



Australian Government

Department of Health
Therapeutic Goods Administration

Manufacturer evidence for medical devices and IVD medical devices

11 October 2019

A Manufacturer's Evidence application must be submitted in TBS and accepted by the TGA before you can commence an application for any medical device or IVD medical device other than:

- Class I non-sterile, non-measuring
- Class I IVD medical device
- Class I (export only)
- Class I IVD (export only)

Note

Do not commence your new medical device or IVD medical device application until your Manufacturer's Evidence has been approved by the TGA.

The following guidance outlines:

- Acceptable Manufacturer Evidence
- How to submit new Manufacturer Evidence
- How to submit a variation to existing Manufacturer Evidence

Note

All Manufacturer's Evidence, including attachments, must be provided in English.

On this page: [Acceptable Manufacturer Evidence](#) | [How to submit new Manufacturer Evidence](#) | [What happens next?](#) | [How to submit a variation to existing Manufacturer Evidence](#)

Acceptable Manufacturer Evidence

The following documentation is considered to be acceptable Manufacturer Evidence (depending on the classification of the device you intend to include in the ARTG):

- A TGA Conformity Assessment Certificate.
- Overseas market authorisation evidence from a [comparable overseas regulator](http://www.tga.gov.au/comparable-overseas-regulators-medical-device-applications) (<http://www.tga.gov.au/comparable-overseas-regulators-medical-device-applications>)

- Declaration of Conformity to clause 7.5 of Schedule 3 of the Regulations for a system or procedure pack. For guidance and templates regarding the Declaration of Conformity refer to the [Declaration of conformity templates \(medical devices\)](http://www.tga.gov.au/form/declaration-conformity-templates-medical-devices) (<http://www.tga.gov.au/form/declaration-conformity-templates-medical-devices>) or [Declaration of conformity templates \(IVD medical devices\)](http://www.tga.gov.au/form/declaration-conformity-templates-ivds) (<http://www.tga.gov.au/form/declaration-conformity-templates-ivds>) webpage.
- A Certificate issued under an MRA (Mutual Recognition Agreement) in accordance with Schedule 3 of the Regulations by a recognised Notified Body (relevant to medical devices only).

Note

Certificates issued under MRAs may no longer be acceptable for some higher risk devices including Class III and AIMDs. Please review the information available on the TGA's website [Regulation impact statement: Changes to premarket assessment requirements for medical devices - Background](http://www.tga.gov.au/book/background) (<http://www.tga.gov.au/book/background>).

How to submit new Manufacturer Evidence

If you have not previously submitted Manufacturer Evidence for your medical device, or IVD medical device, you will need to follow the steps below to submit a Manufacturer Evidence application.

Note

You must submit your Manufacturer Evidence and have it accepted by the TGA before you commence your application for inclusion in the ARTG.

If you have previously submitted Manufacturer's Evidence that applies to your new application, you will not need to undertake this process again. Your manufacturer information should be available to you in your new application form.

If you are unsure whether you have previously submitted Manufacturer Evidence, you are able to check what evidence is available in your TBS account under:

- "Your TGA"
- "Medical device evidence"

Open the [TBS home page](https://www.ebs.tga.gov.au/) (<https://www.ebs.tga.gov.au/>):

- Select 'Login to Business Services'
- Type in your user name and password
- From the 'Applications' menu, select 'Manufacturer Evidence' under the 'Medical Device' heading. This will take you to the Manufacturer Evidence page.
- 'Sponsor's own reference' is a free text box. Please use any words that will help you identify the specific documentation you are submitting for your own purposes.
- Select your manufacturer through the "Search" button.



Note

- If your manufacturer does not appear under "Search", please select "New Manufacturer".
 - Selecting "New Manufacturer" will open a sub-form where you can enter the manufacturer's details and attach documentation to confirm the details you have entered.
 - Once you have entered your information and clicked "Send", you will need to wait for the TGA to process your information before continuing your Manufacturer's Evidence application.
 - You will receive email notifications from the TBS system upon submission of your information and completion of the process.
 - Acceptance of the new information may take 24-48 hours.
- Once you have selected the manufacturer, please complete all remaining fields including selecting "Type of product".

Note

Be careful to select the correct source of certification when completing your application.

Some organisations have extremely similar names that are only discerned by a number. For example BSI 0086 and BSI 2797 are two different entities for the purposes of this application form. Entering the incorrect BSI entity will result in your application being rejected.

Name and address of the manufacturer should be consistent with the details in the conformity assessment document. If the details are incorrect or inconsistent, request TBS to update the client details by sending an email to ebs@tga.gov.au (<mailto:ebs@tga.gov.au>).

- Attach supporting documentation.

Note

Only one piece of evidence should be attached to your application.

If the information in your application does not match the information in the attached evidence or if multiple documents are attached, your application will be rejected.

E.g. If you have an ISO 13485 and an EC Certificate, you should only attach the EC Certificate to your application.

- Select 'Validate'. This will only check that all fields are completed and that documentation is attached. It will not validate that the information is correct.
 - If validation is successful 'Validation successful' will appear at the top of the application together with a unique Evidence Identifier number

- If you have missed an entry the system will not validate and will provide you with a message relating to any missing information (e.g. you have not attached documents). You will need to complete the missing information before you can proceed.
- Once you have successfully validated your application you will be able to select 'Submit'
- The Manufacturer Evidence will be submitted electronically to the TGA.
- To view your lodged Manufacturer Evidence click on 'View lodged submissions.'

Note

There is no fee associated with a Manufacturer's Evidence application.

What happens next?

Your Manufacturer Evidence will be reviewed and you will receive notification with one of the following outcomes:

- Accepted.
- Rejected.

Note

We aim to process Manufacturer Evidence applications within 15 [working days](http://www.tga.gov.au/acronyms-glossary#summary-w). This is a target, not a legislative, time frame only and in some cases your application may take longer.

Accepted

You will receive an automated email in your inbox in TBS advising that your Manufacturer Evidence has been accepted.

You can view your accepted Manufacture Evidence in TBS by selecting 'Your TGA information' from the menu on the left in your portal, and then selecting 'Medical Device Evidence'.

The Manufacturer Evidence Identifier number is unique to your evidence and is required to complete an application for inclusion.

Note

Manufacturer Evidence will only appear in the TBS application for inclusion form after it has been accepted by the TGA. For this reason it is imperative that you do not start your application for inclusion in TBS until you receive notification that we have accepted your Manufacturer Evidence.

Rejected

You will receive written notification outlining the reasons for the rejection.

Ensure that any deficiencies outlined in the notification of rejection are rectified before you submit a new Manufacturer Evidence application or a variation to an existing accepted Manufacturer Evidence application.

You can recommence the process of submitting Manufacturer Evidence at any time.

How to submit a variation to existing Manufacturer Evidence

You will need to submit a variation to Manufacturer Evidence under the following circumstances:

- Change in name and address of the Manufacturer
- Change to the issuer certification number
- Change to evidence issue date
- Change to evidence expiry date
- Change to evidence re-issue date
- Change to conformity assessment procedure
- Change to the certification body issuing the certificate

Note

You can only submit one variation at a time to each previously accepted evidence through TBS. Please wait until your variation has been processed before you submit each additional variation.

To submit a variation to Manufacturer Evidence, log in to TBS via [TGA Business Services](https://www.tga.gov.au/tga-business-services) ([//www.tga.gov.au/tga-business-services](https://www.tga.gov.au/tga-business-services)) and:

- Go to 'Your TGA Information' in the menu on the left of the portal.
- Select 'Medical Device Evidence'.
- Click on the appropriate accepted Manufacturer Evidence.
- Select the 'Create Variation' button - an information message will be displayed 'Please wait while the variation is being created'
- Select 'OK'
- Another information message will be displayed 'A variation document has been created - refer to the view drafts from the TBS portal'
- Select 'OK'.
- If the message - 'A variation or replacement of this document already exists - a variation has not been created' - select 'OK'.
- 'Close' the accepted Manufacturer Evidence view

Note

You cannot submit a variation to existing Manufacturer Evidence if you are changing the source of certification (e.g., Changing from an EC certificate to an Auditing Organisation for MDSAP certification) In this situation you must submit the certificate as new Manufacturer Evidence and then request the new evidence to be linked to relevant ARTG inclusions by sending an email to devices@tga.gov.au (<mailto:devices@tga.gov.au>).

This will create draft evidence that will enable you to edit the form.

- Select 'Home'
- Open the 'Portal' and select 'View Drafts'
- Find and select the new draft evidence created above
- Select 'Edit' button to edit the form
- Make your amendment(s)
- You will need to attach electronic supporting documentation to proceed (see below for more information on the documentation required)
- Select 'Validate'
- If the validation is successful 'Validation successful' will appear at the top of the application.
- If you missed an entry, the system will not validate and will provide you with a message relating to any missed information (for example, you have not attached any documents)
- Select 'Submit' and the Manufacturers Evidence variation will be submitted to us for review.

To confirm changed details (manufacturer's name and/or address) in Client the TGA will require documentation supporting the change. For example:

- A letter or evidence from the notified body documenting the history of the change of name and confirming that it is the same legal entity and indicating if the change in address is an additional site. If it is an additional site further documentation from the certification body to verify whether this new site is considered to be the same manufacturer.

Note

ARTG entries that are linked to the accepted Manufacturer Evidence variation will not automatically be updated to reflect a change to the manufacturer's name and/or address. Once your variation has been ACCEPTED you will be notified of the approval and sent a request to submit a Device Change Request (DCR) application to be processed under section 9D of the *Therapeutic Goods Act 1989* (<https://www.legislation.gov.au/Series/C2004A03952>).

More information about [varying entries in the ARTG for medical devices](http://www.tga.gov.au/publication/varying-entries-artg-medical-devices-and-ivds) (<http://www.tga.gov.au/publication/varying-entries-artg-medical-devices-and-ivds>) is available on our website.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch	October 2019

Category: Medical devices/IVDs

URL: <https://www.tga.gov.au/node/882090> (<https://www.tga.gov.au/node/882090>)



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