



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 - Public respirator,
single-use**

ARTG Identifier	341927
ARTG Start Date	21/08/2020
Product Category	Medical Device Included Class 1
GMDN	57793
GMDN Term	Public respirator, single-use
Intended Purpose	A non-sterile N95 mask designed to be placed over the nose and mouth of a healthcare and frontline worker to permit normal breathing while protecting the worker and patients from the transfer of airborne particulate materials during medical, surgical, dental, and isolation procedures - incorporates a forming nosepiece (metal wire); it is secured using elastic head straps. This is a single-use device.

Manufacturer Details	Address	Certificate number(s)
Suzhou Fantian Industries Co Ltd	Xiehe Building No 158 Jinmen Road Suzhou City , Jiangsu , 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. Public respirator, single-use

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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