



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 135185 Ultra Health Medical International Pty Ltd - Gown, isolation, single use

ARTG entry for Medical Device Included Class 1
Sponsor Ultra Health Medical International Pty Ltd
Postal Address 48 Pacific Drive, Keysborough, VIC, 3173
Australia
ARTG Start Date 21/02/2007
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
Xian Tao Fushi Protective Products Co Ltd	89 Penchang Avenue Xian Tao, Hubei, 433016 China

Products

1 . Gown, isolation, single use

Product Type	Single Device Product	Effective Date	21/02/2007
GMDN	35492 Gown, isolation, single use		
Intended Purpose	A MULTIPURPOSE GARMENT WORN BY HEALTHCARE PROVIDERS TO ISOLATE THEM FROM THE PATIENT		

Specific Conditions

No Specific Conditions included on Record

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