



**EU Declaration of Conformity
according to MDR**

Document ID: PD-590432 Rev:01
Created by: Pia Malmberg
State: Released
Approved by: Christina Lewing
Release date: 2022-09-28 07:11:52

Title: Mesorb

Dates and times in Greenwich Mean Time, 24 hours format

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:	Mesorb
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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
Common Specification: No CS is applicable

Certificate number:	MDR 722028	
Issued by:	BSi	Id No: 2797
	(Notified Body Name)	
<i>NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.</i>		

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: 2022-09-28 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
Intended Purpose:	Mesorb is intended for use in moderately to heavily exuding wounds. Mesorb can be used as a primary dressing (directly on the wound), or as a secondary dressing where high absorbency is required.
Basic UDI-DI:	733243000000000023JL
GMDN Code:	44970 Exudate - absorbent dressing, non-gel

Product References Covered by this Declaration:	Product Descriptor:
677001	Absorbent dressing
677080	Absorbent dressing
677201	Absorbent dressing
677280	Absorbent dressing
677401	Absorbent dressing
677480	Absorbent dressing
677601	Absorbent dressing
677680	Absorbent dressing
677701	Absorbent dressing
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677801	Absorbent dressing
677880	Absorbent dressing