Mölnlycke <sup>®</sup>	EU Declaration of Conformity according to MDR	Document ID:	PD-583981 <b>Rev:</b> 00
		Created by:	Pam Hague
		State:	Released
		Approved by:	Christina Lewing
		Release date:	2022-01-17 18:38:43
Title: Melgisorb Plus		Dates and times in Greenwich Mean Time, 24 hours format	

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of the Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: , Not applicable

Trade name / Product name:	Melgisorb Plus	
Product Classification:	MDR Class IIb	
MDR Classification Rule	4	
Sterility:	Sterile	
Measuring Function:	Νο	
Γ		

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IX

Common Specification: No CS is applicable

Certificate number:	MDR 722028		
Issued by:	BSi	ld No:	2797
	(Notified Body Name)		
Note. For non-sterile, non-measuring class I products there is no Notified Body certificate			

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Place of Issue: Göteborg, Sweden

Date: 2022-01-17

Function:

Global Regulatory Affairs Director

Name: Christina Lewing

Signature:

Clumberry



## **EU Declaration of Conformity** according to MDR

**Document ID:** PD-583981 Rev:00 Created by: Pam Hague State: Released Approved by: **Christina Lewing Release date:** 2022-01-17 18:38:43

Title: Melgisorb Plus

Dates and times in Greenwich Mean Time, 24 hours format

Generic product information		
Intended Purpose:	Melgisorb Plus is intended for a wide range of moderately to heavily exuding wounds, both infected and non-infected, such as: Pressure sores, Venous and arterial ulcers, Diabetic ulcers, Post-operative wounds, Dermal lesions and other external wounds inflicted by trauma.	
Basic UDI-DI:	7332430000000015JM	
GMDN Code:	43186 Exudate - absorbent dressing, hydrophilic-gel, sterile	

Product References Covered by this Declaration:	Product Descriptor:
252000	Absorbent Alginate Dressing
252200	Absorbent Alginate Dressing
252380	Absorbent Alginate Dressing
252500	Absorbent Alginate Dressing
252580	Absorbent Alginate Dressing
253500	Absorbent Alginate Cavity Dressing
253580	Absorbent Alginate Cavity Dressing