



This form, when completed, will be classified as 'For official use only'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<<https://www.tga.gov.au/treatment-information-provided-tga>>.

Application for certificate of free sale / export certificate for a medical device

I am applying for a:

- Certificate of free sale** and have a current ARTG inclusion that allows the product(s) to be supplied and sold within Australia; or an
- Export certificate** and have a current Export Only ARTG inclusion for the product(s).

Please note: A certificate of free sale or an export certificate can **only** be issued for a kind of medical device that has been included in the Australian Register of Therapeutic Goods (ARTG) under the *Therapeutic Goods Act 1989* or is exempt under item 1.2, Part 1, Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Section 1 Sponsor details

Sponsor's business name	
Sponsor address	
Email address	
Contact person	
Contact number	
eBS Client Identification Number	

Section 2 Certificate details

Form of certificate (please choose **one** option only): Electronic copy via email
Hard copy via post

If requesting hard copies, please advise how many you require [five (5) maximum]

Section 3 Medical device details

Your certificate of free sale or export certificate will show the ARTG Number and GMDN codes for your products, the sponsor's name and address, and 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.

ARTG Number	GMDN Code

Section 4 Schedules

If the country of import requires your certificate of free sale or export certificate to include additional information about the products to which the certificate relates, then the additional information must accompany this application in a schedule on your company letterhead.

The schedule heading should describe the contents. If the schedule requires more than one page, subsequent pages should have the same heading followed by 'page 2', etc.

Please indicate if your application is accompanied by a schedule.

Section 5 Fees

There is an application fee associated with the processing of your application for a certificate of free sale or an export certificate. The current fee is outlined under "Export" on the [Fees and Charges](#) webpage.

Please indicate the current fee for the processing of your application, and ensure you include a completed and signed credit card authorisation form for this amount when you submit your application.

Section 6 Sponsor declaration



Important note

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*.

I declare that the kinds of medical devices specified in this application are kinds of medical devices that are currently included in the Australian Register of Therapeutic Goods.

I declare that the products set out in the accompanying schedule (if any) relate to the kinds of medical devices currently included in the ARTG as specified in this application.

I declare that these products are available for lawful supply, for use in humans or as an IVD, in Australia.

I further declare that all information contained in this application form, and in any schedule accompanying this form, is true and correct as at the date of signing.

Signature of authorised person

Name
(please print)

Date

Your position/title/office
in relation to the
sponsor



Please note: It is the sponsor's responsibility to ensure this application is accompanied by all relevant documentation. This includes the appropriate application fee(s).

[Credit card authorisation](#) forms can be found on the TGA website.

The current application fees for certificates of free sale and export certificates can be found on the TGA's [Fees and Charges](#) website under "Exports".

Please forward your application, any accompanying schedule(s) and your completed credit card authorisation to accountsrec@health.gov.au.