



EU Declaration of Conformity according to MDR

Title: Mepilex Border Sacrum and Mepilex Border Heel Prevention, RoW Assortment

We, Mölnlycke Health Care AB, Entreprenörstråket 21, SE-431 53, Mölndal, 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 Sacrum and Mepilex Border Heel
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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)

NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

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: Mölndal, Sweden

Date: 2025-05-08

Function: Regulatory Affairs Excellence Director

Name: Karin Darle Olsson

Signature:

Title: Mepilex Border Sacrum and Mepilex Border Heel Prevention, RoW Assortment

Generic product information	
Intended Purpose:	Mepilex Border is designed to be part of a prophylactic therapy to prevent skin damage, e.g. pressure ulcers and to reduce postoperative blistering. Mepilex Border is also designed for a wide range of exuding wounds such as pressure ulcers, leg ulcers, foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border can also be used on dry/necrotic wounds in combination with gels.
Basic UDI-DI:	733243000000000035JT
GMDN Code:	46854 Wound - nonadherent dressing, absorbent, sterile
EMDN Code:	M04040701 SILICONE DRESSINGS, NON-COMBINED

Product References Covered by this Declaration:	Product	Product Descriptor:
282010	Mepilex Border Sacrum 16x20cm	Self-adherent soft silicone multi-layer foam dressing
282040	Mepilex Border Protect Sacrum 16x20cm FR	Sacrum. Self-adherent soft silicone multi-layer foam dressing
282050	Mepilex Border Sacrum 16x20cm	Self-adherent soft silicone multi-layer foam dressing
282060	Mepilex Border Sacrum 16x20cm, HC DACHBE	Self-adherent soft silicone multi-layer foam dressing
282410	Mepilex Border Sacrum 22x25cm	Self-adherent soft silicone multi-layer foam dressing
282440	Mepilex Border Protect Sacrum 22x25cm, FR	Sacrum. Self-adherent soft silicone multi-layer foam dressing
282450	Mepilex Border Sacrum 22x25cm	Self-adherent soft silicone multi-layer foam dressing
282460	Mepilex Border Sacrum 22x25cm, HC DACHBE	Self-adherent soft silicone multi-layer foam dressing
282710	Mepilex Border Heel 22x23cm	Self-adherent soft silicone multi-layer foam dressing
282720	Mepilex Border Protect Talon 22x23cm, FR	Talon. Self-adherent soft silicone multi-layer foam dressing



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282750	Mepilex Border Heel 22x23cm	Self-adherent soft silicone multi-layer foam dressing
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