



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Industree Group

for approval to supply

Industree Group - Surgical/medical respirator, single use

ARTG Identifier	344154
ARTG Start Date	23/09/2020
Product Category	Medical Device Included Class 1
GMDN	57794
GMDN Term	Surgical/medical respirator, single-use
Intended Purpose	A filtering AS/NZS 1716:2012 and AS 4381:2015 Level 3, Single-use Non-Sterile face mask for use in Surgical and Health Care with filter efficiency greater than 94%, designed to be placed over the nose and mouth of a member of the Hospital, Health care staff and general public to protect the wearer from large and small particles when considered necessary (e.g., viral epidemic, fluid resistance). It is typically made of multiple layers of non-woven polymers to produce a soft, flexible mask that will create a seal against the user's face and typically secured using elastic head loops or ties; it may incorporate a forming nose piece (metal wire) and/or an exhalation valve. This is a single-use device.

Manufacturer Details	Address	Certificate number(s)
Xiamen PinzTec Co Ltd	5/F Dongfu Industrial Park 9# Building No 2877 Dongfu Avenue Haicang , Xiamen , 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.