



EU Declaration of Conformity according to MDR

Title: Mepore Film

We, Mölnlycke Health Care AB, Entreprenörstråket 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:	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
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Common Specification: No CS is applicable

Certificate number:	MDR 722028
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Issued by:	BSi
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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: 2025-10-13

Function: RA Director Wound Care

Name: Katarina Branzell

Signature:

Title: Mepore Film

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
EMDN Code:	M04010202 POLYURETHANE FIXING DRESSINGS

Product References Covered by this Declaration:	Product	Product Descriptor:
270600	Mepore Film 6x7cm	Transparent, breathable, adhesive film dressing
270670	Mepore Film 6x7 cm, ph	Transparent, breathable, adhesive film dressing
271500	Mepore Film 10x12 cm	Transparent, breathable, adhesive film dressing
271570	Mepore Film 10x12 cm, ph	Transparent, breathable, adhesive film dressing
272500	Mepore Film 10x25 cm	Transparent, breathable, adhesive film dressing
272570	Mepore Film 10x25 cm, ph	Transparent, breathable, adhesive film dressing
273000	Mepore Film 15x20 cm	Transparent, breathable, adhesive film dressing
273500	Mepore Film 20x30 cm	Transparent, breathable, adhesive film dressing