



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 337717 A R Medicom Australia Pty Ltd - Mask, surgical, 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 11/06/2020
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
A.R. Medicom Inc (Shanghai) Co Ltd	No 290&302 Xiangche Road Songjiang District, Shanghai, 201611 China

Products

1 . Mask, surgical, single use

Product Type	Single Device Product	Effective Date	11/06/2020
GMDN	35177 Mask, surgical, single use		
Intended Purpose	Non-Sterile single-use medical device to cover the medical professional mouth and nose to prevent cross contamination.		

Specific Conditions

No Specific Conditions included on Record

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