



**EU Declaration of Conformity
according to MDR**

Document ID: PD-707794 Rev:1
Created by: Pia Malmberg
State: Released
Approved by: Christina Lewing
Release date: 2022-04-04 15:30:36

Title: Meporo Pro/Ultra

Dates and times in Greenwich Mean Time, 24 hours format

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

Certificate number:	MDR 722028	
Issued by:	BSi	Id No: 2797
	(Notified Body Name)	
<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: 2022-03-29 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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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

Product References Covered by this Declaration:	Product Descriptor:
670820	Absorbent shower proof adhesive dressing
670920	Absorbent shower proof adhesive dressing
670990	Absorbent shower proof adhesive dressing
671020	Absorbent shower proof adhesive dressing
671090	Absorbent shower proof adhesive dressing
671120	Absorbent shower proof adhesive dressing
671125	Absorbent shower proof adhesive dressing
671190	Absorbent shower proof adhesive dressing
671220	Absorbent shower proof adhesive dressing
671225	Absorbent shower proof adhesive dressing
671290	Absorbent shower proof adhesive dressing
671320	Absorbent shower proof adhesive dressing
671325	Absorbent shower proof adhesive dressing
671390	Absorbent shower proof adhesive dressing
680825	Absorbent shower proof adhesive dressing
680860	Absorbent shower proof adhesive dressing
680925	Absorbent shower proof adhesive dressing
680940	Absorbent shower proof adhesive dressing
680960	Absorbent shower proof adhesive dressing
681025	Absorbent shower proof adhesive dressing



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681040	Absorbent shower proof adhesive dressing
681060	Absorbent shower proof adhesive dressing
681140	Absorbent shower proof adhesive dressing