



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 443029 O&M Halyard Australia Pty Ltd - Gown, operating room, single use

ARTG entry for Medical Device Included Class 1
Sponsor O&M Halyard Australia Pty Ltd
Postal Address Tenancy 1 Level 1 Triniti 3 39 Dehli Road, North Ryde, NSW, 2113
Australia
ARTG Start Date 1/03/2024
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
KenPax International Limited	Flat 5 5/F Wing on Plaza 62 Mody Road Tsim Sha Tsui, Kowloon, 999077 Hong Kong - SAR of China

Products

1 . Gown, operating room, single use

Product Type	Single Device Product	Effective Date	1/03/2024
GMDN	35091 Gown, operating room, single use		
Intended Purpose	Non-sterile surgical gowns used for medical procedure.		

Specific Conditions

No Specific Conditions included on Record

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