



Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

XXXXXXXXXXXXXX

for approval to supply

XXXXXXXXXXXXXX- Public respirator, single-use

ARTG Identifier [REDACTED]
ARTG Start Date 26/05/2020
Product Category Medical Device Included Class 1
GMDN 57793
GMDN Term Public respirator, single-use
Intended Purpose Filtration Face Masks (filter efficiency 95%) designed to be placed over the nose and mouth of a member of the general public to permit normal breathing while protecting the wearer from exposure to pathogenic biological airborne particulates. The product 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. It is a single-use device.

Manufacturer Details	Address	Certificate number(s)
[REDACTED]	[REDACTED]	

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. Public respirator, single-use

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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