Mölnlycke[®]

Declaration of Conformity EU

Document ID: Created by: Approved by: Approval date: PD-408564 Rev: 14 Technia Support Karin Darle Olsson 2021-03-03

Title: Mepilex Ag / Mepilex Heel Ag

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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 Ag / Mepilex Heel Ag

Product classification:

Sterility Status: Sterile

Measuring function: No

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

Annex/es:

Certificate number: CE 01965;CE 514235

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: 2021-03-03 Function: Regulatory Affairs Manager

Compliance

Name: Karin Darle Olsson Signature:

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Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
287021	Antimicrobial soft silicone foam dressing	47042 Wound - nonadherent dressing, absorbent, antimicrobial
287050	Antimicrobial soft silicone foam dressing	47042 Wound - nonadherent dressing, absorbent, antimicrobial
287110	Antimicrobial soft silicone foam dressing	47042 Wound - nonadherent dressing, absorbent, antimicrobial
287121	Antimicrobial soft silicone foam dressing	47042 Wound - nonadherent dressing, absorbent, antimicrobial
287210	Antimicrobial soft silicone foam dressing	47042 Wound - nonadherent dressing, absorbent, antimicrobial
287221	Antimicrobial soft silicone foam dressing	47042 Wound - nonadherent dressing, absorbent, antimicrobial
287310	Antimicrobial soft silicone foam dressing	47042 Wound - nonadherent dressing, absorbent, antimicrobial
287321 Document template: Declaration of	Antimicrobial soft silicone foam dressing Conformity EU Rev: 05	47042 Wound - nonadherent



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Product Reference:	Product Descriptor:	GMDN Code:
		dressing, absorbent, antimicrobial
287410	Antimicrobial soft silicone foam dressing	47042 Wound - nonadherent dressing, absorbent, antimicrobial
287510	Antimicrobial soft silicone foam dressing	47042 Wound - nonadherent dressing, absorbent, antimicrobial
388100	Antimicrobial soft silicone foam dressing	47042 Wound - nonadherent dressing, absorbent, antimicrobial
388300	Antimicrobial soft silicone foam dressing	47042 Wound - nonadherent dressing, absorbent, antimicrobial

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