Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Manufacturing medical devices for COVID-19 including 3-D printing

Guidance to assist manufacturers of medical devices and their component parts with meeting their regulatory obligations.

Last updated:
28 January 2021

As a result of the COVID-19 pandemic, the Therapeutic Goods Administration (TGA) is receiving an increased number of enquiries from people seeking to develop medical devices or component parts of medical devices including using 3-D printing or other advanced manufacturing technology.

The following guidance aims to assist manufacturers of medical devices and their component parts with meeting their regulatory obligations.

Introduction

Medical devices, including in vitro diagnostic (IVD) medical devices, are regulated by the TGA in accordance with:

- the *Therapeutic Goods Act 1989 (https://www.legislation.gov.au/Series/C2004A03952)* (the Act)
- the *Therapeutic Goods (Medical Devices) Regulations 2002 (https://www.legislation.gov.au/Series/F2002B00237)* (the Regulations)
- the *Therapeutic Goods Regulations 1990 (https://www.legislation.gov.au/Series/F1996B00406)*.

Any medical device (unless excluded or exempt under the Act) must meet all relevant regulatory requirements before it can be legally imported into, supplied within or exported from Australia.

If you are able to manufacture devices or device components we recommend that you register your interest and core competencies on the Advanced Manufacturing Growth Centre (AMGC)'s COVID-19 manufacturer response page (https://www.amgc.org.au/covid-19-manufacturer-respon

se/). The AMGC will help you make appropriate industry connections with manufacturers who are already certified to manufacture and supply medical devices in Australia.

Examples of products that may be manufactured to assist with the response to COVID-19 include:

- valves for ventilators
- respirator masks
- face shields
- isolation gowns
- face masks
- collection swabs (https://www.tga.gov.au/node/289529)

Note

There are civil and criminal penalties associated with the supply of devices that do not meet the relevant regulatory requirements.

Manufacturing and supplying medical devices for COVID-19

If you are manufacturing or supplying medical devices, including 3-D printed medical devices or components of medical devices in response to the COVID-19 pandemic, you must ensure that your device meets all relevant regulatory requirements. We recommend you take the following steps to ensure you meet your obligations under the legislation:

1. Establish whether your product is a medical device that requires inclusion on the Australian Register of Therapeutic Goods (ARTG (https://www.tga.gov.au/node/286556)).
2. If your product meets the definition of a medical device and needs to be included on the ARTG before you supply it, you will need to check the classification of the device (https://www.tga.gov.au/node/386) as there are different regulatory requirements depending on the device's classification. For more information about the regulation of your medical device, please review the following guidance:
    - Class I, non-sterile, non-measuring devices (#class1)
    - All other classes of medical device (#other).

3. Some products may not need to be included on the ARTG. Please review the advice below about exceptions and exemptions (#exceptions).

Note

As part of the TGA response to COVID-19 (https://www.tga.gov.au/node/284770), the TGA is prioritising and expediting all COVID-19-related assessments, reviews, and responses to queries.

The guidance below for including a medical device is a summary only. For the full guidance for including a medical device on the ARTG, see Medical device inclusion process (https://www.tga.gov.au/node/328960).

Supplying Class I non-sterile medical devices

If you have determined that your product is a Class I non-sterile, non-measuring device you will need to complete the following steps:

1. Complete an organisation details form (https://www.tga.gov.au/node/288314) and submit it to eBS@health.gov.au. This will allow you to become a client of the TGA. You will be given a username and password in order to access our online eBusiness portal. The portal allows you to submit applications for medical devices to be included on the ARTG.
2. Ensure that your manufacturer has:
    - applied appropriate conformity assessment procedures to the device
    - has evidence demonstrating that the device complies with the Essential Principles
    - has a system for post-market monitoring and taking corrective action in place.
3. If your manufacturer has met these obligations, you will need to have them complete a Declaration of Conformity (https://www.tga.gov.au/node/288300) for your device.
4. Once you have received your client logon details, you will need to submit an application for your device to be included on the ARTG. For guidance on this step, see Medical device inclusion process (https://www.tga.gov.au/node/328960).

Example scenarios for the inclusion of Class I medical devices on the ARTG

Scenario 1: A non-sterile face mask that does not claim to be for use in a clinical setting or which does not claim to prevent the transmission of micro-organisms or bacteria between people **does not meet the definition of a medical device** and **does not need to be**

included on the ARTG before it can be supplied in Australia.

Scenario 2: A non-sterile face mask that claims to be for use in a clinical setting is classified as a Class I non-sterile, non-measuring medical device. This product **meets the definition of a medical device** and **must be included on the ARTG** before it can be supplied within Australia.

Scenario 3: Holding tubes for ventilators are classified as Class I non-sterile, non-measuring medical devices and will **need to be included on the ARTG** before they can be supplied in Australia.

Note

You will need to pay an application fee for your device to be included on the ARTG. Please refer to the current fees and charges for medical devices (https://www.tga.gov.au/node/287173).

Class 1 non-sterile, non-measuring devices are automatically included on the ARTG. You will receive your certificate and be able to view your inclusion on the Register the day after you receive confirmation that your application has been accepted and your fee has been paid.

These devices may be reviewed by the TGA after they are included on the ARTG.

After your device is included on the ARTG

Once your device is included on the ARTG, you will have ongoing responsibilities (https://www.tga.gov.au/node/286564) including:

- Ensuring advertising for the device is compliant with the Therapeutic Goods Advertising Code (https://www.tga.gov.au/node/288202)
- keeping distribution records (https://www.tga.gov.au/node/287915)
- reporting adverse events (https://www.tga.gov.au/node/289466)
- ensuring your device continues to meet all relevant regulatory requirements.

Supplying all other classes of medical device

Unlike Class I non-sterile, non-measuring devices, all other classes of medical devices must be reviewed by the TGA, a designated conformity assessment body or a comparable overseas regulator to establish appropriate evidence and documentation of conformity assessment. Conformity assessment (https://www.tga.gov.au/node/287644) is the systematic and ongoing examination of evidence and procedures to ensure that a medical device (including IVD medical devices) complies with the Essential Principles (https://www.tga.gov.au/node/290010). These Principles relate to aspects of the device including its design and construction. Demonstrating compliance with the Essential Principles establishes that the product is safe and fit for its intended purpose.

For information about the kind of evidence/documentation that you can use, see Table 2 in Use of market authorisation evidence from comparable overseas regulators/assessment bodies for medical devices (including IVDs) (https://www.tga.gov.au/node/285179).

Manufacturers of all medical devices (including IVD medical devices) manufactured and/or supplied in Australia should ensure that they have:

- appropriate conformity assessment procedures in place for the device
- appropriate documentation demonstrating compliance of the device with the essential principles.

If your device is any classification other than Class I non-sterile non-measuring, you will need to complete the following steps:

- Complete an organisation details form (https://www.tga.gov.au/node/288314) and submit it to eBS@health.gov.au. This will allow you to become a client of the TGA. You will be given a username and password in order to access our online eBusiness portal. The portal allows you to submit applications for medical devices to be included on the ARTG.
- Complete a Declaration of Conformity (https://www.tga.gov.au/node/288300) for your device if the manufacturer has applied TGA's conformity assessment procedures. Please note that this step does not need to be followed if your application is supported by documentation from a comparable overseas regulator (https://www.tga.gov.au/node/289428).
- Once you have received your client logon details, you will need to submit a Manufacturer's Evidence application (https://www.tga.gov.au/node/287913).
- Once you receive notification that your Manufacturer's Evidence has been accepted by the TGA, you will need to submit an application for your device to be included on the ARTG. For guidance on this step, see Medical device inclusion process (https://www.tga.gov.au/node/286560).

Example classifications of medical devices

Scenario 1: Breathing circuits and condense traps for ventilators are classed as Class IIa medical devices.

Scenario 2: Sterile face masks that claim to be for use in a clinical setting are classified as Class I (sterile) medical devices.

Scenario 3: Patient monitors for use in intensive care units are classified as either Class IIa or IIb medical devices depending on their intended purpose.

Scenario 4: Filters for invasive ventilators and breathing circuit filters are classified as Class IIa medical devices.

Scenario 5: Central venous catheters are classified as Class III medical devices.

All of these devices must be supported by documentation demonstrating that they comply with the Essential Principles and have undergone appropriate conformity assessment or approval from a comparable overseas regulator before an Australian sponsor can apply to include them on the ARTG and supply them within Australia.

> **Note**
>
> Your Manufacturer's Evidence application will be processed for free but you will need to pay an application fee for your device to be included on the ARTG. Please refer to the current fees and charges for medical devices (https://www.tga.gov.au/node/287173) .The TGA is currently expediting all applications associated with testing for, treatment of, or prevention of COVID-19. You do not need to write to the TGA to request that your application is fast-tracked.

After your device is included on the ARTG

Once your device is included on the ARTG, you will have ongoing responsibilities (https://www.tga.gov.au/node/286564) including:

- ensuring advertising for the device is compliant with the Therapeutic Goods Advertising Code (https://www.tga.gov.au/node/288202)
- keeping distribution records (https://www.tga.gov.au/node/287915)
- reporting adverse events (https://www.tga.gov.au/node/289466)
- ensuring your device continues to meet all relevant regulatory requirements.

Exceptions

In some circumstances a medical device is not required to be included on the ARTG before it is supplied. You are able to supply a medical device without including it on the ARTG if you meet the following criteria.

- Your product meets the definition of a custom made medical device (https://www.tga.gov.au/node/289270). Custom made medical devices are devices that are:
    - made specifically in accordance with a request by a health professional specifying its design characteristics or construction.
    - intended to be used only in relation to a particular individual, or by a health professional to meet special needs arising in the course of his or her practice.
- You are importing the device for yourself or a direct family member and not for a commercial purpose.
- The device is the subject of an exemption made under section 41GS of the *Therapeutic Goods Act 1989* (https://www.tga.gov.au/node/287254).

Example of a medical device that does not need to be included on the ARTG

In a case where a diagnostic image is taken and used to manufacture a 3-D printed mask or tube to fit a particular patient being treated for respiratory distress with invasive ventilation, this product will meet the definition of a custom made medical device and will not need to be included on the ARTG before it is supplied.

3-D printing of medical devices

For information on manufacturing with 3-D printing, visit 3-D printing (additive manufacturing) of medical devices (https://www.tga.gov.au/node/289530)

Note

Homemade medical devices bring with them a number of potential risks to their users and to those around them.

Medical devices that appear simple (such as face masks) often require a high degree of scientific and engineering knowledge, design, testing, and production expertise to ensure they are safe and that they perform as intended. For instance, the filter material used in face masks is a specialist non-woven fabric designed to filter out infectious agents while also providing sufficient breathability for the wearer.

The TGA recommends that individuals **use medical devices that are included on the ARTG wherever possible**.

For more information about face masks visit Face masks and COVID-19 (https://www.tga.gov.au/node/288080).

Topics:

Medical devices (https://www.tga.gov.au/products/medical-devices)

In Vitro Diagnostic medical devices (IVDs) (https://www.tga.gov.au/vitro-diagnostic-medical-devices-ivds)

Featured in:

COVID (https://www.tga.gov.au/covid)