



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	384581	Werko Australia - Gown, isolation, single use
ARTG entry for	Medical Device Included Class 1	
Sponsor	Werko Australia	
Postal Address	2/140 Hotham Street, Balaclava, VIC, 3183 Australia	
ARTG Start Date	23/02/2022	
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 Guohong Industrial & Trading Co Ltd	Room 2103 Building 4 Blue Whale International Mansion Shengli Road Hefei , Anhui Province, China

Products

1 . Gown, isolation, single use

Product Type	Single Device Product	Effective Date	23/02/2022
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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