



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 333937 Essenza Health Pty Ltd - Glove, <specify>

ARTG entry for Medical Device Included Class 1
Sponsor Essenza Health Pty Ltd
Postal Address 1 Corbusier Place, BALCATT, WA, 6021
Australia
ARTG Start Date 10/04/2020
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
Anhui Haojie Plastic and Rubber Products Co Ltd	170 Daqing Road Bengbu, , 233010 China

Products

1 . Glove, <specify>

Product Type	Single Device Product	Effective Date	10/04/2020
GMDN	11879 Glove, <specify>		
Intended Purpose	a protective barrier between the user's hands and the external environment, such as an infection barrier between healthcare provider and patient.		

Specific Conditions

No Specific Conditions included on Record

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