Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Applying for an export certification for medical devices

This guidance is to assist you to apply for a Certificate of Free Sale or an Export Certificate for medical devices, including in-vitro diagnostic medical devices (IVDs) and Other Therapeutic Goods (OTGs).

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Purpose

This guidance is to assist you to apply for a Certificate of Free Sale or an Export Certificate for medical devices, including in-vitro diagnostic medical devices (IVDs) and Other Therapeutic Goods (OTGs).

If you plan to export a medical device from Australia, you must meet certain regulatory requirements set out in the Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002, in addition to other relevant Commonwealth and state or territory legislation. Criminal and civil penalties may apply if you do not meet these legal requirements.
For additional information about medical devices and IVDs refer to Medical devices & IVDs.

Legislation

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices) Regulations 2002

ARTG inclusion

The *Therapeutic Goods Act 1989* requires therapeutic goods to be included in the Australian Register of Therapeutic Goods (ARTG), before they can be imported into, supplied in, or exported from Australia, unless the goods are the subject of an ARTG exemption or exclusion.

If you intend to export a medical device, you need to have either:

- a current ARTG inclusion that allows the medical device to be supplied and sold within Australia and exported from Australia
- a current Export Only ARTG inclusion for the medical device that allows it to be exported from Australia.

The only exception is if those goods are:

- **exempt** medical devices
    - some therapeutic goods are exempt from the requirement to be entered in the ARTG
    - for the complete list of exempt medical devices, refer to Therapeutic Goods (Medical Devices) Regulations 2002
- **excluded** medical devices
    - some low-risk products are excluded from the TGA's regulatory framework and should not be included in the ARTG.

Refer to How to determine if your product should be included in the ARTG for further information about exempt and excluded devices.

Export certification for medical devices

When exporting medical devices from Australia, you need to comply with the regulatory requirements of the importing country and should contact the relevant Embassy, High Commission or Consulate for advice on their importation requirements.

To facilitate export, the TGA issues export certification for medical devices that are included in the Australian Register of Therapeutic Goods (ARTG) under Section 58 of the *Therapeutic Goods Act 1989*. Export certification is not a requirement of the Australian Government.

If certification is required by the importing country, medical device sponsors can apply to the TGA for a Certificate of Free Sale or an Export Certificate.

Certificate of Free Sale

A Certificate of Free Sale is provided for a medical device that has a current ARTG inclusion that allows the medical device to be supplied and sold within Australia and exported from Australia.

Export Certificate

An Export Certificate is provided for a medical device that has a current Export Only ARTG inclusion that allows the medical device to be exported from Australia.

Eligibility to apply for a certificate

To be eligible to apply for a Certificate of Free Sale or an Export Certificate you must be either:

- the person in relation to whom the medical device is included in the ARTG
- an agent authorised to act on behalf of the person in relation to whom the medical device is included in the ARTG.

Devices available for supply in Australia

If the device is included in the ARTG for supply in and export from Australia, you can apply for a Certificate of Free Sale.

Export Only devices

If the device is listed as an Export Only device, you can apply for an Export Certificate.

Export Only devices cannot be supplied or sold in Australia.

> Export Only devices will not be issued a Certificate of Free Sale.

Information included on a certificate

Certificates of Free Sale and Export Certificates provide details regarding the medical device as reflected in the ARTG.

Product details

The following details are included on the certificate:

- ARTG number
- medical device description based on the Global Medical Device Nomenclature (GMDN) code
- GMDN code for your medical device
- medical device class.

A maximum of five devices can be listed on the first page of the certificate, due to size and formatting restrictions.

If your application includes 5 or less devices, the details will be listed in a table as shown below:

Products:

ARTG Entry	Medical Device Description	GMDN Code	Class

If you require more than 5 devices to be included on the certificate, the device will need to be provided in a schedule attached to the certificate.

The table will be replaced with:

Products:	Refer to Schedule 1 (attached)

You will need to prepare your own schedule and provide this with your application. The TGA will not prepare your schedule.

Sponsor and manufacturing details

The sponsor and manufacturing details included on the certificate are:

- the sponsor's name and address as it appears in the ARTG
- the manufacturer's name and address as it appears in the ARTG.

> The manufacturer listed on the certificate is the manufacturer included in the ARTG.
>
> If the devices have different manufacturers, the manufacturing section will be removed from the first page of the certificate.

Importing country

The importing country is not included on a Certificate of Free Sale or Export Certificate. To include the importing country, you need to email Exports to advise us prior to the issue of the certificate.

How your certificate will look

Certificates of Free Sale and Export Certificates are issued in an A4 single-sided document, in portrait layout. If you include a schedule, it will be transferred to a TGA letterhead attached to your certificate.

> Your certificate will reference the schedule as in the example below:
>
> The attached schedule is part of this certificate and contains product details supplied by the sponsor. There is one (1) schedule comprising one (1) page attached to this certificate.

Before applying for a certificate

Before applying for a certificate, ensure you understand the importing country's requirements and confirm the ARTG details of the device are accurate.

Check the importing country's requirements

We recommend you contact the relevant authority of the importing country for their requirements.

> The TGA does not provide advice regarding requirements for importing countries.

Check the ARTG details are current and correct

To apply for a Certificate of Free Sale, you need to have a current ARTG inclusion for your device that allows it to be supplied in and exported from Australia.

To apply for an Export Certificate, you need to have a current Export Only ARTG inclusion for your device that allows it to be exported from Australia.

The information contained on the Certificate of Free Sale or Export Certificate comes directly from the ARTG.

It is your responsibility to ensure the ARTG details for your device are accurate and up-to-date prior to submitting your application.

The exports team will not:

make changes to the ARTG for the device

include information on the certificate that does not align with the ARTG details for the device.

Application process

To apply for a Certificate of Free Sale or an Export Certificate, you will need to email the following to accountsrec@health.gov.au:

- a completed application form
- a schedule (if needed)
- a remittance of upfront payment via TGA's on-line payment portal. Select Biller Code '3 – Certificate of Free Sale' and enter your Client Identification Number prefixed by 'TGA00' (e.g. 'TGA00XXXXX').

Only one application form and one schedule (if needed) can be submitted per certificate request.

Information needed from applicants

To apply for a Certificate of Free Sale or an Export Certificate, you need to provide the following information:

- sponsor details
    - sponsor name, address, TGA Business Services (TBS) Client Identification Number, contact person, contact number and email address
- ARTG number(s)
- the GMDN code(s) for the medical device(s).

Manufacturer of the device

The manufacturer listed on the certificate is the manufacturer included in the ARTG.

If the devices have different manufacturers, the manufacturing section will be removed from the first page of the certificate.

Schedule of devices

If additional information is required, you will need to provide that information in a schedule accompanying your application form.

Preparing your schedule

Your schedule must be:

- in a Microsoft Word document format
    - in portrait orientation
- schedules provided with a different orientation may not format as desired
- provided on your company letterhead.

Information to include in your schedule

You can only include the following information in your schedule:

- ARTG number(s)
- GMDN code(s)
- trade/product name(s)
- internal reference/catalogue number(s)
- manufacturing sites.

You do not need to include all of this information.

Any additional information will not be included.

Application form

The application form for a Certificate of Free Sale or Export Certificate for a device is on the TGA website.

> Submit one application form per certificate request.

Incorrect or incomplete applications

Applications for a Certificate of Free Sale or Export Certificate will be rejected if:

- you are not the sponsor of the device or an authorised agent acting on behalf of the sponsor
- your application is incorrect or incomplete (for example, you have included a medicine on your application form instead of a device).

If your application is put on hold, you have a maximum of 3 months to resolve your application issues. After 3 months your application will be withdrawn.

Sponsor declaration

Before submitting your application for a Certificate of Free Sale or Export Certificate, you need to sign a sponsor declaration.

By doing this, you are declaring that the:

- kinds of devices specified in the application are kinds of devices that are currently included in the ARTG

- devices set out in the accompanying schedule relate to the kinds of devices that are currently included in the ARTG
- devices are available for lawful supply for use in humans, or as an IVD, in Australia
- information contained in the application form and any accompanying schedule, is true and correct as at the date of signing.

> Providing information that is false or misleading to a Commonwealth entity or in connection with a Commonwealth law is a serious offence subject to criminal penalties under the *Criminal Code Act 1995*.

Electronic or hard copies

The certificate can be supplied either electronically **or** as a hard copy by mail.

Indicate your preference on your application form. If you select both options, you will pay two fees.

If you select hard copy, you will receive 2 copies via mail.

If you select electronic copy, the certificate will be emailed as a PDF document.

Fees

The current application fees for Certificates of Free Sale and Export Certificates can be found in the Schedule of fees and charges. You will need to indicate the current application fee for your certificate on your application form and in your credit card authorisation form.

> Your application will not be processed until your payment has been applied.

Receiving your certificate

The TGA aims to process applications for Certificates of Free Sale and Export Certificates within 10 working days.

After your application has been processed, the certificate will be emailed to the applicant or posted to the address listed on the application form.

Certificates will only be posted to authorised addresses registered in TGA Business Services.

Topics Import and export

Page history

19 January 2026

Added link in application process section.

15 November 2024

Title changed from 'Export certification for medical devices guidance' to 'Applying for an export certification for medical devices' as part of migration to new 'Guidance' content type:

- Consistent ‘Purpose’ heading.
- ‘Legislation’ section to clearly show which laws the Guidance relates to.
- ‘Page history’ section replaces document version history.
- New page navigation features.
- Updated page summaries.
- Complex images include long descriptions.
- New ‘Save as PDF’ feature.

1 May 2023

Minor update based on certificate formatting requirements.

1 September 2021

Major update based on public consultation feedback.

1 February 2019

Minor update based on external stakeholder feedback regarding exempt devices.
