



**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

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

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 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)	
<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: 2022-05-03 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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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

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