



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, Gamlestadsvägen 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	
Intended Purpose:	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.
Basic UDI-DI:	733243000000000036JV
GMDN Code:	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