



EU Declaration of Conformity according to MDR

Document ID: PD-702047 Rev:1
Created by: Anu-Maria Hokkanen
State: Released
Approved by: Christina Lewing
Release date: 2021-12-08 10:33:09

Title: Mepilex XT

Dates and times in Greenwich Mean Time, 24 hours format

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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product name:	Mepilex XT
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Product Classification: MDR Class IIb
MDR Classification Rule: 4
Sterility: Sterile
Measuring Function: No

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IX
Common Specification: No CS is applicable

Certificate number:	MDR 722028	
Issued by:	BSi	Id No: 2797
	(Notified Body Name)	
<i>Note. For non-sterile, non-measuring class I products there is no Notified Body certificate</i>		

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Place of Issue: Göteborg, Sweden

Date: 2021-12-08 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
Intended Purpose:	Mepilex XT is a dressing designed for a wide range of exuding acute and chronic wounds in all healing stages such as leg and foot ulcers, pressure ulcers and traumatic wounds, e.g. skin tears and secondary healing wounds.
Basic UDI-DI:	733243000000000033JP
GMDN Code:	46854 Wound - nonadherent dressing, absorbent, sterile

Product References Covered by this Declaration:	Product Descriptor:
211015	Soft silicone foam dressing
211100	Soft silicone foam dressing
211110	Soft silicone foam dressing
211121	Soft silicone foam dressing
211160	Soft silicone foam dressing
211200	Soft silicone foam dressing
211210	Soft silicone foam dressing
211221	Soft silicone foam dressing
211260	Soft silicone foam dressing
211300	Soft silicone foam dressing
211310	Soft silicone foam dressing
211321	Soft silicone foam dressing
211360	Soft silicone foam dressing
211400	Soft silicone foam dressing
211410	Soft silicone foam dressing
211421	Soft silicone foam dressing
211460	Soft silicone foam dressing
211500	Soft silicone foam dressing