Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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

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TGA Health Safety Regulation

Contents

Overview 4

Conformity assessment evidence accepted by the TGA 4

TGA Conformity Assessment Certificates 5

EC certificates issued by an EU Notified Body 5

ISO 13485 certificates issued by a recognised body 6

Manufacturer's Evidence accepted by the TGA 7

Manufacturer's Declaration of Conformity 9

Submitting Manufacturer's Evidence 9

Maintaining currency of Manufacturer's Evidence 9

Expired certificates 9

Variations to existing Manufacturer's Evidence 10

Changes to existing manufacturer's certificates 10

Next steps 10

What information should be on an EC/ISO 13485 certificate 11

Overview

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.

The Australian sponsor is responsible for:

- having procedures in place, including a written agreement with the IVD 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 – Post market 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 located
- ensuring any advertising material relating to the IVD complies with the TGA requirements – for more information see ***Section – Information about a medical device***.

Conformity assessment evidence accepted by the TGA

In accordance with the legislation, for IVDs manufactured outside Australia the TGA is able to accept the assessment of certification bodies that are considered to have the appropriate authority and expertise. There are IVDs that are exceptions to this determination (see ***TGA Conformity Assessment Certificates*** below).

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

- a Conformity Assessment Certificate issued by the TGA – this is mandatory for some manufacturers and IVDs in some classes (see ***TGA Conformity Assessment Certificates*** below)

- 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 (for IVD applications until 26 May 2023) issued by:
  - a certification body that is also a Notified Body designated under the IVDD 98/79/EC
  - 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

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 that are manufactured overseas because both quality management certification and evidence of appropriate product review is required prior to entry of the IVDs in the ARTG.

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 (***See – Manufacturer's Evidence accepted by the TGA***). Depending on the certification used and the Class of IVD, further conformity assessment evidence that specifically demonstrates product assessment may also need to be provided to the TGA at the time of submission of an application for inclusion in the ARTG; e.g. where an ISO 13485 certificate is submitted as Manufacturer's Evidence after 26 May 2023 and used in an application for a Class 3 IVD.

The sponsor should ensure that they have the appropriate conformity assessment evidence for the IVDs before submitting the evidence to the TGA. The evidence should be carefully checked to ensure it is appropriate for the IVDs to avoid delays in submissions being processed—see following sections for guidance on appropriate evidence.

Multiple certificates may be required to cover all IVDs included in an application for entry in the ARTG. To accommodate this requirement, the application form for entry in the ARTG can be linked to multiple Manufacturer's Evidence submissions, with each Manufacturer's Evidence submission representing a single certificate.

TGA Conformity Assessment Certificates

The TGA accepts TGA Conformity Assessment Certificates as Manufacturer's Evidence for any manufacturer. For details on how to apply for a TGA Conformity Assessment Certificate please see ***Section – What a manufacturer needs to know about conformity assessment for IVDs.***

EC certificates issued by an EU Notified Body

The TGA has determined that IVDD certificates issued by Notified Bodies may be accepted as Manufacturer's Evidence (***See – Manufacturer's Evidence accepted by the TGA***) and evidence of product review. An EC certificate may only be used if the IVD is included in the certificate's scope.

The following table provides the parallel references for the Australian and EU conformity assessment procedures:

Australian reference **Therapeutic Goods (Medical Devices) Regulations 2002**	EU reference **IVDD 98/79/EC**
Schedule 3 Part 1 – Full quality assurance procedures	Annex IV
Schedule 3 Part 1, Clause 1.6 – Examination of design of Class 4 IVD medical device and Class 4 In-house IVD medical device	Annex IV.4
Schedule 3 Part 2 – Type examination procedures	Annex V
Schedule 3 Part 4 – Production quality assurance procedures	Annex VII
Schedule 3 Part 6 – Declaration of conformity procedures	Annex III

For some Class 2, 3 and 4 IVDs covered by EC Certificates a mandatory application audit (technical file review) will be conducted once the sponsor lodges an application for inclusion in the ARTG with the TGA. The application audit is to confirm that the manufacturer of an IVD has carried out conformity assessment procedures appropriate to the classification of the device. For more information, please see ***Section – Application audits of IVD medical device applications.***

Some Notified Bodies in Europe may issue a special kind of CE certification known as "OEM Labelling", "Private Labelling" or "Own Brand Labelling". These certificates are issued to a manufacturer who re-labels another manufacturer's medical device that has CE certification. The TGA will accept CE certificates for "Own Brand Labelling" as Manufacturer's Evidence, without requiring additional information, provided the original manufacturer's CE certificate, quality management system documentation and product technical documentation are available on request.

The TGA will request the EC certificate of the original manufacturer and other documents during application audit or post market review of a device covered by an "Own Brand Labelling" certificate. Failure to provide the additional information is sufficient grounds for rejection/suspension/cancellation.

ISO 13485 certificates issued by a recognised body

The TGA has determined that ISO 13485 certificates issued by recognised bodies may be accepted as Manufacturer's Evidence for IVD applications until 26 May 2023. (***See – Manufacturer's Evidence accepted by the TGA***)

An ISO 13485 certificate:

- covers the quality management system but does not include review of the product
- does not provide assurance that the Australian legislative requirements (e.g. the Essential Principles) have been taken into consideration.

Therefore, some applications to include IVDs in the ARTG that use ISO 13485 certification as Manufacturer's Evidence may be required, under the provisions of Regulation 5.3, to undergo additional pre-market review.

For Class 2 IVDs, ISO 13485 certificates are generally sufficient for entry of an IVD in the ARTG. Unless the device is selected for an application audit under any of the subparagraphs (1)(j)(i)–(vii) in Regulation 5.3, or for a non-mandatory application audit under section 41FH (1) (b), an application for a Class 2 IVD that uses an ISO 13485 certificate as Manufacturer's Evidence will not undergo additional pre-market review.

Under subparagraph (1)(j)(viii) in Regulation 5.3, Class 3 IVDs covered by an ISO 13485 certificate will be subject to a mandatory application audit once the sponsor lodges an application for inclusion in the ARTG. For more information, please see ***Section – Application audits of IVD medical device applications.***

Manufacturer's Evidence accepted by the TGA

For all IVDs, except Class 1 IVDs and Class 1, 2 and 3 in-house IVDs, the sponsor must submit Manufacturer's Evidence to the TGA and have it accepted **before** applying to include the IVD in the ARTG.

The TGA accepts the following certificates as Manufacturer's Evidence:

- a Conformity Assessment Certificate issued by the TGA for Schedule 3 Part 1 (Full quality assurance) or Schedule 3 Part 4 (Production quality assurance) of the Therapeutic Goods (Medical Devices) Regulations 2002– this is mandatory for some manufacturers and IVDs in some classes
- an EC certificate issued by an EU Notified Body for Annex IV.3 (Full quality assurance) or Annex VII (Production quality assurance) of the EU IVDD 98/79/EC
- an ISO 13485 *Medical devices -- Quality management systems -- Requirements for regulatory purposes* compliance certificate for IVD applications until 26 May 2023 issued by a:
  - a certification body that is also a Notified Body for the purposes of the IVDD 98/79/EC
  - a certification body that is accredited by a signatory of the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA) to perform ISO 13485 certification.

Details of the current IVDD Notified Bodies can be found at <https://ec.europa.eu/growth/tools-databases/nando/index.cfm>.

Details of the current CMDCAS recognised Registrars can be found at <http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/list_liste_regist-eng.php>.

For a list of accreditation bodies that are signatories of the IAF, refer to IAF Members section at <http://www.iaf.nu/>.

For each class of IVD there are restrictions on type of certificates that may be used to demonstrate that a manufacturer has the appropriate manufacturing processes to make the IVD (Manufacturer's Evidence). These are shown on the following table.

Certificate issued number	Certificate type	Allowable Class of IVD
Therapeutic Goods (Medical Devices) Regulations 2002 (TGA) *	Schedule 3 Part 1 (Full Quality Assurance)	Class 4 IVD Class 4 in-house IVD Class 3 IVD Class 2 IVD
	Schedule 3 Part 4 (Production Quality Assurance)	Class 4 IVD Class 3 IVD Class 2 IVD
Directive 98/79/EC (IVDD) (EU Notified Body)	Annex IV.3 (Full Quality Assurance)	Class 4 IVD Class 3 IVD Class 2 IVD
	Annex VII (Production Quality Assurance)	Class 4 IVD Class 3 IVD Class 2 IVD
ISO 13485 (certification body accredited by signatory of IAF MLA or a certification body that is also an EU Notified Body within the meaning of Directive 98/79/EC before 26 May 2023)	ISO 13485	Class 3 IVD Class 2 IVD

– see TGA Conformity Assessment Certificates

Certificates relating only to the design of the device are **not** accepted for submission as Manufacturer's Evidence. This includes Design Examination and Type Examination certificates issued by the TGA under Schedule 3 Clause 1.6 or Part 2 of the Australian regulations or a Notified Body under the IVDD Annex IV.4 or V. Where relevant, the TGA may require copies of such certificates to be electronically attached to the device application for inclusion or provided upon request during the application audit process.

There is no fee for submitting Manufacturer's Evidence. The TGA has a target time frame of 15 working days to consider and, where appropriate, accept the Manufacturer's Evidence. When an application for inclusion is received the TGA will check the Manufacturer's Evidence to ensure its relevance to the particular IVD(s) in the application.

The sponsor should check the details on the certificate to ensure it is appropriate for the IVD/s. ***See - What information should be on an EC/ISO 13485 certificate***

Manufacturer's Declaration of Conformity

The *Declaration of Conformity* includes details about the manufacturer and the IVDs and declares that the device complies with the applicable:

- provisions of the Essential Principles
- classification rules
- conformity assessment procedures.

For Class 3 IVDs, the sponsor is required to provide the manufacturer's Australian *Declaration of Conformity (DoC)* as an attachment to the device application form. For other IVD classes, the sponsor may be requested to submit a copy of the DoC to the TGA, e.g., as part of an application audit or post-market review.

The DoC should not be submitted as Manufacturer's Evidence.

Submitting Manufacturer's Evidence

Before submitting Manufacturer's Evidence, the Australian sponsor must establish an eBusiness Services (eBS) account which is used to make electronic applications for medical devices including IVDs. The forms and instructions for establishing an eBS account can be found at <http://www.ebs.tga.gov.au/>

Once the sponsor has access to eBS, they must lodge an electronic submission to register the conformity assessment certification as Manufacturer's Evidence.

To do this, the sponsor should open their eBS portal view and select the option under Medical Devices to 'Manufacturer Evidence' and follow the prompts.

Guidance on completing the Manufacturer's Evidence form is available via the HELP button in the eBS form.

Please note: The lodgement process requires that an electronic copy of the certificate be attached to the submission. It will help the sponsor ensure they are lodging the correct certificate if they have a copy of the manufacturer's Australian Declaration of Conformity to refer to when completing the electronic application. Each certificate requires a separate lodgement as Manufacturer's Evidence

Maintaining currency of Manufacturer's Evidence

Expired certificates

In most cases the manufacturers' certifications are current for 5 years from the last date of issue.

The expiry date as stated on the certificate is recorded on eBS. This expiry date may be used by the TGA to send reminder letters to sponsors advising that the Manufacturer's Evidence has expired and provide a timeframe for sponsors to submit updated evidence.

Variations to existing Manufacturer's Evidence

The information on the manufacturer's certificates may change over time and as a consequence the certification body will generally audit the facility and/or issue a revised certificate.

These revised certificates must be submitted to the TGA as a "variation to manufacturer's evidence" quoting the unique Manufacturer's Evidence ID number. Any changes to the certifications need to be incorporated in the variation notification form in eBS.

If there has been a change in manufacturer's name and/or site address, sponsors will need to attach documentation from the certification body which provides evidence of the change. This requirement is to prove to the TGA that the change in manufacturer's name and/or address is as a result of corporate changes only and not:

- a result of a new manufacturer taking on responsibility for the production of the devices
- an alternate manufacturer of the devices already included on the ARTG.

If either of the options listed above occur, the devices are regarded as a different kind of device under section 41BD of the Act and require new device applications to be submitted for the IVDs to be included in the ARTG.

Changes to existing manufacturer's certificates

The changes to existing manufacturer's certificates which can change over time include:

- expanding the range of products covered under the scope of the certificate
- reducing the range of products covered under the scope of the certificate
- updating the:
  - certificate number following re-issue of a certificate
  - re-issue date following a surveillance audit and re-issue of the certificate
- altering the conformity assessment procedures (change to the annex route)
- changing the Notified Body or certification body undertaking the audit; or
- amending the manufacturer's details (change to name and/or address).

The TGA needs to be advised if any of these changes occur. The process for updating this information is to submit a variation to Manufacturer's Evidence via eBS.

Next steps

The TGA will notify the sponsor via email if the Manufacturer's Evidence submission is successful.

If the submission is not accepted the sponsor will be notified by email, outlining the reasons for the rejection.

Once the evidence has been successfully submitted, the sponsor can then lodge an application to include an IVD in the ARTG. Please see ***Section – Including IVD medical devices in the ARTG.***

What information should be on an EC/ISO 13485 certificate

There are a number of important details that a sponsor should check to ensure that the certificate is valid for particular IVDs. Wording and formatting will vary between certification bodies. Following is a mock-up of what an EC/ISO 13485 certificate should contain.

EC CERTIFICATE
for the
Quality Assurance System

As a notified body of the European Union (Reg no. 0413) *Company ABC* hereby approved the Quality Assurance System applied for design, manufacture and final inspection by the company

CERTIFICATE NUMBER 8000

Manufacturer ABC

Location:
23 Rue de Flower 12345 Forneaux

France

Approval is based on the result of the certification audit with report number 0000-aa-00 and is performed in accordance with the stipulations of

Annex IV, Section 3 of the Directive 98/79/EC

of the council dated June 14, 1993 governing In Vitro Diagnostic Medical Devices. The certification is applicable to the devices specified in the Annex. The manufacturer complies with the requirements of Annex IV, Section 3 of the Directive 98/79/EC.

The listed devices may be affixed with the CE marking indicated below.

IVDs included in this certificate:
Products for the detection of infectious markers, tumour markers and self monitoring of blood sugar and other parameters

CE 1234

Issue date **08.08.1998**
This certificate is valid until **26.07.2014**

Date of the last recertification: **27.07.2009**

Registration No: **8000**

Check the logo is from a Notified Body or recognised certification body

Certificate number

Check the manufacturer's name corresponds with the information on the IVD/IVD label.

Address must include the complete street address and country of origin.

A postal address is not sufficient.

Check the Annex Route is appropriate for the class of the device (EC certificates only).

Check that either the IVD Directive (and the Annex route) or ISO 13485 is specified on the certificate.

Check the scope of the certificate describes the IVD (this information may be on a 2nd page (Annex) of the certificate)

Look for Notified Body number (EC certificates only)

Date this site was first inspected

Date of most recent inspection

Certificate number

Check expiry date of the certificate

Please note: Certificates may reference attachments or additional information such as:

- “see overleaf”
- Annexes
- Enclosures
- Schedules
- Addendums
- IVDD product lists

This information MUST be provided with the certificate. If the certificate has page numbers, then ALL pages must be provided.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Authorisation Branch	March 2011
V1.1	Update to reflect the extended acceptance of ISO13485 certificates	Medical Devices Authorisation Branch	September 2022

Therapeutic Goods Administration

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