



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

## Public Summary

<b>Summary for ARTG Entry:</b>	347410	SOFTMED MANUFACTURING PTY LTD - Surgical/medical respirator, single-use
<b>ARTG entry for</b>	Medical Device Included Class 1	
<b>Sponsor</b>	SOFTMED MANUFACTURING PTY LTD	
<b>Postal Address</b>	131 National Boulevard, Campbellfield, VIC, 3061 Australia	
<b>ARTG Start Date</b>	5/11/2020	
<b>Product Category</b>	Medical Device Class 1	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	5/11/2020
<b>GMDN</b>	57794 Surgical/medical respirator, single-use		
<b>Intended Purpose</b>	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

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