



## EU Declaration of Conformity according to MDR

**Document ID:** PD-708633 **Rev:**3  
**Created by:** Pia Malmberg  
**State:** Released  
**Approved by:** Christina Lewing  
**Approval date:** 2023-02-09 18:08:23  
**Release date:** 2023-02-09 18:08:30

**Title:** Mepore Film and Pad

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 and pad
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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

(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: 2023-02-09

Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
<b>Intended Purpose:</b>	Mepore Film & Pad is intended for use on low to moderately exuding wounds, such as surgical wounds, cuts and abrasions
<b>Basic UDI-DI:</b>	733243000000000006JL
<b>GMDN Code:</b>	34864 Adhesive bandage

Product References Covered by this Declaration:	Product Descriptor:
275100	Absorbent adhesive film dressing
275110	Absorbent adhesive film dressing
275200	Absorbent adhesive film dressing
275210	Absorbent adhesive film dressing
275300	Absorbent adhesive film dressing
275310	Absorbent adhesive film dressing
275400	Absorbent adhesive film dressing
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275800	Absorbent adhesive film dressing
275900	Absorbent adhesive film dressing