



EU Declaration of Conformity according to MDR

Document ID: PD-702374 Rev:3
Created by: Sofie Ludvigsson
State: Released
Approved by: Christina Lewing
Approval date: 2023-06-01 09:39:40
Release date: 2023-06-01 09:39:45

Title: Mepilex Border Post-op

Dates and times in Greenwich Mean Time, 24 hours format

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
----------------------------	------------------------

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

Common Specification: No CS is applicable

Certificate number: MDR 722028

Issued by: BSi

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: 2023-06-01

Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



**EU Declaration of Conformity
according to MDR**

Document ID: PD-702374 **Rev:**3
Created by: Sofie Ludvigsson
State: Released
Approved by: Christina Lewing
Approval date: 2023-06-01 09:39:40
Release date: 2023-06-01 09:39:45

Title: Mepilex Border Post-op

Dates and times in Greenwich Mean Time, 24 hours format

Generic product information	
Intended Purpose:	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.
Basic UDI-DI:	733243000000000030JH
GMDN Code:	34864 Adhesive bandage

Product References Covered by this Declaration:	Product Descriptor:
496100	Self-adherent soft silicone surgical dressing
496200	Self-adherent soft silicone surgical dressing
496300	Self-adherent soft silicone surgical dressing
496400	Self-adherent soft silicone surgical dressing
496405	Self-adherent soft silicone surgical dressing
496450	Self-adherent soft silicone surgical dressing
496455	Self-adherent soft silicone surgical dressing
496600	Self-adherent soft silicone surgical dressing
496605	Self-adherent soft silicone surgical dressing
496650	Self-adherent soft silicone surgical dressing