



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 375561 Molnlycke Health Care Pty Ltd - Avance Solo Adapt NPWT System Sets - 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	Gamlestadsavagen 3C Box 13080 , Goteburg, SE-402 52 Sweden

Products

1 . Avance Solo Adapt NPWT System Sets - Negative-pressure wound therapy system dressing set

Product Type	Medical device system	Effective Date	30/09/2021
GMDN	47956 Negative-pressure wound therapy system dressing set		
Intended Purpose	The Avance Solo Adapt Sets are part of Avance Solo Adapt Negative Pressure Wound Therapy System. This device consists of a foam, film and transfer port. Avance Solo Adapt NPWT System is indicated for removal of low to moderate amounts of exudate from pressure ulcers/injuries.		

Specific Conditions

No Specific Conditions included on Record

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