

Title: Mepilex XT

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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 XT
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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 AB Care

Date: **2021-04-22**

Function:

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

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
211015	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211100	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211110	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211121	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211160	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211200	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211210	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211221	Soft silicone foam dressing	46854 Wound - nonadherent

Product Reference:	Product Descriptor:	GMDN Code:
		dressing, absorbent, sterile
211260	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211300	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211310	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211321	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211360	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211400	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211410	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211421	Soft silicone foam dressing	46854 Wound - nonadherent



Product Reference:	Product Descriptor:	GMDN Code:
		dressing, absorbent, sterile
211460	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
211500	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile