



## EU Declaration of Conformity according to MDR

**Title:** Mepilex Border Post-op

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 Post-op
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Product Classification: MDR Class IIa

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
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Certificate number:	MDR 722028
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Issued by:	BSi
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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: 2024-04-19

Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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**Title:** Mepilex Border Post-op

Generic product information	
<b>Intended Purpose:</b>	Mepilex Border Post-Op is a self-adhesive absorbent surgical dressing designed for exuding wounds. It is intended for acute wounds, such as surgical wounds, cuts and abrasions.
<b>Basic UDI-DI:</b>	733243000000000030JH
<b>GMDN Code:</b>	34864 Adhesive bandage
<b>EMDN Code:</b>	M04040701 SILICONE DRESSINGS, NON-COMBINED

Product References Covered by this Declaration:	Product	Product Descriptor:
496100	Mepilex Border Post Op 6x8cm	Self-adherent soft silicone surgical dressing
496200	Mepilex Border Post Op 9x10cm	Self-adherent soft silicone surgical dressing
496300	Mepilex Border Post Op 10x15cm	Self-adherent soft silicone surgical dressing
496400	Mepilex Border Post Op 10x20cm	Self-adherent soft silicone surgical dressing
496405	Mepilex Border Post Op 10x20cm	Self-adherent soft silicone surgical dressing
496450	Mepilex Border Post Op 10x25cm	Self-adherent soft silicone surgical dressing
496455	Mepilex Border Post Op 10x25cm	Self-adherent soft silicone surgical dressing
496600	Mepilex Border Post Op 10x30cm	Self-adherent soft silicone surgical dressing
496605	Mepilex Border Post Op 10x30cm	Self-adherent soft silicone surgical dressing
496650	Mepilex Border Post Op 10x35cm	Self-adherent soft silicone surgical dressing