

# Certification Pack.

3M N95 Respirator. 45386

This pack contains
TGA Certificate

Date Released

**June 2022** 

Certification Pack 45386 | Veridia Australia



## 3M 1870+ N95 Particulate Respirator & Surgical Mask

45386

Features	<ul> <li>Unique 3-panel flat fold design allows for greater facial movement and comfort</li> <li>Flat fold allows for convenient storage</li> <li>Mouldable nose clip for secure fit, seal and reduction of eyewear fogging</li> <li>BFE&gt;99%, PFE&gt;95% (at 0.3µm particle size)</li> <li>Highest level of fluid resistance according to ASTM F1862 at 160 mm Hg</li> </ul>
Туре	- Flat Fold N95
Unit	- Each (individually wrapped)
Pack Qty	- 20
Carton Qty	- 20 x 12



## Australian Government

## **Department of Health**

## Therapeutic Goods Administration

## **Public Summary**

Summary for ARTG Entry: 3M Australia Pty Ltd - Public N95 respirator 334581

ARTG entry for Medical Device Included Class 1

Sponsor 3M Australia Pty Ltd

Postal Address Locked Bag 19, NORTH RYDE BC, NSW, 1670

18/04/2020 ARTG Start Date

**Product Category** Medical Device Class 1

Status Active

Medical Devices Approval Area

#### 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.

#### Manufacturers

#### **Address** Name

3M Company 3M Healthcare dba 3M Consumer 2510 Conway Avenue St Paul

Health Care 3M Center

Minnesota, 55144 United States Of America

#### **Products**

### 1. Public N95 respirator

**Product Type Effective Date** 18/04/2020 Single Device Product

GMDN 57793 Public respirator, single-use

**Intended Purpose** A P2 filtering mask [N95 (filter efficiency 95%)] designed to be placed over the nose and mouth to protect from particulates. This

respirator may also help reduce breathing in some pathogenic biological airborne particulates such as influenza virus, but does not

eliminate the risk of infection or disease. This is a single-use device.

## **Specific Conditions**

No Specific Conditions included on Record

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