EU Declaration of Conformity according to MDR

Title: Mepilex Transfer

We, Mölnlycke Health Care AB, Entreprenörsstråket 21, SE-431 53, Mölndal, Sweden, SRN SE-MF-000014042, 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 Transfer

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)		

NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Mölndal, Sweden

Date:	2025-05-08	Function:	Regulatory Affairs Excellence Director
Name:	Karin Darle Olsson	Signature:	

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Title: Mepilex Transfer

Generic product information	
Intended Purpose:	Mepilex Transfer is intended for a wide range of exuding wounds. Mepilex Transfer can also be used as protection of compromised and/or fragile skin.
Basic UDI-DI:	733243000000000032JM
GMDN Code:	46855 Wound - nonadherent dressing, permeable
EMDN Code:	M04040701 SILICONE DRESSINGS, NON-COMBINED

Product References Covered by this Declaration:	Product	Product Descriptor:
294502	Mepilex Transfer 20x50 cm	Soft silicone exudate transfer dressing
294599	Mepilex Transfer 20x50 cm, US	Soft silicone exudate transfer dressing
294600	Mepilex Transfer 7,5x8,5 cm	Soft silicone exudate transfer dressing
294621	Mepilex Transfer 7,5x8,5cm, FR	Soft silicone exudate transfer dressing
294700	Mepilex Transfer 10x12 cm	Soft silicone exudate transfer dressing
294720	Mepilex Transfer 12,5x12,5 cm, FR	Soft silicone exudate transfer dressing
294800	Mepilex Transfer 15x20cm	Soft silicone exudate transfer dressing
294821	Mepilex Transfer 14x15cm, ph FR	Soft silicone exudate transfer dressing
294899	Mepilex Transfer 15x20cm, US	Soft silicone exudate transfer dressing
294920	Mepilex Transfer 17,5x17,5 cm, FR ph	Soft silicone exudate transfer dressing