



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 300771 A R Medicom Australia Pty Ltd - Polyisoprene surgical glove, non-powdered

ARTG entry for Medical Device Included Class IIa
Sponsor A R Medicom Australia Pty Ltd
Postal Address PO Box 226, THORNLEIGH, NSW, 2120
Australia
ARTG Start Date 14/03/2018
Product Category Medical Device Class IIa
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
Semperit Investments Asia Pte Ltd	8 Jurong Town Hall Road #29 - 03 to 06 JTC , Summit, 609434 Singapore

Products

1 . Polyisoprene surgical glove, non-powdered

Product Type	Single Device Product	Effective Date	14/03/2018
GMDN	56293 Polyisoprene surgical glove, non-powdered		
Intended Purpose	To be worn on the hands of healthcare providers at the surgical site as used as a two-way barrier to protect both the patient and the staff against contamination from microorganisms and latex allergy.		

Specific Conditions

No Specific Conditions included on Record

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