



Australian Government
Department of Health
Therapeutic Goods Administration

Record Summary	342055	Rowe Scientific Pty Ltd - Public respirator, single-use
Sponsor	Rowe Scientific Pty Ltd	
Therapeutic Type	Medical Device	
Product Category	Included Class 1	
ARTG Start Date	24/08/2020	
Postal Address	11 Challenge Boulevard, Wangara, WA, 6065 Australia	
Billing Address	11 Challenge Boulevard, Wangara, WA, 6065 Australia	
Product Type	Medical Device - Class 1 - Included	
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	Certificate number(s)
Wenzhou Xumei Technology Co Ltd	Floor 5 of Building 12 Floor 2 Building 10 No 36 Binhai Sixth Road Yongxing Sub-district Longwan District Wenzhou City , Zhenjiang Province , China	

Products

1 . Public respirator, single-use

Product Type	Single Device Product	Status	Current
		Effective Date	24/08/2020
GMDN	57793 Public respirator, single-use		
Functional Description	Not included on record		
Intended Purpose	A form-shaped KN95 filtering mask, single use device. Designed to be worn over the nose and mouth by the general public to permit normal breathing whilst protecting them from large and small particles.		

Variant Information

Device Information

Record Summary

Specific Conditions

No Specific Conditions included on Record

Record Summary



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Rowe Scientific Pty Ltd

for approval to supply

Rowe Scientific Pty Ltd - Public respirator, single-use

ARTG Identifier	342055
ARTG Start Date	24/08/2020
Product Category	Medical Device Included Class 1
GMDN	57793
GMDN Term	Public respirator, single-use
Intended Purpose	A form-shaped KN95 filtering mask, single use device. Designed to be worn over the nose and mouth by the general public to permit normal breathing whilst protecting them from large and small particles.

Manufacturer Details	Address	Certificate number(s)
Wenzhou Xumei Technology Co Ltd	Floor 5 of Building 12 Floor 2 Building 10 No 36 Binhai Sixth Road Yongxing Sub-district Longwan District Wenzhou City , Zhenjiang Province , China	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

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- 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.

Therapeutic Goods Administration
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ARTG Identifier: 342055
ARTG Start Date: 24/08/2020