



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	395538	A R Medicom Australia Pty Ltd - Surgical/medical respirator, single-use
ARTG entry for	Medical Device Included Class 1	
Sponsor	A R Medicom Australia Pty Ltd	
Postal Address	5 Yulong Close, MOOREBANK, NSW, 2170 Australia	
ARTG Start Date	6/09/2022	
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
AMD Ritmed Inc (Canada)	1200 / 55th Avenue Lachine, Quebec, H8T3J8 Canada

Products

1 . Surgical/medical respirator, single-use

Product Type	Single Device Product	Effective Date	6/09/2022
GMDN	57794 Surgical/medical respirator, single-use		
Intended Purpose	A form-shaped filtering mask designed to be placed over the nose and mouth of a healthcare worker to permit normal breathing while protecting the wearer and patient from large particles (e.g., blood, body fluids, and airborne particulate materials) and small particles (e.g., bacteria and viruses) during medical, surgical, dental, and isolation procedures.		

Specific Conditions

No Specific Conditions included on Record

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