



EU Declaration of Conformity according to MDR

Title: Mepilex Up

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 up
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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
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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: 2024-07-11

Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:

Title: Mepilex Up

Generic product information	
Intended Purpose:	Mepilex Up is intended for the management of a wide range of exuding wounds in all healing stages such as chronic wounds e.g. leg ulcers, foot ulcers and pressure ulcers, and traumatic wounds e.g. skin tears and secondary healing wounds.
Basic UDI-DI:	733243000000000033JP
GMDN Code:	46854 Wound - nonadherent dressing, absorbent, sterile
EMDN Code:	M04040701 SILICONE DRESSINGS, NON-COMBINED

Product References Covered by this Declaration:	Product	Product Descriptor:
212015	Mepilex Up 5x5cm	Soft silicone foam dressing
212050	Mepilex Up 5x5cm, AC DACHBE	Soft silicone foam dressing
212100	Mepilex Up 10x10cm	Soft silicone foam dressing
212110	Mepilex Up 12,5x12,5cm	Soft silicone foam dressing
212121	Mepilex Up 14x15cm, FR ph	Soft silicone foam dressing
212150	Mepilex Up 10x10cm, AC DACHBE	Soft silicone foam dressing
212155	Mepilex Up 10x10cm, HC DACHBE	Soft silicone foam dressing
212160	Mepilex Up 10x11cm	Soft silicone foam dressing
212199	Mepilex Up 10x10cm, US AC	Soft silicone foam dressing
212200	Mepilex Up 10x20cm	Soft silicone foam dressing
212250	Mepilex Up 10x20cm, AC DACHBE	Soft silicone foam dressing
212255	Mepilex Up 10x20cm, HC DACHBE	Soft silicone foam dressing
212260	Mepilex Up 11x20cm	Soft silicone foam dressing
212299	Mepilex Up 10x20cm, US AC	Soft silicone foam dressing
212300	Mepilex Up 15x15cm	Soft silicone foam dressing

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212310	Mepilex Up 17,5x17,5cm	Soft silicone foam dressing
212321	Mepilex Up 17,5x17,5cm, FR ph	Soft silicone foam dressing
212350	Mepilex Up 15x15cm, AC DACHBE	Soft silicone foam dressing
212355	Mepilex Up 15x15cm, HC DACHBE	Soft silicone foam dressing
212360	Mepilex Up 15x16cm	Soft silicone foam dressing
212399	Mepilex Up 15x15cm, US AC	Soft silicone foam dressing
212400	Mepilex Up 20x20cm	Soft silicone foam dressing
212410	Mepilex Up 21x22cm	Soft silicone foam dressing
212421	Mepilex Up 21x22cm, FR ph	Soft silicone foam dressing
212450	Mepilex Up 20x20cm, AC DACHBE	Soft silicone foam dressing
212455	Mepilex Up 20x20cm, HC DACHBE	Soft silicone foam dressing
212460	Mepilex Up 20x21cm	Soft silicone foam dressing
212499	Mepilex Up 20x20cm, US AC	Soft silicone foam dressing
212500	Mepilex Up 20x50cm	Soft silicone foam dressing
212550	Mepilex Up 20x50cm, AC DACHBE	Soft silicone foam dressing