Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Evidence requirements for face masks that are medical devices

If you are considering supplying face masks (including respirators) that meet the definition of a medical device in Australia, you will need to apply for the inclusion of these products in the ARTG.

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If you are considering supplying face masks (including respirators) that meet the definition of a medical device in Australia (https://www.tga.gov.au/node/288017), you will need to apply for the inclusion (https://www.tga.gov.au/node/286559) of these products in the Australian Register of Therapeutic Goods (ARTG).

As the legal entity responsible for importing and supplying face masks (i.e.: you are the sponsor), you must ensure all regulatory requirements relating to the products being supplied are met. All face mask applications for inclusion in the ARTG will be subject to an audit by the TGA and the following information and documents will be requested:

- The manufacturer's Declaration of Conformity (https://www.tga.gov.au/node/288300) to the Australian requirements;
- A copy of the manufacturer's technical documentation or specifications which state the manufacturer's intended purpose of the face mask or respirator (this is the manufacturer's documentation and not a copy of the GMDN term selected with the application for inclusion in the ARTG);
- Details of the manufacturing standards (if applicable, the international or Australian standards) the devices conform to and evidence of compliance to those standards, which includes:
    - certification by an accredited certification body and/or
    - **all** test reports demonstrating compliance to particular components of the standard or claims made by the manufacturer.
- The number of face masks or respirators manufactured in each lot;

- A copy of all packaging and labelling as supplied to the Australian consumer. You must ensure the above test evidence is provided if the labelling makes reference or claims to:
    - conformity to one or more standards, and/or
    - filtration efficiency, sterility, facial fit, breathability, or fluid resistance.
- A copy of the Instructions for Use that are supplied with your product (if applicable);
- Where the intended purpose of the device claims to protect the wearer from specific viral infections or bacteria, such as COVID-19 or tuberculosis, either specifically or by implication, appropriate evidence to support such a claim (for example, evidence from a clinical trial, or testing from an accredited laboratory to a recognised standard) will be required.

Given the high number of inconsistencies we have received in test reports, the following information provides an overview of our expectations so that you can prepare for the audit process. This is not an exhaustive list of parameters and will be updated as further areas of clarification are identified.

The video below provides manufacturers and suppliers technical information on face masks and respirators that are regulated as medical devices.

Standards

If the manufacturer's declaration of conformity, or the labelling on the device, indicates that the product is certified to, or complies with all aspects of a particular standard, be that by use of common labelling terms such as P2, KN95, FFP2, or N95, or with the name of the standard, such as AS/NZ 1716:2012 or ISO 13485, the manufacturer must hold evidence to support those claims. You will be required to provide this information.

Note: There are civil and criminal penalties associated with supplying a medical device that is not included in the ARTG or subject to an exemption, for providing false or misleading information to the TGA, and for misleading advertising.

Required test reports

If the manufacturer's intended purpose for the face mask, including the labelling of the product, indicates that the device:

- has a level of fluid resistance (this may be implied by the use of the word 'surgical' in the labelling of the product), or
- there is a particular level of particulate/bacterial/viral filtration efficiency (PFE / BFE / VFE), or
- the product is sterile,

you will need to provide test reports from the manufacturer that support those claim(s). The test reports require sufficient information to be traceable to the product, such as the name of the manufacturer, type/model of the product being tested, and the batch numbers.

The information below provides additional details about what the test reports should contain. This is not an exhaustive list of test reports – e.g.: test reports about breathability, BFE, VFE, and sterility, have not been provided below, but these types of reports should also be provided if the mask claims to have these features.

Fluid resistance

To effectively prevent disease transmission through fluid droplets, face masks and surgical respirators must include a fluid resistant barrier. Non-surgical respirators do not need to be fluid resistant. For face masks and surgical respirators you will need to provide evidence from the manufacturer that:

1. Identifies all areas of the mask that are intended to provide a barrier to fluid penetration; this is expected to be in the technical documentation for the device. Areas near or covering the mouth and nose **must** provide a barrier to fluid penetration.
2. The device provides resistance to fluid penetration across all areas of the mask intended to do so:
    a. evidence must be in the form of test reports which detail the area tested, the number of samples tested at each area of the face mask, and the specifications of the testing that was carried out. A summary that only states pass or fail is insufficient.
    b. areas that have differences in material type or thickness, or seams or embossed portions in the central area of the mask, need to be specifically tested for fluid resistance as well as the main body of the mask.
3. All areas of difference on the face mask should be tested. Each area of difference should be tested to the acceptable quality limit (AQL) of 4.0% or better[1] (#fn1), with a general inspection level II recommended. In addition, the minimum sample size for each location of difference must be at least 32 to be consistent with the requirements of the ISO 22069:2004

and the ASTM F1862/F1862M-17. A new mask **must be used to test each area of difference**.

4. Three non-consecutive lots have been tested or evidence to demonstrate that lot to lot variability in performance is within acceptable limits.

Particulate filtration efficiency

For masks where the intended purpose (or implied intended purpose) is to provide particulate filtration efficiency (PFE) at a specified level, such as >95%, you will be required to provide evidence from the manufacturer that:

1. The device provides particulate filtration efficiency at the specified level. The TGA requires that this evidence is in the form of test reports which details the number of samples tested and the specifications of the testing that was carried out – a summary that only states pass or fail is insufficient.
2. The number of samples tested must be at least 10 or the sample size requirement of the referenced standard (Table 1), **whichever is larger**.
3. Three non-consecutive lots have been tested or evidence to demonstrate that lot to lot variability in performance is within acceptable limits.

Table 1: Common respirator standards and their sample size requirements for PFE testing

Standards (Common designation)	**AS/NZS 1716:2012 (P2)**	**42 CFR 84 (N95)**	**EN 149:2001+A1:2009 (FFP2)**	**GB 2626:2019 (KN95)**	**GB 2626:2006 (KN95)**	**GB 19083: 2010**
PFE testing sample size by the Standard	Unspecified	20	9	20	15	6

Footnotes

[1] (#fn1s) AQL of 4.0% is referenced by multiple relevant standards, including ASTM F2100-19e1, ISO 22069:2004, and ASTM F1862/F1862M-17. Examples of acceptable sampling plans can be found in ISO 2859-1:1999.

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

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