

Medical device inclusion process

Steps in the process

26 August 2021

This guidance is intended for [sponsors \(//www.tga.gov.au/acronyms-glossary#summary-s\)](https://www.tga.gov.au/acronyms-glossary#summary-s) applying for inclusion of a 'kind of medical device', including IVD medical devices, in the Australian Register of Therapeutic Goods ([ARTG \(//www.tga.gov.au/acronyms-glossary#summary-a\)](https://www.tga.gov.au/acronyms-glossary#summary-a)).

For guidance on exporting medical devices (from Australia) refer to [Application for certificate of free sale or export certificate for a medical device \(//www.tga.gov.au/form/application-certificate-free-sale-or-export-certificate-medical-device\)](https://www.tga.gov.au/form/application-certificate-free-sale-or-export-certificate-medical-device) web page.

Note

Before you can apply for a Certificate of Free Sale or an Export Certificate you may need to have an ARTG inclusion for your product. Please review the guidance relating to this process on our website at [Certificates of free sale and export certificates for medical devices \(//www.tga.gov.au/certificates-free-sale-and-export-certificates-medical-devices\)](https://www.tga.gov.au/certificates-free-sale-and-export-certificates-medical-devices).

Medical devices, including IVD medical devices, are regulated by the Therapeutic Goods Administration (TGA). We regulate medical devices in accordance with:

- The [*Therapeutic Goods Act 1989*](https://www.legislation.gov.au/Series/C2004A03952) (the Act)
- The [*Therapeutic Goods \(Medical Devices\) Regulations 2002*](https://www.legislation.gov.au/Series/F2002B00237) (the Regulations)
- The [*Therapeutic Goods Regulations 1990*](https://www.legislation.gov.au/Series/F1996B00406)

Any medical device (unless excluded or exempt under the Act) must be included in the ARTG before it can be legally imported into, supplied within or exported from Australia.

Steps in the process

The following web pages:

- identify the process you will need to follow to include your device in the ARTG,
- navigate you through the inclusion processes step-by-step,
- contain hyperlinks to the regulatory and technical guidance, and application forms you will need to complete each step in the process, and
- identify when the process is complete.

These are the steps in the medical device inclusion process covered in the following web pages and their associated guidance documents:

- Step 1 - [Is your product a medical device that requires inclusion in the ARTG? \(//www.tga.gov.au/book-page/step-1-your-product-medical-device-or-ivd-medical-](https://www.tga.gov.au/book-page/step-1-your-product-medical-device-or-ivd-medical-)

- [device-requires-inclusion-artg\)](#)
- Step 2 - [Things to consider prior to application \(//www.tga.gov.au/book-page/step-2-things-consider-prior-application\)](#)
 - [Kind of medical device, including IVD medical device \(//www.tga.gov.au/kind-medical-device\)](#)
 - [Manufacturer evidence for a medical device or IVD medical device \(//www.tga.gov.au/manufacturer-evidence-medical-devices-and-ivd-medical-devices\)](#)
 - [Classification of medical device \(//www.tga.gov.au/sme-assist/what-classification-my-medical-device\) or IVD medical device](#)
 - [Priority review designation \(//www.tga.gov.au/book-page/criteria-priority-review-designation\)](#)
 - [Supporting documentation for inclusion of a medical device or IVD medical device, in the ARTG \(//www.tga.gov.au/supporting-documentation-inclusion-medical-device\)](#)
 - [Auditing of applications for ARTG inclusion of a medical device or IVD medical device in the ARTG \(//www.tga.gov.au/auditing-medical-device-including-ivd-medical-device-applications\)](#)
- Step 3 - [Accessing TGA Business Services system \(TBS\) \(//www.tga.gov.au/book-page/step-3-accessing-tga-business-services\)](#)
- Step 4 - [Submitting an application in TBS for Class I non-sterile, non-measuring and Class 1 IVD medical devices \(//www.tga.gov.au/book-page/step-4-submitting-application-tbs-class-i-non-sterile-non-measuring-and-class-1-ivd-medical-devices\)](#)
- Step 5 - [Submitting an application in TBS for Class I Medical Device \(Export Only\) and Class 1 IVD medical device \(Export Only\) \(//www.tga.gov.au/book-page/step-5-submitting-application-tbs-class-i-medical-device-export-only-and-class-1-ivd-medical-device-export-only\)](#)
- Step 6 - [Submitting an application in TBS \(for all classes except Class I non-sterile, non-measuring medical device, Class 1 IVD medical device and Class I medical device/Class 1 IVD medical device Export Only\) \(//www.tga.gov.au/book-page/step-6-submitting-application-tbs-all-classes-except-class-i-non-sterile-non-measuring-medical-device-class-1-ivd-medical-device-and-class-i-medical-deviceclass-1-ivd-medical-device-export-only\)](#)
- Step 7 - [Processing your application \(//www.tga.gov.au/book-page/step-7-processing-your-application\)](#)
- Step 8 - [Printing your ARTG certificate of inclusion \(//www.tga.gov.au/book-page/step-8-printing-your-artg-certificate-inclusion\)](#)
- [Ongoing responsibilities \(//www.tga.gov.au/book-page/step-9-ongoing-responsibilities\)](#)

Step 1 - Is your product a medical device or an IVD medical device that requires inclusion in the ARTG?

To ensure that your product is a medical device that requires inclusion in the ARTG you need to check the following:

- [Is your product a medical device or IVD medical device?](#)
- [Has your product been declared not to be a medical device?](#)
- [Is your product a good that has been excluded from regulation?](#)

- Is your product exempt from inclusion in the ARTG?
- Is your product a therapeutic good other than a medical device?

Is your product a medical device or IVD medical device?

Does the manufacturer's intended purpose meet the definition of a medical device ([//www.tga.gov.au/what-medical-device](http://www.tga.gov.au/what-medical-device)) under section 41BD of the Act and, if applicable, the definition of an IVD medical device ([//www.tga.gov.au/ivd-medical-devices-definitions-links](http://www.tga.gov.au/ivd-medical-devices-definitions-links)) in the Regulations?

Check if your product has been specified a medical device under:

- Therapeutic Goods (Articles that are Medical Devices) Specification 2014 (<https://www.legislation.gov.au/Details/F2014L01741>).

Note

The manufacturer is responsible for determining the intended purpose of your product. The intended purpose of the product can be ascertained from the manufacturer's instructions from use, advertising material, technical documentation, and/or project label(s)

If you change the intended purpose of the product, you will meet the legislative definition of a manufacturer and you will need to meet the manufacturer's obligations under the relevant legislation.

Has your product been declared not to be a medical device?

Check if your product is declared not to be a medical device under:

- Therapeutic Goods (Articles that are not Medical Devices) Order No.1 2017 (<https://www.legislation.gov.au/Series/F2017N00051>)
- Therapeutic Goods (Articles that are not Medical Devices) Order. No.1 of 2010 ([//www.tga.gov.au/publication/device-medicine-boundary-products](http://www.tga.gov.au/publication/device-medicine-boundary-products))
- Therapeutic Goods (Articles that are not Medical Devices) Order No.2 of 2004 ([//www.tga.gov.au/therapeutic-goods-articles-are-not-medical-devices-order-no-2-2004](http://www.tga.gov.au/therapeutic-goods-articles-are-not-medical-devices-order-no-2-2004)).

Has your product been excluded from regulation?

Check the Therapeutic Goods (Excluded Goods) Determination 2018 (<https://www.legislation.gov.au/Series/F2018L01350>) to see if your product has been excluded from regulation. Products excluded from regulation do not need to be included in the ARTG before they can be exported from, imported to or supplied within Australia.

Is your IVD medical device intended for self-testing and is it prohibited from supply in Australia?

To determine whether your IVD medical device is prohibited from supply in Australia for self-testing purposes, please review the following:

- The [Therapeutic Goods \(Excluded Purposes\) Specification 2010](https://www.legislation.gov.au/Series/F2010L01889) (<https://www.legislation.gov.au/Series/F2010L01889>).

Is your product exempt from inclusion in the ARTG?

Medical devices that are exempt from inclusion in the ARTG are those products:

- supplied for [clinical trials](http://www.tga.gov.au/clinical-trials) (<http://www.tga.gov.au/clinical-trials>) in Australia,
- prescribed by [authorised prescribers](http://www.tga.gov.au/form/authorised-prescribers) (<http://www.tga.gov.au/form/authorised-prescribers>),
- supplied under the [Special Access Scheme](http://www.tga.gov.au/form/special-access-scheme) (<http://www.tga.gov.au/form/special-access-scheme>),
- imported for personal use under the [Personal Importation Scheme](http://www.tga.gov.au/publication/personal-import-scheme) (<http://www.tga.gov.au/publication/personal-import-scheme>), or
- that are [custom-made medical devices](http://www.tga.gov.au/custom-made-medical-devices) (<http://www.tga.gov.au/custom-made-medical-devices>).

Is your product a therapeutic good other than a medical device?

To determine whether your product is a therapeutic good other than a medical device (e.g. a medicine) that requires inclusion in the ARTG, please review the following:

- [What are therapeutic goods?](http://www.tga.gov.au/what-are-therapeutic-goods) (<http://www.tga.gov.au/what-are-therapeutic-goods>)
- [Regulation of therapeutic goods in Australia.](http://www.tga.gov.au/industry) (<http://www.tga.gov.au/industry>).
- [Overview of supplying therapeutic goods in Australia](http://www.tga.gov.au/overview-supplying-therapeutic-goods-australia) (<http://www.tga.gov.au/overview-supplying-therapeutic-goods-australia>).
- [Device - medicine boundary products](http://www.tga.gov.au/publication/device-medicine-boundary-products) (<http://www.tga.gov.au/publication/device-medicine-boundary-products>).

Your product is not a medical device that requires inclusion in the ARTG if it:

- does not meet the definition of a medical device; or
- has been declared not to be a medical device; or
- has been excluded from regulation; or
- is an exempt medical device; or
- is regulated as a therapeutic good other than a medical device.

Where to next?

If your product is a medical device or an IVD medical device that requires inclusion in the ARTG go to [Step 2 - Things to consider prior to application](http://www.tga.gov.au/book-page/step-2-things-consider-prior-application) (<http://www.tga.gov.au/book-page/step-2-things-consider-prior-application>).

Step 2 - Things to consider prior to application

Before submitting your application for inclusion you will need to consider the following:

- Does your device require conformity assessment? You will need to view the information about [conformity assessment \(//www.tga.gov.au/conformity-assessment\)](http://www.tga.gov.au/conformity-assessment) and [overseas market authorisation \(//www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds\)](http://www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds) prior to application, to ensure you are submitting the device under the right classification with the right conformity assessment documentation:
 - [Medical Devices \(//www.tga.gov.au/form/declaration-conformity-templates-medical-devices\)](http://www.tga.gov.au/form/declaration-conformity-templates-medical-devices)
 - [IVDs \(//www.tga.gov.au/form/declaration-conformity-templates-ivds\)](http://www.tga.gov.au/form/declaration-conformity-templates-ivds)

Note

Some medical devices must have a TGA Conformity Assessment certificate. An application for their inclusion into the ARTG cannot be made with evidence from a comparable overseas regulator. Devices that are required to have a TGA Conformity Assessment certificate are listed in Regulation 4.1 of the [*Therapeutic Goods \(Medical Devices\) Regulations 2002*](https://www.legislation.gov.au/Series/F2002B00237) (<https://www.legislation.gov.au/Series/F2002B00237>).

- If you are intending to supply a medical device, or IVD medical device, in Australia, you will need to ensure that you meet the definition of a sponsor under the [*Therapeutic Goods Act 1989*](https://www.legislation.gov.au/Series/C2004A03952) (<https://www.legislation.gov.au/Series/C2004A03952>). These requirements include that you must be a recognised Australian-based legal entity.

As a first step before you submit an application for inclusion, you will need to establish a relationship with the manufacturer of your device in order to:

- obtain documentation/information required to demonstrate that the kind of medical device complies with the regulatory requirements in Australia;
 - provide documentation/information relating to the regulatory, technical, clinical and safety aspects of the device that we may request at any time while you are supplying the device in Australia; and
 - advise you of any problems, safety alerts or recalls that may arise with the use of the device.
- ['Kind of Medical Device' \(//www.tga.gov.au/kind-medical-device\)](http://www.tga.gov.au/kind-medical-device): Applications for inclusion of medical devices and IVD medical devices, in the ARTG are made for a kind of medical device. This allows low to medium risk devices to be grouped by defined characteristics under one ARTG entry rather than requiring each product to have its own separate entry in the ARTG.
 - In addition to acquiring the appropriate Manufacturer's Evidence prior to making an application, sponsors should also consider having their manufacturer provide them with a [Declaration of Conformity \(//www.tga.gov.au/form/declaration-conformity-templates-medical-devices\)](http://www.tga.gov.au/form/declaration-conformity-templates-medical-devices) in support of their medical device, or [IVD medical device \(//www.tga.gov.au/form/declaration-conformity-templates-ivds\)](http://www.tga.gov.au/form/declaration-conformity-templates-ivds), as the TGA may request this documentation at any time. You should review [Supporting](#)

[documentation for inclusion of a device \(//www.tga.gov.au/supporting-documentation-inclusion-medical-device\)](http://www.tga.gov.au/supporting-documentation-inclusion-medical-device) for more information about the documentation you may require throughout the inclusion process.

- Classification of your medical device or IVD medical device: The classification rules are stated in the *Therapeutic Goods (Medical Devices) Regulations 2002* (<https://www.legislation.gov.au/Series/F2002B00237>). The TGA has also produced an online tool to help you determine what classification your medical device is. You can find the tool at [What classification is my medical device? \(//www.tga.gov.au/sme-assist/what-classification-my-medical-device\)](http://www.tga.gov.au/sme-assist/what-classification-my-medical-device)

Note

It is important to ensure that your medical device or IVD medical device has been correctly classified by the manufacturer according to Australian classification rules before you make, and pay for, an application for inclusion. Australian classification can be different from other comparable overseas regulator's classification rules and the TGA will not refund your application fee if you submit, and pay for, an application for the incorrect classification for your device.

This tool is for guidance only for medical devices. Currently a classification tool is not available for IVD medical devices.

- Whether your device qualifies for [Priority Review \(//www.tga.gov.au/publication/priority-review-designations-medical-devices-including-ivds\)](http://www.tga.gov.au/publication/priority-review-designations-medical-devices-including-ivds) designation. If your device is intended for the monitoring, treatment, prevention or diagnosis of a life threatening or seriously debilitating condition; and there is currently an unmet need for your device; and your device represents breakthrough technology or provides a clinical advantage (or public health need for IVD medical devices), you may qualify for Priority Review designation, which will allow your application 'front-of-queue' priority status.
- If your application is selected for audit, you may be asked to provide further documentation. Please review the following for more information:
 - [Auditing of medical device, including IVD medical device, applications. \(//www.tga.gov.au/auditing-medical-device-including-ivd-medical-device-applications\)](http://www.tga.gov.au/auditing-medical-device-including-ivd-medical-device-applications)

Go to [Step 3 - Accessing TGA Business Services \(TBS\) \(//www.tga.gov.au/book-page/step-3-accessing-tga-business-services\)](http://www.tga.gov.au/book-page/step-3-accessing-tga-business-services)

Step 3 - Accessing TGA business services

You will need to have a Client ID and access to the TBS website in order to submit your medical device application.

Applying for a Client ID

If you are a first time applicant and you do not have a Client ID, you need to apply to register your details with the TGA by completing and submitting the [Organisation details form](http://www.tga.gov.au/form/organisation-details) ([//www.tga.gov.au/form/organisation-details](http://www.tga.gov.au/form/organisation-details)) in TBS.

The TGA will then issue you with a Client Identification number.

Your Client Identification number will be used in all your application forms.

Note

Ensure that you only nominate persons on your organisation details form who you authorise to undertake business/regulatory correspondence with us on your behalf as we will only engage in business/regulatory correspondence with those persons. You will also need to ensure that the details of authorised persons on your account remain current at all times.

Updating your client details

TBS is our primary method of communicating with you. You should ensure that your client details are up-to-date at all times, particularly in relation to:

- your postal and email address,
- your company contact phone number and your mobile phone number, and
- the person(s) you authorise to be your representative or agent.

More information about keeping your information current can be found on the:

- [TBS - How to use the site](http://www.tga.gov.au/tga-business-services-how-use-site) ([//www.tga.gov.au/tga-business-services-how-use-site](http://www.tga.gov.au/tga-business-services-how-use-site)) page
- [TBS - Questions and answers for administrators](http://www.tga.gov.au/tga-business-services-questions-and-answers-administrators) ([//www.tga.gov.au/tga-business-services-questions-and-answers-administrators](http://www.tga.gov.au/tga-business-services-questions-and-answers-administrators)) page.

Where to next?

Once you have TBS access, and your details are up to date:

- for Class I non-sterile, non-measuring medical devices and Class 1 IVD medical devices go to [Step 4 - Submitting an application in TBS for Class I non-sterile, non-measuring and Class 1 IVD medical devices](http://www.tga.gov.au/book-page/step-4-submitting-application-tbs-class-i-non-sterile-non-measuring-and-class-1-ivd-medical-devices) ([//www.tga.gov.au/book-page/step-4-submitting-application-tbs-class-i-non-sterile-non-measuring-and-class-1-ivd-medical-devices](http://www.tga.gov.au/book-page/step-4-submitting-application-tbs-class-i-non-sterile-non-measuring-and-class-1-ivd-medical-devices))
- for Class I medical device/Class 1 IVD medical device Export Only go to [Step 5 - Submitting an application in TBS for Class I Medical Device \(Export Only\) and Class 1 IVD medical devices](http://www.tga.gov.au/book-page/step-5-submitting-application-tbs-class-i-medical-device-export-only-and-class-1-ivd-medical-devices) ([//www.tga.gov.au/book-page/step-5-submitting-application-tbs-class-i-medical-device-export-only-and-class-1-ivd-medical-devices](http://www.tga.gov.au/book-page/step-5-submitting-application-tbs-class-i-medical-device-export-only-and-class-1-ivd-medical-devices))

[IVD Medical Device \(Export Only\) \(//www.tga.gov.au/book-page/step-5-submitting-application-tbs-class-i-medical-device-export-only-and-class-1-ivd-medical-device-export-only\)](http://www.tga.gov.au/book-page/step-5-submitting-application-tbs-class-i-medical-device-export-only-and-class-1-ivd-medical-device-export-only)

- for all other medical devices go to [Step 6 - Submitting an application in TBS \(for all classes except Class I non-sterile, non-measuring medical device, Class 1 IVD medical device and Class I medical device/Class 1 IVD medical device Export Only\) \(//www.tga.gov.au/book-page/step-6-submitting-application-tbs-all-classes-except-class-i-non-sterile-non-measuring-medical-device-class-1-ivd-medical-device-and-class-i-medical-deviceclass-1-ivd-medical-device-export-only\)](http://www.tga.gov.au/book-page/step-6-submitting-application-tbs-all-classes-except-class-i-non-sterile-non-measuring-medical-device-class-1-ivd-medical-device-and-class-i-medical-device-class-1-ivd-medical-device-export-only)

Step 4 - Submitting an application in TBS for Class I non-sterile, non-measuring and Class 1 IVD medical devices

The following process is for:

- Class I non-sterile, non-measuring, and
- Class 1 IVD medical devices.

For Class I medical device/IVD medical device Export Only go to [Step 5 - Submitting an application in TBS for Class I Medical Device \(Export Only\) and Class 1 IVD Medical Device \(Export Only\)](https://www.tga.gov.au/book-page/step-5-submitting-application-tbs-class-i-medical-device-export-only-and-class-1-ivd-medical-device-export-only) ([//www.tga.gov.au/book-page/step-5-submitting-application-tbs-class-i-medical-device-export-only-and-class-1-ivd-medical-device-export-only](https://www.tga.gov.au/book-page/step-5-submitting-application-tbs-class-i-medical-device-export-only-and-class-1-ivd-medical-device-export-only)).

From 1 October, the TGA has made [changes to the ARTG inclusion process for non-measuring, non-sterile Class I medical devices](https://www.tga.gov.au/changes-artg-inclusion-process-non-measuring-non-sterile-class-i-medical-devices-0) ([//www.tga.gov.au/changes-artg-inclusion-process-non-measuring-non-sterile-class-i-medical-devices-0](https://www.tga.gov.au/changes-artg-inclusion-process-non-measuring-non-sterile-class-i-medical-devices-0)). These changes have been incorporated into the guidance in this document.

Note

A Manufacturer Evidence application is not required for Class I non-sterile, non-measuring and Class 1 IVD medical devices. However, for Class I non-sterile, non-measuring devices, you must submit the manufacturer's [Declaration of Conformity](https://www.tga.gov.au/form/declaration-conformity-templates-medical-devices) ([//www.tga.gov.au/form/declaration-conformity-templates-medical-devices](https://www.tga.gov.au/form/declaration-conformity-templates-medical-devices)) with your application for inclusion in the ARTG.

The TGA may also contact you at any time after your device has been included in the ARTG to request documentation demonstrating that your product complies with any aspect of the relevant legislation. Documents that may be requested include, but are not limited to:

- [Manufacturer's Declaration of Conformity \(if your application relates to a Class 1 IVD medical device\)](https://www.tga.gov.au/form/declaration-conformity-templates-medical-devices) ([//www.tga.gov.au/form/declaration-conformity-templates-medical-devices](https://www.tga.gov.au/form/declaration-conformity-templates-medical-devices))
- Product information including labels, packaging, brochures, catalogues, Instructions for Use, etc.

On this page: [How to submit a medical device application for Class I non-sterile, non-measuring medical device or Class 1 IVD medical device](#) | [What happens next?](#) | [Invitation to provide feedback](#)

How to submit a medical device application for Class I non-sterile, non-measuring medical device or Class 1 IVD medical device

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 'Device/OTG Application' under the 'Medical Device' heading. This will take you to the Device Application page:

- In the 'Application for:' box, select 'Medical Device - Included' for a medical device or 'Medical Device - IVD' for an IVD medical device
- 'Sponsor's own reference' is a free text box. Please use any words that will help you identify the specific product for your own purposes.
- For 'Class':
 - select 'Class I' for medical devices
 - for IVD medical devices select 'Class 1'.Note that the fee for your application appears once you select the classification.
- Please answer the remaining questions using the information provided to you by the manufacturer of the product.

Note

In most cases, if you provide an answer to one of the questions that indicates the medical device should be a different classification, you will not be able to validate your form and proceed with your application. There are some questions that are appropriate for more than one class of device - the onus is on the sponsor to make an application for the correct classification.

- Once you have completed the first page, you will need to select 'Next' to progress.
- Select your manufacturer and GMDN code.

Note

If your GMDN code does not appear in the TGA code tables please email the details to devices@tga.gov.au (<mailto:devices@tga.gov.au>).

- Once you have completed the second page and you select 'Next' you will be taken to the 'Applicant's Certification' page. A summary of the information you have entered will be provided.

Note

For Class I non-sterile, non-measuring medical device applications you are required to attach the manufacturers [Declaration of Conformity](http://www.tga.gov.au/form/declaration-conformity-templates-medical-devices) (<http://www.tga.gov.au/form/declaration-conformity-templates-medical-devices>).

- Review the Applicant's Certification. In electronically submitting the application you are declaring, under section 41FD of the [Therapeutic Goods Act 1989](https://www.legislation.gov.au/Details/C2020C00255) (<https://www.legislation.gov.au/Details/C2020C00255>) (the Act), that the information given in the application and the statements in the declaration are current and correct. Please note there are civil and criminal penalties associated with supplying false or misleading information. A false declaration will result in the device entry being removed/cancelled from the ARTG.
- Select 'Validate'

Note

Selecting 'Validate' will ensure that all mandatory fields have been completed. Successful validation does not mean that the information entered has been confirmed as correct, as some responses may be suitable for more than one classification. It is your responsibility to ensure that you have correctly classified your device.

- If validation is successful 'validation successful' will appear at the top of the application.
- If you have missed an entry, or have not attached a manufacturer's Declaration of Conformity (if your application is for a Class I non-sterile, non-measuring device), the system will not validate and will provide you with a message relating to any missing information (e.g. you have not entered the intended purpose). You will need to complete the missing information before you can proceed.
- Once you have successfully validated your application, you will be able to click 'Submit'
- Select 'OK'
- Your application will be submitted electronically.
- The system will provide confirmation that your application has been submitted.
- To view your lodged application click on 'view lodged submissions'.
- An invoice will be sent in TBS to the individual you have nominated to have a financial role.
- Pay the relevant application fee.

What happens next?

Once your application fee is paid, the TGA will assess whether your Class I non-sterile, non-measuring medical device application / Class 1 IVD medical device application meets the requirements to include the device in the ARTG.

If further information is required to determine if your device meets these requirements, or if the kind of device is of concern to the TGA, the TGA may select your application for non-mandatory audit. The TGA may select an applications for non-mandatory audit if the information you provide in or with your application suggests:

- The product is excluded from the requirement to include it in the ARTG¹; or
- Any of the Certifications you made in your application under section 41FD of the Act appear to be incorrect, for example²:
 - The device is not a medical device;
 - The device is incorrectly classified;
 - The device does not comply with the Essential Principles;
 - The device has not had the Conformity Assessment Procedures (<http://www.tga.gov.au/conformity-assessment>) applied to it;
 - The information provided in or with the application is not complete or correct.

It may take up to four (4) business days to review your application and either include it in the ARTG or select it for audit.

The TGA will advise you, via TBS, whether your device has been included in the ARTG.

Note

Class I medical devices included in the ARTG may also be selected for post market review, to determine the correctness of the entry.

Applications for inclusion of Class 1 IVD medical devices that are intended for self-testing or use at the point of care must be selected for audit under Regulation 5.3 of the Regulations.

Go to [Step 8 - Printing your ARTG Certificate of Inclusion \(//www.tga.gov.au/book-page/step-8-printing-your-artg-certificate-inclusion\)](http://www.tga.gov.au/book-page/step-8-printing-your-artg-certificate-inclusion) and [Step 9 - Ongoing responsibilities \(//www.tga.gov.au/book-page/step-9-ongoing-responsibilities\)](http://www.tga.gov.au/book-page/step-9-ongoing-responsibilities).

Invitation to provide feedback

We invite sponsors of Class I medical devices and Class 1 IVD medical devices to provide their feedback on the changes made to the process for including Class I non-sterile, non-measuring medical devices, Class 1 IVD medical devices, and Class I Export Only and Class I IVD Export Only medical devices in the ARTG by answering an [online survey \(https://consultations.health.gov.au/tga/impacts-of-proposed-amendment-to-application\)](https://consultations.health.gov.au/tga/impacts-of-proposed-amendment-to-application).

Footnotes

1. Section 7AA of the *Therapeutic Goods Act 1989* (the Act) allows the Secretary to declare that certain goods are excluded from the requirement to be in the ARTG.
2. The complete list of the certifications you must make are set out in the application form, and in s 41FD of the Act.

Step 5 - Submitting an application in TBS for Class I Medical Device (Export Only) and Class 1 IVD Medical Device (Export Only)

How to submit an application form for Class I Medical Device (Export Only) and Class 1 IVD Medical Device (Export Only)

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

- Click on 'Login to Business Services'
- Type in your user name and password
- From the 'Applications' menu, select 'Device/OTG Application' under the 'Medical Device' heading. This will take you to the Device Application page.
- In the 'Application for:' box, select 'Medical Device - Included (Export Only)' for a medical device or 'Medical Device - IVD (Export Only)' for an IVD medical device
- 'Sponsor's own reference' is a free text box. Please use any words that will help you identify the specific product for your own purposes.
- Note that the fee for your application appears below the classification:
- Please answer the remaining questions using the information provided to you from the manufacturer of the product.
- Once you have completed the first page, you will need to select 'Next' to progress.
- Select your manufacturer and provide the export names of your device(s).
- Once you have completed the second page and you select 'Next' you will be taken to the 'Applicant's Certification' page. A summary of the information you have entered will be provided.

Note

For Class I medical device export only and Class 1 IVD medical device export only applications you are required to attach the manufacturer's Declaration of Conformity to the application.

- Review the Applicant's Certification before selecting Yes or No (in electronically submitting the application you are certifying that the information given in the application and the statements in the certification are current and correct). Please note there are civil and criminal penalties associated with supplying false or misleading information. A false certification will result in the device entry being removed/cancelled from the ARTG.
- Select 'Validate'.
- If validation is successful 'validation successful' will appear at the top of the application.
- 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 entered the intended purpose). You will need to complete the missing information before you can proceed.
- Once you have successfully validated your application, you will be able to click 'Submit'
- Select 'OK'

- Your application will be submitted electronically.
- The system will provide confirmation that your application has been submitted
- To view your lodged application click on 'view lodged submissions'.
- An invoice will be sent in TBS to the individual you have nominated to have a financial role.
- Pay the relevant application fee.

What happens next?

Once your application fee is paid, your Class I export only medical device application / Class 1 IVD export only medical device application will be either included in the ARTG or selected for audit. We may perform an audit of your application if the information provided suggests:

- The product included in your application does not meet the definition of a medical device
- The product included in your application is excluded from inclusion in the ARTG under subsection 7AA of the Act
- Not all declarations you made under section 41FD of the Act appear to be correct, for example the medical device included in your application does not appear to be correctly classified or compliant with the requirements of the Essential Principles.

Invitation to provide feedback

We invite sponsors of Class I medical devices and Class 1 IVD medical devices to provide their feedback on the changes made to the process for including Class I non-sterile, non-measuring medical devices, Class 1 IVD medical devices, and Class I Export Only and Class I IVD Export Only medical devices in the ARTG by answering an [online survey](https://consultations.health.gov.au/tga/impacts-of-proposed-amendment-to-application/) (<https://consultations.health.gov.au/tga/impacts-of-proposed-amendment-to-application/>).

Step 6 - Submitting an application in TBS (for all classes except Class I non-sterile, non-measuring medical device, Class 1 IVD medical device and Class I medical device/Class 1 IVD medical device Export Only)

Before you commence your application for inclusion, please:

- Ensure your Manufacturer's Evidence ([//www.tga.gov.au/manufacturer-evidence-medical-devices-and-ivd-medical-devices](http://www.tga.gov.au/manufacturer-evidence-medical-devices-and-ivd-medical-devices)) has been submitted and accepted.
- Ensure you have any required documentation as outlined in the final column 'Documentation to be provided with the application (Evidence of product assessment)' of Table 2 in the Use of market authorisation evidence from comparable overseas regulators/assessment bodies for medical devices (including IVDs ([//www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds](http://www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds))) as you will need to attach these document/s to your application (if applicable) in order to pass preliminary assessment.
- In addition to the above, you should ensure that you have the following available as it may be requested by the TGA at any time (please note, this information **should not** be attached to your device application):
 - information provided with the kind of medical device and used to promote the kind of medical device in Australia including copies of:
 - labelling
 - pictorial images of the device
 - packaging - inner and outer packaging for the device
 - instructions for use
 - product manual
 - other brochures related to the device
 - advertising material for the medical device including brochures, extracts from web pages, and advertisements.
 - If a device is a borderline medicine/medical device then information such as mechanism of action and rationale to justify whether your product meets the definition of a medical device must be kept available.
 - Evidence to demonstrate compliance with the Essential Principles. For high risk devices this may include the clinical evidence report and/or risk management report.

How to submit a medical device, or IVD medical device, application

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

- Select 'Login to Business Services'
- Type in your user name and password
- Click on 'Portal'
- From the 'Create Applications & Submissions' menu, select 'Device/OTG Application' under the 'Medical Device' heading. This will take you to the Device Application page:
- In the 'Application for:' box, select 'Medical Device - Included' for a medical device or 'Medical Device - IVD' for an IVD medical device

- Complete all questions on all pages
- Select the relevant class of the medical device or IVD medical device. Note that the fee for your application appears once you select the classification.
- Please answer the remaining questions correctly using the information provided to you from the manufacturer of the product.

Note

There are some questions that are appropriate for more than one class of device - the onus is on the sponsor to provide correct information and choose the correct classification for their product.

- Once you have completed the first page, you will need to select 'Next' to progress.
- Select your manufacturer and relevant [Manufacturer Evidence](http://www.tga.gov.au/manufacturer-evidence-medical-devices-and-ivd-medical-devices) ([//www.tga.gov.au/manufacturer-evidence-medical-devices-and-ivd-medical-devices](http://www.tga.gov.au/manufacturer-evidence-medical-devices-and-ivd-medical-devices)) then select the GMDN code.

Note

If your GMDN code does not appear in the TGA code tables please email the details to devices@tga.gov.au (<mailto:devices@tga.gov.au>).

- For Class III medical devices, AIMD medical devices and Class 4 IVD medical devices (except Class 4 IVD medical devices that are immunohaematology reagents) complete the Unique Product Identifier (UPI), functional description, total number of devices covered and where applicable, variant type and variant range.
- Once you have completed the second page and you select 'Next' you will be taken to the 'Applicant's Certification' page. A summary of the information you have entered will be provided.
- Attach any documentation required as outlined in the final column 'Documentation to be provided with the application (Evidence of product assessment)' of Table 2 in the [Use of market authorisation evidence from comparable overseas regulators/assessment bodies for medical devices \(including IVDs\)](http://www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-for-medical-devices-including-ivds) ([//www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-for-medical-devices-including-ivds](http://www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-for-medical-devices-including-ivds)))
- Review the Declaration (in electronically submitting the application you are declaring that in relation to the device the information given in the application and the statements in the declaration are current and correct).
- Select 'Validate' (this will check that all mandatory fields have been completed)
 - if validation is successful 'Validation successful' will appear at the top of the application
 - 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 entered the intended purpose). You will need to complete the missing information before you can proceed.

Note

Selecting 'Validate' will only ensure that all mandatory fields have been completed. Successful validation does not mean that the information entered has been confirmed as correct as some responses may be suitable for more than one classification. It is the sponsor's responsibility to ensure that they have selected the correct classification for their medical device and that the information provided is complete and correct.

- Once you have successfully validated your application, you will be able to click 'Submit'
- Select 'OK'
- The system will provide confirmation that your application has been submitted.
- To view your lodged application click on 'view lodged submissions'.
- An invoice will be sent to you or an individual in your organisation who is responsible for payment of fees.
- Pay the relevant application fee.

Note

You will be required to pay a separate assessment fee if your application is subject to a mandatory [application audit \(//www.tga.gov.au/auditing-medical-device-including-ivd-medical-device-applications\)](https://www.tga.gov.au/auditing-medical-device-including-ivd-medical-device-applications).

How to pay your application fee

We provide a range of payment options for payment of your application fee. For further information refer to the [Payment options \(//www.tga.gov.au/payment-options\)](https://www.tga.gov.au/payment-options) webpage.

Your application will not be processed until you have paid the application fees.

Note

Once you have paid a fee there are very limited circumstances under which you will be able to obtain a refund. For further information refer to the [refunds \(//www.tga.gov.au/refunds\)](https://www.tga.gov.au/refunds) webpage.

What happens next?

Once your application is submitted and the application fee has been paid, the information provided in and with the application will be assessed.

Note

You may be contacted by the TGA and asked to provide product information or your [Declaration of Conformity \(//www.tga.gov.au/form/declaration-conformity-templates-medical-devices\)](https://www.tga.gov.au/form/declaration-conformity-templates-medical-devices) to support your application.

Go to [Step 7 - Processing your Application \(//www.tga.gov.au/book-page/step-7-processing-your-application\)](http://www.tga.gov.au/book-page/step-7-processing-your-application)

Step 7 - Processing your application

Once you have submitted your application and paid the associated application fee, we will assess your application resulting in one of the following outcomes:

- The application is refused if it fails to pass the preliminary assessment
- The kind of medical device is included in the ARTG
- The application has been selected for [audit \(http://www.tga.gov.au/auditing-medical-device-including-ivd-medical-device-applications\)](http://www.tga.gov.au/auditing-medical-device-including-ivd-medical-device-applications)
- Withdrawal of your application as per your request

Note

You will be notified about the decision within 20 working days after the day when your application fee was paid.

The application is refused

Your application fails preliminary assessment if:

- it is not made in accordance with a **form and manner approved for** classification of a medical device or IVD medical device;
- the application **fee is not paid**;
- the application is **not accompanied by the kind of information** prescribed for the application of this classification by legislative instrument and provided in an approved form;
- the device must have a TGA conformity assessment certificate and a **TGA conformity assessment certificate is not in force**; or
- the application contains **information that is false or misleading**.

What happens next?

You will receive written notification outlining that your application is refused and the reasons why your application has failed preliminary assessment.

Any fees paid will not be refunded and cannot be transferred/credited to a new application submitted at a later stage. For further information refer to the [refunds \(http://www.tga.gov.au/refunds\)](http://www.tga.gov.au/refunds) web page.

You cannot supply the kind of medical device as it has not been included in the ARTG.

You can resubmit a new application and recommence the process at any time.

The application has been selected for audit

In some instances your application will be selected for audit. You can find more information about how medical device and IVD medical device applications are selected for audit at [Auditing of medical device, including IVD medical device, applications \(http://www.tga.gov.au/auditing-medical-device-including-ivd-medical-device-applications\)](http://www.tga.gov.au/auditing-medical-device-including-ivd-medical-device-applications).

What happens next?

You will be notified if this occurs and asked to provide further information and supporting documentation and if applicable you will receive an invoice for the assessment fee.

The information provided in and with the application will be assessed.

Further information on [Auditing of medical device and IVD medical device applications \(//www.tga.gov.au/auditing-medical-device-including-ivd-medical-device-applications\)](http://www.tga.gov.au/auditing-medical-device-including-ivd-medical-device-applications) is available on our website.

The decision is made to include the kind of medical device in the ARTG

You will receive an automated email advising that your application has been successful.

What happens next?

You can supply the kind of medical device as it has been included in the ARTG.

Go to [Step 8 - Printing your ARTG Certificate of Inclusion \(//www.tga.gov.au/book-page/step-8-printing-your-artg-certificate-inclusion\)](http://www.tga.gov.au/book-page/step-8-printing-your-artg-certificate-inclusion) and [Step 9 - Ongoing responsibilities \(//www.tga.gov.au/book-page/step-9-ongoing-responsibilities\)](http://www.tga.gov.au/book-page/step-9-ongoing-responsibilities)

Withdrawal of your application

You may withdraw your application at any time prior to a decision being made whether or not to include the medical device, or IVD medical device, in the ARTG. If you wish to withdraw your application, you can do so through TBS.

Note

Any fees you have paid will not be refunded if you withdraw your application.

What happens next?

You will receive an email confirming that your medical device, or IVD medical device, application has been withdrawn.

You cannot supply the kind of medical device as it has not been included in the ARTG.

You can resubmit a new application and recommence the process at any time.

Step 8 - Printing your ARTG certificate of inclusion

When a decision is made to include the kind of medical device in the ARTG, an ARTG entry with an ARTG number will be created for your medical device or IVD medical device.

You can print the ARTG Certificate of Inclusion from the TBS website.

How to print the Australian Register of Therapeutic Goods Certificate of Inclusion

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

- Select 'Login to Business Services'
- Type in your user name and password
- Select 'Portal'
- Select 'Current ARTG entries'
- You will be able to view your ARTG entry and print your certificate by clicking on the arrow to the left of your ARTG entry.

This concludes the medical device, or IVD medical device, inclusion process.

Note:

There are responsibilities and charges associated with maintaining an inclusion on the ARTG. Go to Step 9 - (<http://www.tga.gov.au/book-page/step-9-ongoing-responsibilities>)Ongoing responsibilities

All classes of medical devices, or IVD medical devices, included in the ARTG can be selected for post market review. For further information refer to Post Market tab of the ARGMD (<http://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd>).

Step 9 - Ongoing responsibilities

As a sponsor of a medical device, or IVD medical device, included in the ARTG you have ongoing responsibilities. For further information refer to related information and guidance below.

Conditions of inclusion

If there are specific conditions of inclusion relating to your product, you will be notified at the time of inclusion.

Post market vigilance and monitoring

Requirement	Example(s)	Legislative reference
Allow entry and inspections of premises	<ul style="list-style-type: none">• Allowing a person authorised by the TGA to enter and inspect any premises, including outside Australia, where the devices are manufactured or located.• While on the premises, allowing a person authorised by the TGA to inspect the premises and medical devices on the premises.• Allowing a person authorised by the TGA to take samples of medical devices from the premises.	Section 41FN(1)
Deliver samples upon request	<ul style="list-style-type: none">• Providing samples of the medical device to the TGA upon request.	Section 41FN(2)
Availability of information	<ul style="list-style-type: none">• Facilitating access to the technical documentation that demonstrates compliance with the Essential Principles.• Facilitating access to the evidence that appropriate conformity assessment procedures have been applied.• Providing this information to the TGA within specified timeframes when requested.	Section 41FN(3)
Advertising material	<ul style="list-style-type: none">• Ensuring any advertising material relating to the medical device complies with regulatory requirements.	Section 41FN(5)

Requirement	Example(s)	Legislative reference
Report details of certain incidents and performance issues to the TGA	<ul style="list-style-type: none"> Report events in accordance with the requirements laid out in the <i>Therapeutic Goods Act 1989</i> (https://www.legislation.gov.au/Series/C2004A03952) and the <i>Medical Device Regulations 2002</i> (https://www.legislation.gov.au/Series/F2002B00237) and this guidance document. 	Section 41FN(3)(d)
Report any overseas regulatory actions to the TGA if the product involved is from the same batch or production run that was supplied in Australia	<ul style="list-style-type: none"> When an adverse event has occurred with a product in another country and the ensuing investigation by the manufacturer determines that a batch of the product should be recalled. If the batch is supplied in Australia the sponsor should notify the TGA of the overseas action to determine if the same action should occur in Australia. 	Section 41FN
Report results of investigations undertaken by the manufacturer to the TGA	<ul style="list-style-type: none"> Relay the results to the TGA of an investigation into a returned sample associated with an adverse event report. 	Section 41FN
Assist the TGA and the manufacturer in investigations if an incident occurs	<ul style="list-style-type: none"> Passing information to the TGA and the manufacturer during an investigation of an adverse event. Assisting in the gathering of information and samples from the user. 	Section 41FN
Take corrective action when necessary	<ul style="list-style-type: none"> Recalling medical devices. Informing the public about medical devices that do not comply with requirements. 	Section 41KA

Requirement	Example(s)	Legislative reference
Maintain distribution records for product supplied in or exported from Australia	<ul style="list-style-type: none"> • Records of delivery to: <ul style="list-style-type: none"> ◦ distribution warehouses ◦ manufacturing sites ◦ retail outlets 	Section 41FO Regulation 8.1(b)
Conditions imposed when medical devices are included in the ARTG	<ul style="list-style-type: none"> • Provide annual reports for the first three years a Class III, AIMD, or Class IIb implantable device is available in Australia. 	Section 41FO(2)

Recalls, suspensions, cancellations, and tampering of medical devices

- [Recalls, suspensions, cancellations, and tampering of medical devices](http://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd) (<http://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd>) (including IVD medical devices)
- [Uniform recall procedure for therapeutic goods \(URPTG\)](http://www.tga.gov.au/publication/uniform-recall-procedure-therapeutic-goods-urptg) (<http://www.tga.gov.au/publication/uniform-recall-procedure-therapeutic-goods-urptg>)

Annual charges

There are ongoing [Annual charges](http://www.tga.gov.au/annual-charges-therapeutic-goods) (<http://www.tga.gov.au/annual-charges-therapeutic-goods>) associated with maintaining your inclusion on the ARTG. The annual charge associated with your inclusion on the ARTG is available through the [Schedule of fees and charges](http://www.tga.gov.au/schedule-fees-and-charges) (<http://www.tga.gov.au/schedule-fees-and-charges>) webpage under 'Medical Devices' or 'IVD Medical Devices'.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch	October 2019
V1.1	Remove time-limited content	Medical Devices Authorisation Branch	February 2021
V1.2	Update to requirements for Sponsors	Medical Device Section	May 2021



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