



**EU Declaration of Conformity
according to MDR**

Document ID: PD-702086 Rev:2
Created by: Sofia Horkeby
State: Released
Approved by: Christina Lewing
Release date: 2022-09-20 06:22:49

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
	<i>(Notified Body Name)</i>	
<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: 2022-09-20 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
Intended Purpose:	Mepilex Border Flex Lite / Mepilex Border Flex EM 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/ Mepilex Border Flex EM 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
581100	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
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
581400	Self-adherent soft silicone foam dressing
581500	Self-adherent soft silicone foam dressing
581520	Self-adherent soft silicone foam dressing



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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