



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 217758 A R Medicom Australia Pty Ltd - Public N95 respirator

ARTG entry for Medical Device Included Class 1

Sponsor A R Medicom Australia Pty Ltd

Postal Address PO Box 226, THORNLEIGH, NSW, 2120
Australia

ARTG Start Date 26/11/2013

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 Asia Ltd	21/F Federal Centre 77 Sheung On Street , Chai Wan, Hong Kong - SAR of China

Products

1 . Public N95 respirator

Product Type	Single Device Product	Effective Date	26/11/2013
GMDN	57793 Public respirator, single-use		
Intended Purpose	A non-sterile single-use 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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