



**EU Declaration of Conformity
according to MDR**

Document ID: PD-702004 Rev:1
Created by: Anu-Maria Hokkanen
State: Released
Approved by: Christina Lewing
Release date: 2021-10-18 06:58:00

Title: Mepilex Transfer

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 Transfer
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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: 2021-10-18 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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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

Product References Covered by this Declaration:	Product Descriptor:
294502	Soft silicone exudate transfer dressing
294599	Soft silicone exudate transfer dressing
294600	Soft silicone exudate transfer dressing
294621	Soft silicone exudate transfer dressing
294700	Soft silicone exudate transfer dressing
294720	Soft silicone exudate transfer dressing
294800	Soft silicone exudate transfer dressing
294821	Soft silicone exudate transfer dressing
294899	Soft silicone exudate transfer dressing
294920	Soft silicone exudate transfer dressing