



EU Declaration of Conformity according to MDR

Title: Melgisorb Plus

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden, SRN SE-MF-000014042, 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
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Product Classification: MDR Class IIb

MDR Classification Rule: 4

Sterility: Sterile

Measuring Function: No

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IX
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Common Specification: No CS is applicable

Certificate number:	MDR 722028
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Issued by:	BSi
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Id No: 2797

(Notified Body Name)

NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: 2023-10-30

Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:

Title: Melgisorb Plus

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:	733243000000000015JM
GMDN Code:	43186 Exudate - absorbent dressing, hydrophilic-gel, sterile
EMDN Code:	M04040201 ALGINATE DRESSINGS, NON-COMBINED

Product References Covered by this Declaration:	Product	Product Descriptor:
252000	Melgisorb Plus, 5x5cm	Absorbent Alginate Dressing
252200	Melgisorb Plus, 10x10cm	Absorbent Alginate Dressing
252380	Melgisorb Plus, 10x12cm, FR, 10 pcs	Absorbent Alginate Dressing
252500	Melgisorb Plus, 10x20cm	Absorbent Alginate Dressing
252580	Melgisorb Plus, 10x20cm, FR	Absorbent Alginate Dressing
253500	Melgisorb Plus, Cavity	Absorbent Alginate Cavity Dressing
253580	Melgisorb Plus, Cavity, FR	Absorbent Alginate Cavity Dressing