



**EU Declaration of Conformity  
according to MDR**

**Document ID:** PD-705293 Rev:2  
**Created by:** Sofia Horkeby  
**State:** Released  
**Approved by:** Christina Lewing  
**Release date:** 2022-05-11 14:14:47

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

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/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)	
<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: 2022-05-11      Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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<b>Generic product information</b>	
<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

<b>Product References Covered by this Declaration:</b>	<b>Product Descriptor:</b>
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
595050	Self-adherent soft silicone foam dressing
595060	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
595250	Self-adherent soft silicone foam dressing
595260	Self-adherent soft silicone foam dressing
595277	Self-adherent soft silicone foam dressing



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595300	Self-adherent soft silicone foam dressing
595311	Self-adherent soft silicone foam dressing
595321	Self-adherent soft silicone foam dressing
595350	Self-adherent soft silicone foam dressing
595360	Self-adherent soft silicone foam dressing
595377	Self-adherent soft silicone foam dressing
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