Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Transition to new Manufacturer Evidence for IVD medical devices

Additional case studies and scenarios

November 2023

Contents

Introduction

This guidance provides additional case studies and scenarios about manufacturer evidence for sponsors transitioning to new conformity assessment certification. Many sponsors and manufacturers of In Vitro Diagnostic (IVD) medical devices will be seeking to transition to new manufacturer evidence because of either:

- The new European Union (EU) IVD Regulation 2017/746 (EU IVDR) that replaces EU IVD Directive 98/79/EC (IVDD).
- The TGA phase out of acceptance of many ISO 13485 certificates as manufacturer evidence*, unless supported by manufacturer's EU Declaration of Conformity (DoC) made under the IVDD prior to 26 May 2022.

**The TGA continues to recognise ISO 13485 as an acceptable standard. However, certificates issued by either of the following bodies, are no longer accepted as manufacturer evidence for new IVD inclusion applications unless accompanied by manufacturer's EU DoC made prior to 26 May 2022.*

a) *A body accredited by a signatory to the Multilateral Recognition Arrangement of the International Accreditation Forum (IAF MLA), or*
b) *A Notified Body designated under the EU IVDD*

This guidance is to be read in conjunction with the guidance Transition to new manufacturer evidence for IVD medical devices available on the TGA website.

Case Studies

Example	Case Study
	Michael is an applicant who intends to make an application for inclusion for a Class 3 IVD. He is using an active ISO 13485 certificate issued by a Notified Body designated under the EU IVDD as supporting conformity assessment evidence. **Michael will need to provide an alternative certification acceptable for Class 3 IVD or provide EU DoC issued by the manufacturer under EU IVDD before 26 May 2022 to continue with the ARTG inclusion application. TGA no longer accepts ISO 13485 certificates issued by a Notified Body designated under the EU IVDD as conformity assessment evidence for new ARTG inclusion applications, unless supported by EU DoC.**
	Craig is an applicant who intends to make an application for inclusion for a Class 3 IVD. He is using an active ISO 13485 certificate issued by an accreditation body that is a signatory to the IAF MLA as supporting conformity assessment evidence. **Craig will need to provide an alternative certification acceptable for Class 3 IVD or provide EU declaration of conformity issued by the manufacturer under EU IVDD before 26 May 2022 to continue with the ARTG inclusion application. TGA no longer accepts ISO 13485 certificates issued by a signatory to the IAF MLA as conformity assessment evidence for new ARTG inclusion applications, unless supported by EU DoC.**

Example	Case Study
	Amanda has an ongoing ARTG inclusion application submitted before 26 May 2023 and supported by an ISO 13485 certificate that expired during the application process. **Amanda is required to submit an updated ISO 13485 certificate or an alternative form of evidence before a decision can be made on the application. TGA can progress the assessment of the application, but it will not be able to make a decision without valid conformity assessment evidence at the time of decision.**
	Robert is a sponsor who has an ARTG entry for a Class 3 IVD supported by a valid ISO 13485 certificate and the details have been included in the TGA records. **No action is required at this point as the sponsor can continue to supply devices already included in the ARTG, till supported by valid ISO 13485 certificate. Robert is encouraged to transition to an alternative form of evidence, noting the policy intent to eventually phase out the acceptance of ISO 13485 certificates for existing ARTG entries.**
	Paul is a sponsor who has an ARTG entry for a Class 2 IVD supported by a valid ISO 13485 certificate but has not updated these details in the TGA records. The TGA records only has details of an expired ISO 13485 certificate. **Paul can continue to supply devices already included in the ARTG and is recommended to submit a Manufacturer evidence variation to update the TGA records. Paul is encouraged to transition to alternative form of evidence before the ISO certificate expires, noting the policy intent to eventually phase out the acceptance of ISO 13485 certificates for existing ARTG entries.**
	Nick is a sponsor who has an ARTG entry for a Class 3 IVD which is supported by an expired ISO 13485 certificate. The manufacturer does not have a valid ISO 13485 certificate or any other form of acceptable certification. The TGA records only has details of the expired certificate. **Nick can continue to supply products that were manufactured when the ISO 13485 certificate was valid, but will need to obtain a new form of valid acceptable evidence from the manufacturer to continue to supply in Australia any products manufactured after the certification expired.** **Nick must notify the TGA within 60 days of becoming aware that the ISO 13485 certificate expired using the notification form for lapses in medical device conformity assessment certification.**

Example	Case Study
	Jenny is a sponsor who has an ARTG entry for a Class 4 IVD that is transitioning from EU IVDD to EU IVDR certification. During this process, the IVDD Design Certificate supporting their Class 4 IVD device has expired. For a Class 4 IVD, the *Therapeutic Goods (Medical Devices – Information that Must Accompany Application for Inclusion Determination 2018)* states the conformity assessment evidence related to manufacturers Quality Management System along with Design examination (i.e. product assessment evidence) is required. **Jenny can continue to supply products that were manufactured when the IVDD certificate was valid, but will need to obtain a new form of valid acceptable evidence from the manufacturer to continue to supply in Australia any products manufactured after the certification expired.** **Jenny must notify the TGA within 60 days of becoming aware that the certificate expired using the notification form for lapses in medical device conformity assessment certification.**

Scenarios for IVD ARTG entries and applications

1.What if the scope of the new EU IVDR certificate has changed and the change no longer covers some of the devices that are supplied under the ARTG entries?

The sponsor can continue to supply all products that were manufactured under the previous valid certification, but will need to obtain a new form of valid acceptable evidence to continue to supply in Australia the products that are not covered under the new IVDR certification.

They must notify the TGA within 60 days of becoming aware that the certificate lapsed/expired using the notification form for lapses in medical device conformity assessment certification.

If the sponsor is unable to obtain alternative certification and if the scope of the manufacturer evidence certificate no longer supports all the devices included in the ARTG entries, they must submit a request to the TGA to cancel the relevant ARTG entries not covered by the conformity assessment evidence. The sponsor is encouraged to contact TGA at devices@health.gov.au if they wish to discuss any impact on supply disruptions.

2. I have submitted an inclusion application with ISO 13485 certificate issued before 26 May 2023 as manufacturer evidence. The ISO certificate expires in two months from the application date. Can I submit a renewed certificate later in the application process?

Yes, the sponsor will need to provide the TGA either with an updated ISO 13485 certificate or a new form of acceptable conformity assessment certification for the application to be progressed. The TGA will not be able to progress an application without a valid manufacturer evidence, at the time of decision.

3. I wish to apply for inclusion of Class 2 IVDs in Australia. The manufacturer is transitioning to EU IVDR certification. However, these devices are lower class (i.e., Class A) under EU IVDR regulations. What is the evidence required for the purposes of TGA application?

Class A devices in Europe are self-certified. As the devices are classified as Class 2 IVD in Australia, you will be required to provide an acceptable form of certification for Class 2 IVDs. Refer to *Therapeutic Goods (Medical Devices – Information that Must Accompany Application for Inclusion Determination 2018)* for acceptable conformity assessment evidence.

4. Can I submit an ARTG inclusion application with Class 2 IVD supported by ISO 13485 certificate issued by either an accreditation body that is a signatory to the IAF MLA or a Notified Body designated under the EU IVDD?

Yes, a class 2 IVD inclusion application can be submitted supported by ISO 13485 certificate issued by either an accreditation body that is a signatory to the IAF MLA or a Notified Body designated under the EU IVDD as conformity assessment evidence, if it is associated with the manufacturer's European Declaration of Conformity made under the EU IVDD before 26 May 2022. This is acceptable until 26 May 2027 for Class 2 IVDs.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Authorisation Branch	November 2023

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication #