



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

SOFTMED MANUFACTURING PTY LTD

for approval to supply

SOFTMED MANUFACTURING PTY LTD - Surgical/medical respirator, single-use

ARTG Identifier	347410
ARTG Start Date	5/11/2020
Product Category	Medical Device Included Class 1
GMDN	57794
GMDN Term	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.

Manufacturer Details	Address	Certificate number(s)
SOFTMED MANUFACTURING PTY LTD	131 National Boulevard Campbellfield , VIC , 3061 Australia	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Surgical/medical respirator, single-use

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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ARTG Identifier: 347410
ARTG Start Date: 5/11/2020