



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	336364	Industree Group - Public respirator, single-use
ARTG entry for	Medical Device Included Class 1	
Sponsor	Industree Group	
Postal Address	PO Box 6256, West Gosford, NSW, 2250 Australia	
ARTG Start Date	14/05/2020	
Product Category	Medical Device Class 1	
Status	Active	
Approval Area	Medical Devices	

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.

Manufacturers

Name	Address
Xiamen PinzTec Co Ltd	5/F Dongfu Industrial Park 9# Building No 2877 Dongfu Avenue Haicang, Xiamen, China

Products

1 . Public respirator, single-use

Product Type	Single Device Product	Effective Date	14/05/2020
GMDN	57793 Public respirator, single-use		
Intended Purpose	A filtering KN95 mask with filter efficiency greater than 95%, designed to be placed over the nose and mouth of a member of the general public to protect the wearer from large and small particles 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 a seal against the user's face and typically secured using elastic ear loops, head straps or ties; it may incorporate a forming nosepiece (metal wire) and/or an exhalation valve. This is a single-use device.		

Specific Conditions

No Specific Conditions included on Record

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