



**VERIDIA**

**Certification Pack.**

# **P2/N95 Flat-Fold Respirator.**

**81106**



**This pack contains**  
TGA Certificate

Date Released

**January 2022**



**P2/N95 Particulate Flat-Fold Respirator Ear Loops I/W**

**81106**

Features	<ul style="list-style-type: none"><li>- Flat Fold Design</li><li>- Elastic Ear Loops</li><li>- Plastic Nose Strip</li><li>- Latex Free</li><li>- Meets NIOSH N95 &amp; AS FFP2 Standards</li><li>- TGA Approved - ARTG 341917</li></ul>
Colour	<ul style="list-style-type: none"><li>- White</li></ul>
Unit	<ul style="list-style-type: none"><li>- Each</li></ul>
Pack Qty	<ul style="list-style-type: none"><li>- 50</li></ul>
Carton Qty	<ul style="list-style-type: none"><li>- 50 x 12</li></ul>



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 341917 SOFTMED MANUFACTURING PTY LTD - Public respirator, single-use

**ARTG entry for** Medical Device Included Class 1  
**Sponsor** SOFTMED MANUFACTURING PTY LTD  
**Postal Address** 131 National Boulevard, Campbellfield, VIC, 3061  
Australia  
**ARTG Start Date** 21/08/2020  
**Product Category** Medical Device Class 1  
**Status** Active  
**Approval Area** Medical Devices

### 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

Name	Address
SOFTMED MANUFACTURING PTY LTD	131 National Boulevard Campbellfield, VIC, 3061 Australia

### Products

#### 1 . Public respirator, single-use

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	21/08/2020
<b>GMDN</b>	57793 Public respirator, single-use		
<b>Intended Purpose</b>	A form-shaped filtering mask designed to be placed over the nose and mouth to permit normal breathing while protecting the wearer from particulates. This is a single-use device.		

### Specific Conditions

No Specific Conditions included on Record

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Public Summary