

Title: Mepore Pro and Ultra

Page 1(4)

We, Mölnlycke Health Care AB, Gamlestadvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden 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 Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/ Product name:	Mepore Pro and Ultra
------------------------------	-----------------------------

Product classification: **IIa**Sterility Status: **Sterile**Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
Annex/es:	II

Certificate number:	CE 01965
Issued by:	BSI (2797)
For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2020-06-05**

Function:

**Regulatory Affairs Manager
Compliance**Name: **Karin Darle Olsson**

Signature:





Declaration of Conformity EU

Document ID: PD-501318 Rev: 03
Created by: Åsa Isaksson
Approved by: Karin Darle Olsson
Approval date: 2020-06-05

Title: Mepore Pro and Ultra

Page 2(4)

Document template: Declaration of Conformity EU Rev: 05

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
670820	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
670890	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
670920	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
670990	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
671020	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
671090	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
671120	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
671125	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
671190	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
671220	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
Document template: Declaration of Conformity EU Rev: 05		
671225	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
671290	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
671320	Absorbent shower proof adhesive dressing	34864 Adhesive bandage

Product Reference:	Product Descriptor:	GMDN Code:
671390	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
680825	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
680840	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
680860	Shower proof adhesive dressing for superficial wounds	34864 Adhesive bandage
680925	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
680940	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
680960	Shower proof adhesive dressing for superficial wounds	34864 Adhesive bandage
681025	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
681040	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
681060	Shower proof adhesive dressing for superficial wounds	34864 Adhesive bandage
681140	Absorbent shower proof adhesive dressing	34864 Adhesive bandage