



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	375853	Molnlycke Health Care Pty Ltd - Avance Solo NPWT System - Negative-pressure wound therapy system, battery-powered, single-use
<b>ARTG entry for</b>	Medical Device Included Class IIa	
<b>Sponsor</b>	Molnlycke Health Care Pty Ltd	
<b>Postal Address</b>	Level 4 12 Narabang Way, Belrose, NSW, 2085 Australia	
<b>ARTG Start Date</b>	6/10/2021	
<b>Product Category</b>	Medical Device Class IIa	
<b>Status</b>	Active	
<b>Approval Area</b>	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 NPWT System - Negative-pressure wound therapy system, battery-powered, single-use

<b>Product Type</b>	Medical device system	<b>Effective Date</b>	6/10/2021
<b>GMDN</b>	58202 Negative-pressure wound therapy system, battery-powered, single-use		
<b>Intended Purpose</b>	Avance® Solo Sets are part of Avance Solo Negative Pressure Wound Therapy System. It consists of Pump and Canister. Avance® Solo NPWT System is indicated for removal of low to moderate amounts of exudates from chronic, acute, traumatic, subacute and dehisced wounds, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps, and grafts.		

### Specific Conditions

No Specific Conditions included on Record

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