



Australian Government

Department of Health  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

## Safety & Medical Manufacturers Limited

for approval to supply

### Safety & Medical Manufacturers Limited - Surgical/medical respirator, single-use

<b>ARTG Identifier</b>	335470
<b>ARTG Start Date</b>	30/04/2020
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	57794
<b>GMDN Term</b>	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. It is typically made of multiple layers of non-woven polymers to produce a soft, flexible mask that will create an airtight seal against the user's face and typically secured using elastic head straps or ties; it may incorporate a forming nosepiece (metal wire) and/or an exhalation valve. This is a single-use device.

Manufacturer Details	Address	Certificate number(s)
Quality Safety International	Unit 6/20 Pacific Place , Whanganui , 4501 New Zealand	

#### 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.