Australian Government
Department of Health
Therapeutic Goods Administration

Certificates of free sale and export certificates for medical devices

Version 1.1, February 2019

TGA Health Safety Regulation

Contents

Introduction

When exporting medical devices to other countries, sponsors sometimes are asked by the country of import to supply a "certificate of free sale" or an "export certificate". Certificates of free sale and export certificates are documents supplied by the Therapeutic Goods Administration (TGA) outlining that the relevant medical device(s) are included in the Australian Register of Therapeutic Goods (ARTG) and are either able to be freely supplied and sold within Australia or are able to be exported from Australia.

To apply for a **certificate of free sale** you will need to have a current ARTG inclusion for your product(s) that allows them to be supplied and sold within Australia or are otherwise exempt.

To apply for an **export certificate** you will need to have a current Export Only ARTG inclusion for your product(s) or are otherwise exempt.

Eligibility to apply for a Certificate of Free Sale or an Export Certificate

In order to be eligible to apply for a certificate of free sale or an export certificate you must:

- Be the sponsor of the device(s) in question, or be a recognised agent of the product's sponsor as recorded in the TGA eBS system.
- Have a current inclusion on the ARTG for a kind of medical device that covers the product(s) in question.
- Be exempt under Item 1.2, Part 1, Schedule 4 of the Therapeutic Goods (Medical Devices) Regulations 2002.

Please note

Certificates of free sale are not available where the products are included as Export Only devices in the Australian Register of Therapeutic Goods (ARTG).

Export certificates are available for products that are either included as Export Only devices on the ARTG or that are exempt from inclusion under Item 1.2, Part 1, Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002.*

If you are applying for an export certificate for a product that is exempt from inclusion under Item 1.2, Part 1, Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002,* you will need to provide a statement of exemption that contains a detailed explanation of the circumstances or purposes of the export and the products to be exported including the export destinations.

Before you make your application

Certificates of free sale and export certificates aim to **meet the needs of the importing country**. Before applying for a certificate we recommend that you contact the relevant foreign government through their consulate to ascertain what information must be supplied in order to facilitate the export of your medical devices to their country.

Please note

The TGA does not maintain a list of requirements for individual countries.

Making your application

Your application will need to include, at a minimum, the current ARTG number for the kinds of medical devices you are seeking to export, and the GMDN codes for those devices. Your certificate of free sale or export certificate will display information regarding your medical device.

The following information is included on the certificate:

- ARTG number(s)
- device description based on the GMDN code(s)
- GMDN code(s) for your medical device
- the medical device class
- the sponsor's name and address
- the primary manufacturer's name and address.

If your product is a Class III included device, your certificate of free sale will also contain the product / trade name as it appears on your ARTG inclusion. Instead of listing individual ARTG numbers on the application form, you may include the statement: Refer to Schedule. This will remove the table from your certificate and replace it with a statement to refer to the attached schedule.

Further information that the importing country requires to be included in your certificate can be provided via a schedule accompanying your application form.

Please note

Your GMDN codes **must match** the GMDN codes on your current ARTG certificate otherwise your application will be rejected.

Schedules of products

Depending on the information required by the importing country, your certificate may need to contain additional information relating to the kinds of medical device covered. If additional information is required, you will need to provide that information in a schedule accompanying your application form and which is in an accessible electronic document on your company's letterhead.

Schedules should include information limited to the following:

- ARTG number(s)
- GMDN code(s)
- trade/product name(s)

- internal reference/catalogue number(s)
- manufacturing sites.

While your schedule may not include all of this information, **it should not include any fields other than those listed**.

Presentation of your schedule

Every page of your schedule should be on your company's letterhead and should contain, in the header, the following statement "Schedule accompanying application for certificate of free sale/export certificate".

Your schedule should be submitted electronically to the TGA. It will appear on the TGA letterhead as a schedule attachment to your certificate.

IMPORTANT

When you submit your application for a certificate of free sale or an export certificate, you will need to make a declaration stating that the information provided relates to a current inclusion for a kind of medical device in the ARTG. You will also be declaring that all information provided in the application form and accompanying schedule (if any) is true and correct.

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.*

Fees

The current application fees for certificates of free sale and export certificates can be found on the Fees and Charges website under "Export". You will need to indicate on your application form and in your credit card authorisation form the current application fee for your certificate.

Please note

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

Submitting your application

When submitting your application you will need to provide the following to accountsrec@health.gov.au:

- a completed application form
- a schedule containing additional information (if required) that is to be included in your certificate
- a completed credit card authorisation form.

What to expect

The TGA aims to process applications for certificates of free sale and export certificates within ten (10) business days.

Please note

Your application may take longer if there appear to be discrepancies between your application and information in the ARTG inclusion for your products, or if your application is voluminous in nature.

Your certificate, including additional information set out in an attached schedule (if required), can be supplied either electronically or by post. Please indicate your preference on your application form.

If you elect to have hard copies sent to you, you are able to request **up to five (5) copies**. If you are requesting hard copies, please indicate on your application form how many copies you require.

Please note

If you are not the sponsor of the products in question, or a recognised agent of the sponsor in their eBS account, your application will be rejected.

If your application is rejected as a result of you supplying incorrect information or because you are not the sponsor of the products in question (or a recognised agent of the sponsor of the products) your application fee **will not be refunded**.

More information about the circumstances under which you are entitled to a refund can be found at: Refunds.

Please note

We **strongly recommend** you contact the relevant Embassy, High Commission or Consulate of the country of import before you apply for a certificate of free sale or an export certificate to determine what information they require in the certificate and what form the certificate should take.

If your certificate is required to be presented in a particular way, please provide the details in a separate document with your application at the time of submission.

Once we have received your application and associated payment we will contact you to discuss your requirements if they deviate from the standard format. Please be aware that this may delay the processing of your application.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Prescription Medicines Authorisation Branch	August 2018
V1.1	Updated based on sponsor feedback	Prescription Medicines Authorisation Branch	February 2019

Therapeutic Goods Administration

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

Reference/Publication #