

EU Declaration of Conformity according to MDR

Document ID: PD-702139 Rev:3

Created by: Petra Rosén State: Released

Approved by: Christina Lewing

Release date: 2022-05-03 14:10:33

Dates and times in Greenwich Mean Time, 24 hours format

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

> 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 Mepilex Border Sacrum and Mepilex Border Heel name:

Product Classification: MDR Class IIb

MDR Classification Rule:

Sterility: Sterile

Measuring Function: Nο

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

BSi Id No: 2797 Issued by:

(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: Göteborg, Sweden

Clumberry Date: 2022-05-03 Function:

Signature: Christina Lewing Name:



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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

Product References Covered by this Declaration:	Product Descriptor:
282010	Self-adherent soft silicone multi-layer foam dressing
282040	Sacrum. Self-adherent soft silicone multi- layer foam dressing
282050	Self-adherent soft silicone multi-layer foam dressing
282060	Self-adherent soft silicone multi-layer foam dressing
282410	Self-adherent soft silicone multi-layer foam dressing
282440	Sacrum. Self-adherent soft silicone multi- layer foam dressing
282450	Self-adherent soft silicone multi-layer foam dressing
282460	Self-adherent soft silicone multi-layer foam dressing
282710	Self-adherent soft silicone multi-layer foam dressing
282720	Talon. Self-adherent soft silicone multi-layer foam dressing
282750	Self-adherent soft silicone multi-layer foam dressing