



## EU Declaration of Conformity according to MDR

**Document ID:** PD-705293 **Rev:**1  
**Created by:** Sofia Horkeby  
**State:** Released  
**Approved by:** Christina Lewing  
**Release date:** 2021-11-01 09:15:51

**Title:** Mepilex Border Flex/Mepilex Border Comfort

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden 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/Mepilex Border Comfort
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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)

*Note. For non-sterile, non-measuring class I products there is no Notified Body certificate*

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Place of Issue: Göteborg, Sweden

Date: 2021-11-01

Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
<b>Intended Purpose:</b>	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
<b>Basic UDI-DI:</b>	733243000000000036JV
<b>GMDN Code:</b>	46854 Wound - nonadherent dressing, absorbent, sterile

Product References Covered by this Declaration:	Product Descriptor:
583300	Self-adherent soft silicone foam dressing
583320	Self-adherent soft silicone foam dressing
583400	Self-adherent soft silicone foam dressing
583420	Self-adherent soft silicone foam dressing
583500	Self-adherent soft silicone foam dressing
583520	Self-adherent soft silicone foam dressing
583620	Self-adherent soft silicone foam dressing
595000	Self-adherent soft silicone foam dressing
595011	Self-adherent soft silicone foam dressing
595021	Self-adherent soft silicone foam dressing
595200	Self-adherent soft silicone foam dressing
595211	Self-adherent soft silicone foam dressing
595221	Self-adherent soft silicone foam dressing
595277	Self-adherent soft silicone foam dressing
595300	Self-adherent soft silicone foam dressing
595311	Self-adherent soft silicone foam dressing
595321	Self-adherent soft silicone foam dressing
595377	Self-adherent soft silicone foam dressing



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595400	Self-adherent soft silicone foam dressing
595411	Self-adherent soft silicone foam dressing
595421	Self-adherent soft silicone foam dressing
595477	Self-adherent soft silicone foam dressing
595600	Self-adherent soft silicone foam dressing
595611	Self-adherent soft silicone foam dressing
595621	Self-adherent soft silicone foam dressing
595800	Self-adherent soft silicone foam dressing
595820	Self-adherent soft silicone foam dressing
595850	Self-adherent soft silicone foam dressing
595900	Self-adherent soft silicone foam dressing
595920	Self-adherent soft silicone foam dressing
596011	Self-adherent soft silicone foam dressing
596211	Self-adherent soft silicone foam dressing
596311	Self-adherent soft silicone foam dressing
596411	Self-adherent soft silicone foam dressing
596611	Self-adherent soft silicone foam dressing
596800	Self-adherent soft silicone foam dressing
596900	Self-adherent soft silicone foam dressing