Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

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 consent to import, supply or export a medical device that does not comply with the Essential Principles

Therapeutic Goods Act 1989

Sponsor name	**Client ID**

Contact name	**Contact number**

Contact email	**Fax number**

There are Criminal Offences under S41MA and Civil Penalties under S41MAA of the *Therapeutic Goods Act 1989*, for persons who import, supply or export medical devices that do not meet the Essential Principles for safety and performance, unless consent has been granted by the Secretary of the Department of Health.

The TGA expects compliance with the Essential Principles, however there may be some extenuating circumstances preventing compliance to one or more parts of an Essential Principle for a limited period of time.

In seeking consent an authorised representative of the sponsor needs to:

- complete this 'Application for consent to import, supply or export a medical device that does not comply with the essential principles' form
- attach all the relevant documentation
- submit the completed form to the TGA together with the applicable application fee.

The delegate of the secretary will take all relevant information into consideration when determining whether to grant consent.

Note: The application fee for consent applies to each ARTG Entry ($490 for the first and $100 for each subsequent ARTG entry) covered in the request form.

Information to be submitted with your application to allow the Secretary to make a determination

The following information needs to be provided as an attachment to this form. The sponsor should complete the checklist to ensure all the mandatory information has been provided.

Tick	Information
☐	A list of ARTG Numbers to be covered by the exemption. Specify for each ARTG Entry if it is for: • importation and supply in Australia; or • importation, supply in Australia and exportation from Australia; or • only exportation from Australia.
☐	Specify the relevant Essential Principle or parts of an Essential Principle for which consent is requested
☐	An explanation of the circumstances that led to the devices not complying to the Essential Principles
☐	An indication of the stock levels of the non compliant devices
☐	The expected timeframe to deplete the non compliant devices
☐	An analysis of the real or potential risks associated with the non compliance and the strategies implemented to address these risks
☐	The strategies the manufacturer is to implement to rectify the non compliance and the expected time frame for the implementation

Details of included medical devices that do not comply with the essential principles

List the ARTG Inclusions for the kinds of medical devices which do not comply

ARTG No.	Volume of stock	Expected depletion date of stock	Expected date for implementing corrections by the manufacturer
Total Number of ARTG Entries			

* If more than 10 ARTG Inclusions require consent of the Secretary as they do not comply with the Essential Principles, please duplicate this page, sign and attach additional pages.

Calculation of total application fee

A list of current fees and charges, and a Credit Card Authorisation form, is available on the TGA website <https://www.tga.gov.au/fees-and-payments>. The application fee for consent of the secretary to import, supply or export a medical device that does not comply with the essential principles is located under Medical Devices - *Miscellaneous*.

ARTG entries	Fee	Application fee
First ARTG entry	**$490**	$490.00
Number of additional entries	**X $100 (per entry)**	$ 0.00
Total application fee payable		$ 490.00

Full Name			
Signature		Date	

Please send the completed form and processing fee to the Product Billing and Industry Assistance Section at the address below:

Product Billing and Industry Assistance Section (Accounts Receivable)
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Email: accountsrec@health.gov.au