



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 375552 Molnlycke Health Care Pty Ltd - Negative-pressure wound therapy system dressing set

ARTG entry for Medical Device Included Class IIb
Sponsor Molnlycke Health Care Pty Ltd
Postal Address Level 4 12 Narabang Way, Belrose, NSW, 2085
Australia
ARTG Start Date 30/09/2021
Product Category Medical Device Class IIb
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
Molnlycke Health Care AB	Gamlestadsvagen 3C Box 13080 , Goteburg, SE-402 52 Sweden

Products

1 . Negative-pressure wound therapy system dressing set

Product Type	Single Device Product	Effective Date	30/09/2021
GMDN	47956 Negative-pressure wound therapy system dressing set		
Intended Purpose	Avance Solo Border Dressing is part of Avance Solo NPWT System and Avance Solo Adapt Negative Pressure Wound Therapy (NPWT) System. This device is intended to achieve a tight seal to the skin, distribute the negative pressure to the wound and manage exudate.		

Specific Conditions

No Specific Conditions included on Record

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