



EU Declaration of Conformity according to MDR

Title: Mepore Pro/Ultra

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 Pro/Ultra
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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	Id No: 2797
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(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
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Name: Karin Darle Olsson

Signature:

Title: Mepore Pro/Ultra

Generic product information	
Intended Purpose:	Mepore Pro/Mepore Ultra is intended for use on low to moderately exuding wounds, such as surgical wounds, cut and abrasions.
Basic UDI-DI:	733243000000000004JG
GMDN Code:	34864 Adhesive bandage
EMDN Code:	M04010101 NON-WOVEN ADHESIVE DRESSINGS, WITH ABSORBENT PAD)

Product References Covered by this Declaration:	Product	Product Descriptor:
670820	Mepore Pro 6x7cm	Absorbent shower proof adhesive dressing
670920	Mepore Pro 9x10cm	Absorbent shower proof adhesive dressing
670990	Mepore Pro 9x10 cm, US	Absorbent shower proof adhesive dressing
671020	Mepore Pro 9x15cm	Absorbent shower proof adhesive dressing
671090	Mepore Pro 9x15 cm, US	Absorbent shower proof adhesive dressing
671120	Mepore Pro 9x20cm	Absorbent shower proof adhesive dressing
671125	Mepore Ultra 9x20cm	Absorbent shower proof adhesive dressing
671190	Mepore Pro 9x20 cm, US	Absorbent shower proof adhesive dressing
671220	Mepore Pro 9x25 cm	Absorbent shower proof adhesive dressing
671225	Mepore Ultra 9x25cm	Absorbent shower proof adhesive dressing
671290	Mepore Pro 9x25 cm, US	Absorbent shower proof adhesive dressing
671320	Mepore Pro 9x30 cm	Absorbent shower proof adhesive dressing
671325	Mepore Ultra 9x30cm	Absorbent shower proof adhesive dressing
671390	Mepore Pro 9x30 cm, US	Absorbent shower proof adhesive dressing
680825	Mepore Ultra 7x8 cm	Absorbent shower proof adhesive dressing
680860	Mepore Pro 6x7cm OTC Norden	Absorbent shower proof adhesive dressing



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680925	Mepore Ultra 10x11 cm	Absorbent shower proof adhesive dressing
680940	Mepore Pro 9x10cm	Absorbent shower proof adhesive dressing
680960	Mepore Pro 9x10cm OTC Norden	Absorbent shower proof adhesive dressing
681025	Mepore Ultra 11x15 cm	Absorbent shower proof adhesive dressing
681040	Mepore Pro 9x15cm, ph	Absorbent shower proof adhesive dressing
681060	Mepore Pro 9x15cm OTC Norden	Absorbent shower proof adhesive dressing
681140	Mepore Pro 9x20cm	Absorbent shower proof adhesive dressing