



EU Declaration of Conformity according to MDR

Document ID: PD-563501 **Rev:**00
Created by: Kristin Ödling
State: Released
Approved by: Karin Darle Olsson
Release date: 2022-06-21 14:23:22

Title: MDR DoC Mepilex Transfer Ag

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, 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 Ag
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Product Classification: MDR Class III

MDR Classification Rule: 4, 14

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, MDR 758929

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: Göteborg, Sweden

Date: 2022-06-21

Function:

Regulatory Affairs Excellence
Manager

Name: Karin Darle Olsson

Signature:



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Generic product information	
Intended Purpose:	Mepilex Transfer Ag is designed for a wide range of low to high exuding leg and foot ulcers, pressure ulcers, malignant wounds, partial thickness burns and donor sites, where there is a risk of infection. Mepilex Transfer Ag may be used on infected wounds as part of a treatment regimen under supervision of a qualified health care professional. Mepilex Transfer Ag can be used under compression bandaging.
Basic UDI-DI:	733243000000000029JY
GMDN Code:	47203 Wound - nonadherent dressing, permeable, antimicrobial

Product References Covered by this Declaration:	Product Descriptor:
394000	Antimicrobial soft silicone exudate transfer dressing
394100	Antimicrobial soft silicone exudate transfer dressing
394500	Antimicrobial soft silicone exudate transfer dressing
394700	Antimicrobial soft silicone exudate transfer dressing
394800	Antimicrobial soft silicone exudate transfer dressing