

Title: Mepilex Border Lite / Mepilex Border EM**Page** 1(5)

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 Lite / Mepilex Border EM****Product classification:** **IIb****Sterility Status:** **Sterile****Measuring function:** **No**

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

Annex/es: **II****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: **2021-03-19****Function:****Regulatory Affairs Manager
Compliance****Name:** **Karin Darle Olsson****Signature:**

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
281000	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281020	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281100	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281166	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281200	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281220	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281266	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281277	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent

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Product Reference:	Product Descriptor:	GMDN Code:
		dressing, absorbent, sterile
281300	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281320	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281366	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281377	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281400	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281440	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281500	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281520	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent

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Product Reference:	Product Descriptor:	GMDN Code:
		dressing, absorbent, sterile
281540	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281566	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281600	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281700	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281800	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281820	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281850	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
281900	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent

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Product Reference:	Product Descriptor:	GMDN Code:
		dressing, absorbent, sterile
281920	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile