



Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Product Category	Medical Device Included Class 1
GMDN	57794
GMDN Term	Surgical/medical respirator, single-use
Intended Purpose	A non-sterile filtering mask designed to be placed over the nose and mouth of a healthcare worker to permit normal breathing while protecting the worker and patients from the transfer of microorganisms, blood, body fluids, and airborne particulate materials during medical, surgical, dental, and isolation procedures. It is typically made of multiple layers of non-woven polymers, and incorporates a forming nosepiece (metal wire); it is typically secured using elastic head straps. This is a single-use device.

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Surgical/medical respirator, single-use

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Start Date: 21/06/2022