



**EU Declaration of Conformity
according to MDR**

Document ID: PD-708451 **Rev:**1
Created by: Anu-Maria Hokkanen
State: Released
Approved by: Christina Lewing
Release date: 2022-04-13 14:05:14

Title: Mepilex Lite /EM

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadvägen 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:	Mepilex Lite / Mepilex EM
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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: 2022-04-13 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
Intended Purpose:	Mepilex Lite/EM is designed for the management of a wide range of non to low exuding wounds, such as leg and foot ulcers, pressure ulcers, partial thickness burns, radiation skin reactions and Epidermolysis Bullosa. Mepilex Lite/EM can also be used as protection of compromised and/or fragile skin.
Basic UDI-DI:	733243000000000039K3
GMDN Code:	46854 Wound - nonadherent dressing, absorbent, sterile

Product References Covered by this Declaration:	Product Descriptor:
284000	Soft silicone foam dressing
284010	Soft silicone foam dressing
284021	Soft silicone foam dressing
284022	Soft silicone foam dressing
284040	Soft silicone foam dressing
284090	Soft silicone foam dressing
284100	Soft silicone foam dressing
284110	Soft silicone foam dressing
284122	Soft silicone foam dressing
284123	Soft silicone foam dressing.
284140	Soft silicone foam dressing
284177	Soft silicone foam dressing
284190	Soft silicone foam dressing
284221	Soft silicone foam dressing
284300	Soft silicone foam dressing
284310	Soft silicone foam dressing
284321	Soft silicone foam dressing
284322	Soft silicone foam dressing
284340	Soft silicone foam dressing



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284377	Soft silicone foam dressing
284390	Soft silicone foam dressing
284500	Soft silicone foam dressing
284599	Soft silicone foam dressing