



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

Product Type	Single Device Product	Effective Date	21/08/2020
GMDN	57793 Public respirator, single-use		
Intended Purpose	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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