



EU Declaration of Conformity according to MDR

Title: Mepilex Lite /EM

We, Mölnlycke Health Care AB, Entreprenörstråket 21, SE-431 53, Mölndal, 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: MDD 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	Id No: 2797
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(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: Mölndal, Sweden

Date: 2025-10-13 Function: RA Director Wound Care

Name: Katarina Branzell

Signature:

Title: Mepilex Lite /EM

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
EMDN Code:	M04040701 SILICONE DRESSINGS, NON-COMBINED

Product References Covered by this Declaration:	Product	Product Descriptor:
284000	Mepilex Lite, 6x8,5 cm	Soft silicone foam dressing
284010	Mepilex Lite 7,5x8,5 cm DE; SE	Soft silicone foam dressing
284021	Mepilex em 7,5x8,5cm FR ph	Soft silicone foam dressing
284022	Mepilex em 7,5x8,5cm	Soft silicone foam dressing
284040	Mepilex Lite, 6x8,5 cm Es	Soft silicone foam dressing
284090	Mepilex Lite, 6x8,5 cm US	Soft silicone foam dressing
284100	Mepilex Lite, 10x10 cm	Soft silicone foam dressing
284110	Mepilex Lite 12,5x12,5 cm DE; SE	Soft silicone foam dressing
284122	Mepilex EM 12,5x12,5cm	Soft silicone foam dressing
284123	Mepilex Lite 12,5x12,5cm	Soft silicone foam dressing.
284140	Mepilex Lite, 10x10 cm Es	Soft silicone foam dressing
284177	Mepilex Lite 10x10 cm	Soft silicone foam dressing
284190	Mepilex Lite, 10x10 cm US	Soft silicone foam dressing
284221	Mepilex EM 14x15cm, ph FR	Soft silicone foam dressing
284300	Mepilex Lite 15x15cm	Soft silicone foam dressing
284310	Mepilex Lite 17,5x17,5 cm DE, SE	Soft silicone foam dressing

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284321	Mepilex EM 17,5x17,5 FR ph	Soft silicone foam dressing
284322	Mepilex EM 17,5x17,5cm	Soft silicone foam dressing
284340	Mepilex Lite 15x15cm, ES	Soft silicone foam dressing
284377	Mepilex Lite 15x15 cm	Soft silicone foam dressing
284390	Mepilex Lite 15x15cm, US	Soft silicone foam dressing
284500	Mepilex Lite 20x50 cm	Soft silicone foam dressing
284599	Mepilex Lite, 20x50, US	Soft silicone foam dressing