



**EU Declaration of Conformity
according to MDR**

Document ID: PD-702086 Rev:3
Created by: Sofia Horkeby
State: Released
Approved by: Christina Lewing
Release date: 2022-10-17 11:59:59

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

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:	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
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: 2022-10-17 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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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

Product References Covered by this Declaration:	Product Descriptor:
581000	Self-adherent soft silicone foam dressing
581011	Self-adherent soft silicone foam dressing
581050	Self-adherent soft silicone foam dressing
581060	Self-adherent soft silicone foam dressing
581070	Self-adherent soft silicone foam dressing
581100	Self-adherent soft silicone foam dressing
581170	Self-adherent soft silicone foam dressing
581200	Self-adherent soft silicone foam dressing
581220	Self-adherent soft silicone foam dressing
581250	Self-adherent soft silicone foam dressing
581260	Self-adherent soft silicone foam dressing
581270	Self-adherent soft silicone foam dressing
581277	Self-adherent soft silicone foam dressing
581300	Self-adherent soft silicone foam dressing
581320	Self-adherent soft silicone foam dressing
581350	Self-adherent soft silicone foam dressing
581360	Self-adherent soft silicone foam dressing
581377	Self-adherent soft silicone foam dressing



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581400	Self-adherent soft silicone foam dressing
581500	Self-adherent soft silicone foam dressing
581520	Self-adherent soft silicone foam dressing
581600	Self-adherent soft silicone foam dressing
581700	Self-adherent soft silicone foam dressing
581800	Self-adherent soft silicone foam dressing
581820	Self-adherent soft silicone foam dressing
581900	Self-adherent soft silicone foam dressing
582011	Self-adherent soft silicone foam dressing
582111	Self-adherent soft silicone foam dressing
582211	Self-adherent soft silicone foam dressing
582311	Self-adherent soft silicone foam dressing
582511	Self-adherent soft silicone foam dressing