



**EU Declaration of Conformity
according to MDR**

Document ID: PD-714051 **Rev:**1
Created by: Anu-Maria Hokkanen
State: Released
Approved by: Christina Lewing
Release date: 2022-09-28 07:09:55
Dates and times in Greenwich Mean Time, 24 hours format

Title: Mepilex / Mepilex Heel / Mepilex Talon

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, Mepilex Heel, Mepilex Talon
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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
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Common Specification: No CS is applicable

Certificate number:	MDR 722028
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Issued by:	BSi	Id No: 2797
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(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: 2022-09-28 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information

Intended Purpose:	Mepilex is intended for a wide range of exuding wounds such as leg and foot ulcers, pressure ulcers and traumatic wounds, e.g. skin tears and secondary healing wounds. Mepilex can be used as a protection of compromised and/or fragile skin and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Basic UDI-DI:	733243000000000031JK
GMDN Code:	46854 Wound - nonadherent dressing, absorbent, sterile

Product References Covered by this Declaration:	Product Descriptor:
288100	Soft silicone foam dressing
288200	Soft silicone foam dressing
288220	Soft silicone foam dressing
288240	Soft silicone foam dressing
288300	Soft silicone foam dressing
288320	Soft silicone foam dressing
294000	Soft silicone foam dressing
294015	Soft silicone foam dressing
294050	Soft silicone foam dressing
294090	Soft silicone foam dressing
294100	Soft silicone foam dressing
294150	Soft silicone foam dressing
294160	Soft silicone foam dressing
294177	Soft silicone foam dressing
294199	Soft silicone foam dressing
294200	Soft silicone foam dressing
294201	Soft silicone foam dressing
294250	Soft silicone foam dressing



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294260	Soft silicone foam dressing
294299	Soft silicone foam dressing
294300	Soft silicone foam dressing
294310	Soft silicone foam dressing
294350	Soft silicone foam dressing
294377	Soft silicone foam dressing
294399	Soft silicone foam dressing
294400	Soft silicone foam dressing
294410	Soft silicone foam dressing
294450	Soft silicone foam dressing
294460	Soft silicone foam dressing
294499	Soft silicone foam dressing
294500	Soft silicone foam dressing