



EU Declaration of Conformity according to MDR

Document ID: PD-702277 Rev:3
Created by: Pia Malmberg
State: Released
Approved by: Christina Lewing
Approval date: 2023-02-09 18:08:24
Release date: 2023-02-09 18:08:30

Title: Mepore Film

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:	Mepore Film
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Product Classification: MDR Class IIa

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

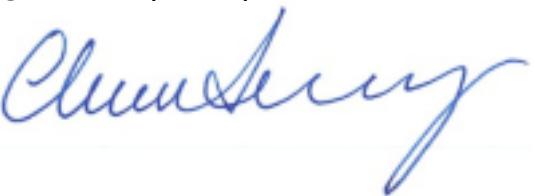
Certificate number:	MDR 722028	
Issued by:	BSI	Id No: 2797
<i>(Notified Body Name)</i>		
<i>NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.</i>		

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: 2023-02-09 Function: Global Regulatory Affairs Director

Name: Christina Lewing Signature: 



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Generic product information	
Intended Purpose:	Mepore Film is intended for protection of intact skin and superficial wounds. Mepore Film can also be used for fixation of medical devices such as wound dressings, tubes and cannulas
Basic UDI-DI:	733243000000000005JJ
GMDN Code:	58301 Synthetic polymer semi-permeable film dressing, adhesive, sterile

Product References Covered by this Declaration:	Product Descriptor:
270600	Transparent, breathable, adhesive film dressing
270670	Transparent, breathable, adhesive film dressing
271500	Transparent, breathable, adhesive film dressing
271570	Transparent, breathable, adhesive film dressing
272500	Transparent, breathable, adhesive film dressing
272570	Transparent, breathable, adhesive film dressing
273000	Transparent, breathable, adhesive film dressing
273500	Transparent, breathable, adhesive film dressing