Mölnlycke[®]

Declaration of Conformity EU

Document ID: Created by: Approved by: Approval date: PD-526342 Rev: 07 Charlotte Berg Karin Darle Olsson 2021-05-04

Title: Mepilex Border Post-Op

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We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden 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 Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/
Product name:

Mepilex Border Post-Op

Product classification: Ila

Sterility Status: Sterile

Measuring function: No

This declaration is supported by a conformity assessment procedure in accordance with

Annex/es:

Certificate number: CE 01965

Issued by: **BSI (2797)**

For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

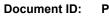
Signed for and on behalf of Mölnlycke Health AB Care

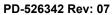
Date: 2021-05-04 Function: Regulatory Affairs Manager

Compliance

Name: Karin Darle Olsson Signature:

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Title: Mepilex Border Post-Op Page 2(2)

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
496100	Self-adherent soft silicone surgical dressing	34864 Adhesive bandage
496200	Self-adherent soft silicone surgical dressing	34864 Adhesive bandage
496300	Self-adherent soft silicone surgical dressing	34864 Adhesive bandage
496400	Self-adherent soft silicone surgical dressing	34864 Adhesive bandage
496405	Self-adherent soft silicone surgical dressing	34864 Adhesive bandage
496450	Self-adherent soft silicone surgical dressing	34864 Adhesive bandage
496455	Self-adherent soft silicone surgical dressing	34864 Adhesive bandage
496600	Self-adherent soft silicone surgical dressing	34864 Adhesive bandage
496605	Self-adherent soft silicone surgical dressing	34864 Adhesive bandage
496650	Self-adherent soft silicone surgical dressing	34864 Adhesive bandage

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