



EU Declaration of Conformity according to MDR

Title: Mepore

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
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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: Mölndal, Sweden

Date: 2025-05-08

Function:

Regulatory Affairs Excellence
Director

Name: Karin Darle Olsson

Signature:



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Generic product information	
Intended Purpose:	Self-adhesive sterile absorbent dressing designed for low to moderately exuding wounds, such as surgical wounds, cuts and abrasions.
Basic UDI-DI:	733243000000000003JE
GMDN Code:	34864 Adhesive bandage
EMDN Code:	M04010101 NON-WOVEN ADHESIVE DRESSINGS, WITH ABSORBENT PAD)

Product References Covered by this Declaration:	Product	Product Descriptor:
670700	Mepore 7x8 cm, UK DE	Adhesive surgical dressing
670800	Mepore 6x7cm	Adhesive dressing for superficial wounds
670840	Mepore 6x7 cm, ph ES	Adhesive dressing for superficial wounds
670860	Mepore 6x7cm OTC Norden	Adhesive dressing for superficial wounds
670880	Mepore 6x7 cm, ph FR	Adhesive dressing for superficial wounds
670900	Mepore 9x10cm	Adhesive dressing for superficial wounds
670940	Mepore 9x10 cm, ph ES	Adhesive dressing for superficial wounds
670960	Mepore 9x10cm OTC Norden	Adhesive dressing for superficial wounds
670970	Mepore 9x10 cm, ph	Adhesive dressing for superficial wounds
670980	Mepore 9x10 cm, ph FR	Adhesive dressing for superficial wounds
671000	Mepore 9x15cm	Adhesive surgical dressing
671040	Mepore 9x15 cm, ph ES	Adhesive surgical dressing
671066	Mepore 9x15cm OTC Norden	Adhesive surgical dressing
671070	Mepore 9x15 cm, ph	Adhesive surgical dressing
671080	Mepore 9x15 cm, ph FR	Adhesive surgical dressing
671100	Mepore 9x20cm	Adhesive surgical dressing
671140	Mepore 9X20 CM, ph ES	Adhesive surgical dressing



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671170	Mepore 9x20 cm, ph	Adhesive surgical dressing
671180	Mepore 9X20 CM, ph FR	Adhesive surgical dressing
671200	Mepore 9x25cm	Adhesive surgical dressing
671299	MEPORE 9X25 CM, US	Adhesive surgical dressing
671300	Mepore 9x30cm	Adhesive surgical dressing
671400	Mepore 9x35cm	Adhesive surgical dressing
671500	Mepore 10x11 cm	Adhesive surgical dressing
671600	Mepore 11x15 cm	Adhesive surgical dressing
672000	Mepore 5x7cm	Adhesive surgical dressing
672100	Mepore 8x10cm	Adhesive surgical dressing
672200	Mepore 8x15cm	Adhesive surgical dressing