



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	428537	Molnlycke Health Care Pty Ltd - Negative-pressure wound therapy system, battery-powered, 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	23/11/2023	
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
Molnlycke Health Care AB	Gamlestadvagen 3C Box 13080 , Goteburg, SE-402 52 Sweden

Products

1 . Negative-pressure wound therapy system, battery-powered, single-use

Product Type	Single Device Product	Effective Date	23/11/2023
GMDN	58202 Negative-pressure wound therapy system, battery-powered, single-use		
Intended Purpose	The Avance® Solo Carrier Case is intended to be used with Avance® Solo NPWT System as an accessory. The Avance® Solo Carrier Case enables an easy way to carry the pump when needed and decreases the cycling sound of the pump during operation.		

Specific Conditions

No Specific Conditions included on Record

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