EU Declaration of Conformity according to MDR

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Title: MDR DoC Mepilex Border Ag and Mepilex Border Sacrum Ag

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 Ag and Mepilex Border Sacrum Ag

Product Classification:	MDR Class III
MDR Classification Rule:	4, 14
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, MDR 758927		
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: Göteborg, Sweden

Date: 2022-08-16 Function: Global Regulatory Affairs Director

Name: Christina Lewing Signature:



Generic product information	
Intended Purpose:	Mepilex Border Ag is designed for the management of medium to high exuding leg and foot ulcers, pressure ulcers, malignant wounds, partial thickness burns, traumatic and surgical wounds where a moist environment, exudate handling, gentle fixation and an antimicrobial action is indicated. Mepilex Border Ag may be used on infected wounds as part of a treatment regimen under supervision of a qualified health care professional. Mepilex Border Ag can be used under compression bandaging.
Basic UDI-DI:	733243000000000028JW
GMDN Code:	47042 Wound - nonadherent dressing, absorbent, antimicrobial

Product References Covered by this Declaration:	**Product Descriptor:**
382000	Self- adherent antimicrobial soft silicone foam dressing
382200	Self- adherent antimicrobial soft silicone foam dressing
382400	Self- adherent antimicrobial soft silicone foam dressing
395010	Self- adherent antimicrobial soft silicone foam dressing
395200	Self- adherent antimicrobial soft silicone foam dressing
395221	Self- adherent antimicrobial soft silicone foam dressing.
395260	Self- adherent antimicrobial soft silicone foam dressing
395300	Self- adherent antimicrobial soft silicone foam dressing
395360	Self- adherent antimicrobial soft silicone foam dressing
395400	Self- adherent antimicrobial soft silicone foam dressing
395410	Self- adherent antimicrobial soft silicone foam dressing
395460	Self- adherent antimicrobial soft silicone foam dressing
395600	Self- adherent antimicrobial soft silicone foam dressing
395660	Self- adherent antimicrobial soft silicone foam dressing

395700	Self- adherent antimicrobial soft silicone foam dressing
395800	Self- adherent antimicrobial soft silicone foam dressing
395900	Self- adherent antimicrobial soft silicone foam dressing