



## EU Declaration of Conformity according to MDR

Title: MDR DoC Mepilex Ag and Mepilex Heel 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 Ag and Mepilex Heel Ag
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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 722079	
Issued by:	BSi	Id No: 2797
	<i>(Notified Body Name)</i>	
<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: 2024-07-11                      Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
<b>Intended Purpose:</b>	Mepilex Ag is an antimicrobial soft silicone foam dressing that is designed for the management of low to moderately exuding leg and foot ulcers, pressure ulcers and partial thickness burns. Mepilex Ag may be used on infected wounds as part of a treatment regimen under supervision of a qualified health care professional. Mepilex Ag can be used under compression bandaging.
<b>Basic UDI-DI:</b>	733243000000000027JU
<b>GMDN Code:</b>	47042 Wound - nonadherent dressing, absorbent, antimicrobial
<b>EMDN Code:</b>	M04040801, SILVER DRESSINGS, NON-COMBINED

Product References Covered by this Declaration:	Product	Product Descriptor:
287021	Mepilex Ag 6x8,5cm	Antimicrobial soft silicone foam dressing
287050	Mepilex Ag 10x10cm, DE	Antimicrobial soft silicone foam dressing
287110	Mepilex Ag 10x10 cm	Antimicrobial soft silicone foam dressing
287121	Mepilex Ag 12,5x12,5cm	Antimicrobial soft silicone foam dressing
287210	Mepilex Ag 10x20 cm	Antimicrobial soft silicone foam dressing
287221	Mepilex Ag 10x21cm	Antimicrobial soft silicone foam dressing
287310	Mepilex Ag 15x15 cm	Antimicrobial soft silicone foam dressing
287321	Mepilex Ag 17,5x17,5cm	Antimicrobial soft silicone foam dressing
287410	Mepilex Ag 20x20 cm	Antimicrobial soft silicone foam dressing
287510	Mepilex Ag 20x50cm	Antimicrobial soft silicone foam dressing
388100	Mepilex Heel Ag, 13x20cm	Antimicrobial soft silicone foam dressing
388300	Mepilex Heel Ag, 15x22 cm	Antimicrobial soft silicone foam dressing