



**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 N95 respirator**

<b>ARTG Identifier</b>	334548
<b>ARTG Start date</b>	18/04/2020
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	57793
<b>GMDN Term</b>	Public N95 respirator
<b>Intended Purpose</b>	A non-sterile KN95 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 microorganisms, blood, body fluids, and airborne particulate materials during medical, surgical, dental, and isolation procedures. It is made of 5 layers of non-woven polymers, and incorporates a forming nose-piece (metal wire); it is typically secured using elastic head straps. This is a single-use device.

Manufacturer Details	Address	Certificate number(s)
Ningbo Yingmed Medical Instruments Co Ltd	Room 1201-9 No 456 Tai'an Middle RD Yinzhou District Ningbo, Zhejiang, 315199 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 N95 respirator

### Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration  
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