



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 354334 Ultra Health Medical Pty Ltd - Nitrile examination/treatment glove, non-powdered

**ARTG entry for** Medical Device Included Class 1

**Sponsor** Ultra Health Medical Pty Ltd

**Postal Address** 48 Pacific Drive, Keysborough, VIC, 3173  
Australia

**ARTG Start Date** 5/02/2021

**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 5019 5 Mile Jalan Muru, Selangor, 41050 Malaysia

### Products

#### 1. Nitrile examination/treatment glove, non-powdered

Product Type	Single Device Product	Effective Date	5/02/2021
--------------	-----------------------	----------------	-----------

**GMDN** 56286 Nitrile examination/treatment glove, non-powdered

**Intended Purpose** A non-sterile device made of nitrile intended as a protective barrier when worn on the hands of healthcare providers during patient examination/treatment or for other sanitary purposes; its inner surface is not covered with talcum powder. The device is used mainly as a two-way barrier to protect patient/staff against contaminants and risk of allergy to latex. It will have appropriate characteristics regarding tactility and comfort of use, and should provide appropriate physical properties (e.g., tensile strength, resistance to puncture, elasticity), and uniformity of dimensions (i.e., sizing consistency). This is a single-use device.

### Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary