



**EU Declaration of Conformity  
according to MDR**

**Document ID:** PD-563410 Rev:00  
**Created by:** Kristin Ödling  
**State:** Released  
**Approved by:** Karin Darle Olsson  
**Release date:** 2022-06-17 12:36:14

**Title:** MDR DoC Mepilex Ag

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadvägen 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 |
|----------------------------|------------|

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: 2022-06-17      Function: Regulatory Affairs Excellence Manager

Name: Karin Darle Olsson

Signature:



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| <b>Generic product information</b> |   |
|------------------------------------|---|
| <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>Product References Covered by this Declaration:</b> | <b>Product Descriptor:</b>                |
|--|---|
| 287021   | Antimicrobial soft silicone foam dressing |
| 287050   | Antimicrobial soft silicone foam dressing |
| 287110   | Antimicrobial soft silicone foam dressing |
| 287121   | Antimicrobial soft silicone foam dressing |
| 287210   | Antimicrobial soft silicone foam dressing |
| 287221   | Antimicrobial soft silicone foam dressing |
| 287310   | Antimicrobial soft silicone foam dressing |
| 287321   | Antimicrobial soft silicone foam dressing |
| 287410   | Antimicrobial soft silicone foam dressing |
| 287510   | Antimicrobial soft silicone foam dressing |
| 388100   | Antimicrobial soft silicone foam dressing |
| 388300   | Antimicrobial soft silicone foam dressing |