



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 94539 Ultra Health Medical International Pty Ltd Glove, patient examination, latex

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 27/05/2003
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
Top Glove Sdn Bhd	Lot 4969 Jalan Teratai Batu 6 off Jalan Meru Klang, Selangor DE, 41050 Malaysia

Products

1 . Glove, patient examination, latex

Product Type	Single Device Product	Effective Date	27/05/2003
GMDN	34020 Glove, patient examination, latex		
Intended Purpose	Hospital Examination and Hygiene, Food Preparation, Dental Hand Protection and Hygiene		

Specific Conditions

No Specific Conditions included on Record

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