Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Exporting a ventilator

Guidance for sponsors and manufacturers about pathways for exporting a ventilator from Australia.

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Purpose

There are three pathways to exporting a ventilator from Australia. This guidance can help you choose the right pathway.

Legislation

Therapeutic Goods (Medical Devices) Regulations 2002

Path 1: Gaining TGA approval

Ventilators exported from Australia as well as being supplied in Australia must meet Australian regulatory requirements.

They must be included in the Australian Register of Therapeutic Goods (the ARTG).

This means the device:

- will likely be classified as a Class IIa or IIb device (all relevant classification rules must be reviewed by the manufacturer); and
- will need to have a Conformity Assessment Certificate issued by the TGA (or a European notified body or other recognised comparable regulator). This certificate indicates that the device:
    - is manufactured under a suitable quality management system; and

- meets safety and performance requirements known as the Essential Principles.

If you are considering applying for TGA Conformity Assessment Certification, familiarise yourself with the expected requirements and relevant fees.

The Essential Principles checklist will help you document compliance with the principles. Completing this checklist will assist when you commence the Conformity Assessment Certification process.

If you have a Conformity Assessment Certificate and would like to supply your ventilator in Australia, you need to include your device in the ARTG. There are also relevant ongoing responsibilities you need to meet.

Path 2: Export only

If you do not intend to supply your ventilator in Australia, but instead wish to export the ventilator to other countries, you must include the ventilator on the ARTG as a Class I (Export Only).

Class I (Export Only) devices are:

- not reviewed by the TGA before processing;
- processed within a matter of days; and
- supported by a self-certification (declaration) made by you that you can demonstrate that the device meets the Essential Principles.

Importing countries are aware that Class I (Export Only) devices have not undergone independent assessment by the TGA (or a European notified body or other recognised comparable regulator) and may not have undergone an appropriate level of assessment under the Australian regulatory framework to ensure the device is safe and fit for its intended purpose.

For this reason, some countries will not import Class I (Export Only) devices.

Declaration of Conformity

While you do not need a Conformity Assessment Certificate from the TGA (or a European notified body or other recognised comparable regulator), the manufacturer of a Class I (Export Only) device will need to make a Declaration of Conformity (DoC).

The DoC can be in any format, but it must include the following information:

- Name and address of the manufacturer.
- Identification of the product (name, type number or model number, or serial number).
- Reference to Conformity Assessment procedure Part 6, (clause 6.6.), which is the DoC you are making.
- A list of harmonised standards/methods you have used to demonstrate that the device meets the Essential Principles.
- The date of issue of the declaration.
- The signature and title of the manufacturer's CEO or equivalent.

DoC templates are available. Class I (Export Only) devices should use the template under Schedule 3, Part 6, Clause 6.6).

Declaring false or misleading information to the Commonwealth is illegal.

By signing the DoC, the manufacturer is declaring that they have prepared technical documentation for the device demonstrating that it meets the Essential Principles.

Technical documentation includes, but is not limited to:

- Design diagrams or drawings, including any components, sub-assemblies, or circuits.
- The test protocols and results to demonstrate performance, biocompatibility, stability, and sterility (if applicable).
- A list of any tests conducted to relevant standards.
- Clinical evidence (i.e., literature review, clinical trial, post market data).
- Risk management documentation (e.g., per ISO 14971).
- Labelling and Information for Use (IFU) (i.e., displaying ‘For export only' if applicable)

The manufacturer must maintain records and provide evidence to substantiate any claims made within the DoC if requested by the TGA.

Advertising claims

Advertising material or information provided with a Class I (Export Only) device must not imply endorsement or approval by the TGA.

In addition, you must make it clear that the device is an export-only device.

Applying for a Class I (Export Only) ARTG entry

Once you have completed the DoC, you can apply to include your Class I (Export Only) device in the ARTG.

The DoC signed by the manufacturer will need to be uploaded with the application.

Ongoing responsibilities

There are ongoing responsibilities and conditions of an inclusion of a Class I (Export only) device.

Ongoing responsibilities include, but are not limited to:

- Monitoring the device's market performance and undertaking recalls and alerts if required.
- Updating any variations or changes to sponsor, manufacturer, or device details.
- Cancelling your ARTG entry when it is no longer required.

Path 3: Charitable donation

You are able to export a device without including it in the ARTG if the device is:

a. not intended for commercial supply;

b. does not contain a substance the export of which is prohibited under the *Customs Act 1901*; and

c. not intended for use for experimental purposes on humans.

See Item 1.2 of part 1 to Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*

Requirements of the importing country

Importing countries may have further requirements. These include the need for a Certificate of Free Sale/Export Certificate.

We don't track individual requirements for other countries around the world. We encourage you contact the country of import through their consulate or embassy.

Topics: COVID-19 Import and export

Page history

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