



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	334314	EVOLVE GROUP PTY LTD - Public respirator, single-use
ARTG entry for	Medical Device Included Class 1	
Sponsor	EVOLVE GROUP PTY LTD	
Postal Address	PO Box 1491, Browns Plains, QLD, 4118 Australia	
ARTG Start Date	16/04/2020	
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
EVOLVE GROUP PTY LTD	15 Titanium Court CRESTMead, QLD, 4132 Australia

Products

1 . Public respirator, single-use

Product Type	Single Device Product	Effective Date	16/04/2020
GMDN	57793 Public respirator, single-use		
Intended Purpose	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.		

Specific Conditions

No Specific Conditions included on Record

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