitting the conformity assessment evidence to the TGA
- applying to include the device in the Australian Register of Therapeutic Goods (ARTG)
- meeting all the ongoing monitoring and reporting requirements applicable to sponsors once a device is included on the ARTG. For more information see **Section – Postmarket monitoring and vigilance**
- providing samples of the IVD to the TGA upon request
- allowing a person authorised by the TGA to enter and inspect any premises, including outside Australia, where the devices are manufactured or located
- ensuring any advertising material relating to the IVD complies with the TGA requirements – for more information see **Section – Information about a medical device**.

The Australian sponsor may also be the manufacturer.

For more detailed information about the role and responsibilities of the Australian sponsor please see *Section – What a sponsor needs to know about conformity assessment and manufacturer’s evidence for IVDs*

Under review

Under review

Therapeutic Goods Administration

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