



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**EVOLVE GROUP PTY LTD**

for approval to supply

**EVOLVE GROUP PTY LTD - Public respirator, single-use**

<b>ARTG Identifier</b>	334314
<b>ARTG Start Date</b>	16/04/2020
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	57793
<b>GMDN Term</b>	Public respirator, single-use
<b>Intended Purpose</b>	A filtering mask designed to be placed over the nose and mouth to permit normal breathing while protecting the wearer from exposure to pathogenic biological airborne particulates during a public health medical emergency (e.g., influenza pandemic). It is typically made of multiple layers of non-woven polymers, and incorporates a forming nosepiece (metal wire); it is typically secured using elastic straps. This is a single-use device.

Manufacturer Details	Address	Certificate number(s)
EVOLVE GROUP PTY LTD	15 Titanium Court CRESTMead , QLD , 4132 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. Public respirator, single-use

### Product Specific Conditions

No specific conditions have been recorded against this entry.

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