



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	375779	Molnlycke Health Care Pty Ltd - Surgical dressing/drape kit
ARTG entry for	Medical Device Included Class Is	
Sponsor	Molnlycke Health Care Pty Ltd	
Postal Address	Level 4 12 Narabang Way, Belrose, NSW, 2085 Australia	
ARTG Start Date	5/10/2021	
Product Category	Medical Device Class Is	
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 . Surgical dressing/drape kit

Product Type	Single Device Product	Effective Date	5/10/2021
GMDN	62934 Surgical dressing/drape kit, single-use		
Intended Purpose	A collection of various different types of sterile drapes, dressings, covers and/or towels intended to be used specifically during a surgical procedure. It does not include any pharmaceuticals, surgical instruments, surgical tubing, or mechanically functional devices and is not designed specifically to support catheterization. This is a single-use device.		

Specific Conditions

No Specific Conditions included on Record

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