

Title: Mepilex Lite / Mepilex EM

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We, Mölnlycke Health Care AB, Gamlestadvägen 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
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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 Care

Date: **2020-10-14**

Function:

**Regulatory Affairs Manager
Compliance**Name: **Karin Darle Olsson**

Signature:





Declaration of Conformity EU

Document ID: PD-399617 Rev: 10
Created by: Anu-Maria Hokkanen
Approved by: Karin Darle Olsson
Approval date: 2020-10-14

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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
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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

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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