Australian Government
Department of Health
Therapeutic Goods Administration

Export certification for medical devices

Applying for a Certificate of Free Sale or an Export Certificate

Version 2.0, December 2019

TGA Health Safety Regulation

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

About this guidance

This guidance is to assist:

- Australian sponsors of a medical device, including in-vitro diagnostic medical devices (IVDs) and other therapeutic goods that require export certification
- authorised agents acting on behalf of the Australian sponsor of the medical device who require export certification

If you wish to export medical devices 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.

For questions regarding the export of medical devices, contact Devices.

Export regulation

The major legislation that controls the approval and regulation of therapeutic goods in Australia is the *Therapeutic Goods Act 1989* (the Act). The TGA is responsible for administering the Act which provides a uniform national framework for the import, manufacture and supply, and export of therapeutic goods. The Act is supported by the *Therapeutic Goods Regulations 1990*, *Therapeutic Goods (Medical Devices) Regulations 2002* and various Therapeutic Goods Orders (TGOs).

Regulatory role of the TGA

The export of therapeutic goods from Australia is regulated by the TGA.

The TGA is committed to:

- ensuring that therapeutic goods exported from Australia comply with the same quality and safety standards as those supplied in Australia
- the protection of public health and safety through the export of safe therapeutic goods of an appropriate quality
- continued participation in international arrangements that promotes the safety and quality of therapeutic goods exported from Australia

Exports are important to the future of the Australian manufacturing sector.

Export regulation of therapeutic goods:

- ensures that therapeutic goods leaving Australia meet appropriate safety and quality standards to support public health
- encourages the development and manufacture of Australian export products

ARTG inclusion is required before export

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; or
- a current Export only ARTG inclusion for the medical device that allows it to be exported from Australia

The 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* - Schedule 4 (Part 1 and 2) – Exempt devices
- **excluded** medical devices
  - some low-risk products are excluded from the TGA 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.

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

Two types of certificates

Certificates of Free Sale and Export Certificates are documents issued by the TGA outlining that the medical device is included in the ARTG and is able to be freely supplied and sold within Australia and/or is able to be exported from Australia.

These certificates are issued under Section 58 of the *Therapeutic Goods Act 1989*.

Certificate of Free Sale

A Certificate of Free Sale is provided for a medical device that either:

- has a current ARTG inclusion that allows the medical device to be supplied and sold within Australia and exported from Australia; or
- is exempt or excluded from the requirement to be included in the ARTG and is supplied in Australia

Export certificate

An Export Certificate is provided for a medical device that either:

- has a current Export only ARTG inclusion that allows the medical device to be exported from Australia; or
- is exempt or excluded from the requirement to be included in the ARTG and are for export 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 the** sponsor of the medical device or an authorised agent acting on behalf of the sponsor.

In addition, the medical device to be exported **must have** a current inclusion in the ARTG, unless the medical device is **exempt** or excluded from the requirement to be included in the ARTG.

Medical devices available for supply in Australia

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

These medical devices are available for supply and 'free sale' in Australia.

Export only medical devices

If the medical device is listed as an export only medical device, you can apply for an Export Certificate.

Export only medical devices cannot be supplied or sold in Australia

Export only medical devices **will not** be issued a Certificate of Free Sale.

Exempt and excluded medical devices

If you need export certification for a medical device that is exempt or excluded from inclusion in the ARTG under the *Therapeutic Goods (Medical Devices) Regulations 2002*, you may be requested to provide evidence to support your application.

For further information, please contact Devices.

Information included on a certificate

The Certificate of Free Sale or Export Certificate will provide details regarding your medical device(s) as they appear on the ARTG.

Product details

The following details will be provided for each product that is included on the certificate:

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

A maximum of five medical device products can be included on the certificate due to size and formatting restrictions.

If your application includes **five or less** products, the details will be presented in a **Product table** as shown below:

Products:

ARTG Entry	Medical Device Description	GMDN Code	Class

If you require more than five medical devices to be included with the application, the details will need to be presented in a schedule attached to the certificate.

This will remove the Product table from your certificate and replace it with the following statement:

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
- the manufacturer's name and address

The manufacturer included on the certificate is the manufacturer included in the ARTG inclusion for the medical device.

If you wish to list medical devices that include different manufacturers, the manufacturer section will be removed from the certificate.

Country of import

The importing country is not included on the Certificate of Free Sale or Export Certificate. Should you wish to include the importing country, you need to email Exports directly and advise this prior to the issue of the certificate.

How your certificate will appear

The Certificate of Free Sale and Export Certificate are provided as an A4 single sided document, in portrait layout.

If you include a schedule, it will be presented on a TGA letterhead as an attached schedule to your certificate.

The schedule will be referenced on the certificate with the following wording:

> *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 you should find out the importing country's requirements and check that the ARTG details of the medical device are accurate.

Check the importing country's requirements

We recommend you contact the relevant authority of the importing country to find out what information must be provided in order to facilitate the export of your medical device(s).

The TGA **does not** maintain a list of requirements from individual importing countries.

Check the ARTG inclusion is current and correct

To apply for a **Certificate of Free Sale**, you need to have a current ARTG inclusion for your medical device that allows it to be supplied and sold within Australia or is exempt from this requirement.

To apply for an **Export Certificate**, you need to have a current export only ARTG inclusion for your medical device or is exempt from this requirement.

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

It is your responsibility to ensure the information contained on the ARTG inclusion for your medical device is accurate and up-to-date **prior** to submission of your application.

The exports area of the TGA **will not**:

- make changes to the ARTG inclusion for the medical device
- include information on the certificate that does not align with the information in the ARTG inclusion for the medical device

Application process

To apply for a Certificate of Free Sale or Export Certificate, you will need to submit an application form, a credit card authorisation form and a schedule (if needed) to accountsrec@health.gov.au.

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 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)

The **Global Medical Device Nomenclature (GMDN)** is an international system used to identify and classify medical devices. We use the GMDN system as one of the criteria to distinguish one kind of medical device from another.

For more information refer to Global Medical Device Nomenclature - GMDN

Manufacturer of the medical device

The manufacturer included on the certificate is the manufacturer included with your ARTG inclusion.

If you wish to list medical devices that include different manufacturers, we will remove the manufacturer section from the certificate.

Schedule of medical devices

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

Preparing your schedule

To ensure the formatting of your schedule can be maintained, your schedule **must** be:

- ✓ in an accessible electronic document, such as a Microsoft Word document
- ✓ 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. However, anything outside of this list **will not be included**.

Application form

The application form for a Certificate of Free Sale or Export Certificate for a medical device can be accessed on the TGA website.

Submit **one** application form per certificate request.

Incorrect or incomplete applications

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

- **you are not the sponsor** of the medical device(s) or **an authorised agent** acting on behalf of the sponsor
- your application is **incorrect** or **incomplete** e.g. you have included a medicine or a biological on your application form instead of a medical device

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

Sponsor declaration

Before submitting your application for a Certificate of Free Sale or an Export Certificate, you need to sign a sponsor declaration. By doing this, you are declaring that the:

- kinds of medical devices specified in the application are kinds of medical devices that are currently included in the ARTG
- products set out in any accompanying schedule relate to the kinds of medical devices that are currently included in the ARTG
- products 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 be expected to pay two fees.

If you elect to receive **hard copies**, you will receive **two** copies via mail.

If you elect to receive an **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 on 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 **ten** working days.

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

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

We cannot provide an update regarding when your certificate will arrive once it has left the TGA. If you wish to enquire about the status of a posted certificate, please wait a **minimum of six weeks** following date of issue prior to contacting Exports.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication: 'Certificates of free sale and export certificates for medical devices'	Application Entry, Support and Export Section	September 2018
V1.1	Minor update based on external stakeholder feedback regarding exempt devices	Application Entry, Support and Export Section	February 2019
V2.0	Title changed. Restructured and updated to incorporate the material in the 'Frequently asked questions about exporting medical devices' as well as minor process improvements.	Application Entry, Support and Export Section	Consultation date: December 2019

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