



VERIDIA

Certification Pack.

P2/N95 Respirator with Head Strap.

65060



This pack contains
TGA Certificate

Date Released
January 2022

Certification Pack 65060 | Veridia Australia

**P2/N95 Particular Cup Respirator Head Strap - Regular****65060**

Features	<ul style="list-style-type: none">- Flat folded, comfort head loop (strap), metal nose strip- PFE 99% and higher- BFE 98% and higher- Fluid Resistance 160mmHg- TGA Approved 347410
Colour	<ul style="list-style-type: none">- White
Unit	<ul style="list-style-type: none">- Each
Pack Qty	<ul style="list-style-type: none">- 20
Carton Qty	<ul style="list-style-type: none">- 20 x 12



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	347410	SOFTMED MANUFACTURING PTY LTD - Surgical/medical 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	5/11/2020	
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 . Surgical/medical respirator, single-use

Product Type	Single Device Product	Effective Date	5/11/2020
GMDN	57794 Surgical/medical respirator, single-use		
Intended Purpose	A form-shaped filtering mask designed to be placed over the nose and mouth of a healthcare worker to permit normal breathing while protecting the wearer and patient from large particles (e.g., blood, body fluids, and airborne particulate materials) and small particles (e.g., bacteria and viruses) during medical, surgical, dental, and isolation procedures. This is a single-use device.		

Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary