



EU Declaration of Conformity according to MDR

Title: Mepilex Border Flex Lite/EM, Mepilex Border Comfort Lite

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:	Mepilex Border Flex Lite/EM, Mepilex Border Comfort Lite
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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:	Notified Body (see CE certificate)
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Id No:

(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: 2023-11-10

Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:

Title: Mepilex Border Flex Lite/EM, Mepilex Border Comfort Lite

Generic product information	
Intended Purpose:	Mepilex Border Flex Lite is designed for the management of a wide range of non- to moderately exuding wounds, such as leg and foot ulcers, pressure ulcers, surgical wounds and traumatic wounds e.g. abrasions, blisters and skin tears. Mepilex Border Flex Lite can also be used as protection of compromised and/or fragile skin.
Basic UDI-DI:	733243000000000073K3
GMDN Code:	46854 Wound - nonadherent dressing, absorbent, sterile
EMDN Code:	M04040701 SILICONE DRESSINGS, NON-COMBINED

Product References Covered by this Declaration:	Product	Product Descriptor:
581011	Mepilex Border Flex Lite 4x5cm	Self-adherent soft silicone foam dressing
581050	Mepilex Border Flex Lite 4x5cm, AC DACHBE	Self-adherent soft silicone foam dressing
581060	Mepilex Border Flex Lite 4x5cm, HC Germany	Self-adherent soft silicone foam dressing
581070	Mepilex Border Flex Lite 4x5cm, OTC Norden	
581100	Mepilex Border Flex Lite 5x12,5cm	Self-adherent soft silicone foam dressing
581170	Mepilex Border Flex Lite 5x12,5cm, OTC Norden	
581200	Mepilex Border Flex Lite 7,5x7,5cm	Self-adherent soft silicone foam dressing
581220	Mepilex Border Flex EM 5x5cm, FR HC	Self-adherent soft silicone foam dressing
581250	Mepilex Border Flex Lite 7,5x7,5cm, AC DACHBE	Self-adherent soft silicone foam dressing
581260	Mepilex Border Flex Lite 7,5x7,5cm, HC Germany	Self-adherent soft silicone foam dressing
581270	Mepilex Border Flex Lite 7,5x7,5cm, OTC Norden	

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Title: Mepilex Border Flex Lite/EM, Mepilex Border Comfort Lite

581277	Mepilex Border Flex Lite 7,5x7,5cm, NL	Self-adherent soft silicone foam dressing
581300	Mepilex Border Flex Lite 10x10cm	Self-adherent soft silicone foam dressing
581320	Mepilex Border Flex EM 6x12cm, FR HC	Self-adherent soft silicone foam dressing
581350	Mepilex Border Flex Lite 10x10cm, AC DACHBE	Self-adherent soft silicone foam dressing
581360	Mepilex Border Flex Lite 10x10cm, HC Germany	Self-adherent soft silicone foam dressing
581377	Mepilex Border Flex Lite 10x10cm, NL	Self-adherent soft silicone foam dressing
581400	Mepilex Border Flex EM 7,5x8,5cm	Self-adherent soft silicone foam dressing
581500	Mepilex Border Flex Lite 15x15cm	Self-adherent soft silicone foam dressing
581520	Mepilex Border Flex EM 9x15cm, FR HC	Self-adherent soft silicone foam dressing
581600	Mepilex Border Flex EM 12,5x12,5cm	Self-adherent soft silicone foam dressing
581700	Mepilex Border Flex EM 17,5x17,5cm	Self-adherent soft silicone foam dressing
581820	Mepilex Border Flex EM 10x20cm, FR HC	Self-adherent soft silicone foam dressing
582011	Mepilex Border Comfort Lite 4x5cm	Self-adherent soft silicone foam dressing
582111	Mepilex Border Comfort Lite 5x12,5cm	Self-adherent soft silicone foam dressing
582211	Mepilex Border Comfort Lite 7,5x7,5cm	Self-adherent soft silicone foam dressing
582311	Mepilex Border Comfort Lite 10x10cm	Self-adherent soft silicone foam dressing
582511	Mepilex Border Comfort Lite 15x15cm	Self-adherent soft silicone foam dressing