



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	386114	Molnlycke Health Care Pty Ltd - Gown, isolation, single use
ARTG entry for	Medical Device Included Class 1	
Sponsor	Molnlycke Health Care Pty Ltd	
Postal Address	Level 4 12 Narabang Way, Belrose, NSW, 2085 Australia	
ARTG Start Date	23/03/2022	
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
Xuchang Zhengde Environstar Medical Products Co Ltd	Area B Baihua Road East South Side of Erji River Industry Cluster District Yanling County Xuchang, Henan, 461200 China

Products

1 . Gown, isolation, single use

Product Type	Single Device Product	Effective Date	23/03/2022
GMDN	35492 Gown, isolation, single use		
Intended Purpose	This Isolation gown is intended to protect health care patients and personnel from the transfer of microorganisms, body fluids and particulate material.		

Specific Conditions

No Specific Conditions included on Record

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