



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**ARMIS INDUSTRIES PTY LTD**

for approval to supply

## ARMIS INDUSTRIES PTY LTD - Public respirator, single-use

<b>ARTG Identifier</b>	341459
<b>ARTG Start Date</b>	13/08/2020
<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 form-shaped filtering mask designed to be placed over the nose and mouth of a member of the general public to permit normal breathing while protecting the wearer from large particles (e.g., blood, body fluids, and airborne particulate materials) and small particles (e.g., bacteria and viruses) when considered necessary (e.g., viral epidemic). 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)
ZI GONG WEIKANG MEDICAL EQUIPMENT CO LTD	C2-07ab Hao Jiaba Industrial Park Xuyang Town Rong County , Sichuan Province , 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.