



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**Strapit Medical and Sports Supplies Pty Ltd**

for approval to supply

**Strapit Medical and Sports Supplies Pty Ltd - Surgical/medical respirator, single-use**

<b>ARTG Identifier</b>	343745
<b>ARTG Start Date</b>	18/09/2020
<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 non-sterile mask designed to be placed over the nose and mouth of a healthcare worker to permit normal breathing while protecting the worker and patients from the transfer of microorganisms, blood, body fluids, and airborne particulate materials during medical, surgical, dental, and isolation procedures. It is typically made of multiple layers of non-woven polymers, and incorporates a forming nosepiece (metal wire); it is typically secured using elastic head straps. This is a single-use device.

Manufacturer Details	Address	Certificate number(s)
Shanghai Zogear Industries Co Ltd	Suite 303 Building 4 No.406 Kang Yi Road Kang Qiao Town Pudong New District , Shanghai , 201315 China	

### 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.