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 Lite / Mepilex 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 M ö lnlycke Health Care

Date: **2020-10-14** Function: **Regulatory Affairs Manager Compliance**

Name: **Karin Darle Olsson** Signature:



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Document template: Declaration of Conformity EU Rev: 05

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Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
284000	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284010	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284021	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284022	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284040	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284090	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284100	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284110	Soft silicone foam dressing	46854 Wound - nonadherent

Product Reference:	Product Descriptor:	GMDN Code:
		dressing, absorbent, sterile
284122	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284140	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284177	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284190	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284221	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284300	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284310	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284321	Soft silicone foam dressing	46854 Wound - nonadherent

Product Reference:	Product Descriptor:	GMDN Code:
		dressing, absorbent, sterile
284322	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284340	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284377	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284390	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284500	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
284599	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile