Declaration of Conformity EU



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

Title: Mepore Pro and Ultra

Page 1(4)

We, Mölnlycke Health Care AB, Gamlestadsvägen 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

lla

Product classification:

Sterility Status: Sterile

Measuring function: No

This declaration is supported by a conformity assessment procedure in accordance with

Annex/es:

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 M ö Inlycke Health Care

Date: 2020-06-05 Function: Regulatory Affairs Manager

Compliance

Name: Karin Darle Olsson Signature:

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Title: Mepore Pro and Ultra Page 2(4)

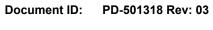
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Title: Mepore Pro and Ultra Page 3(4)

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 Document template: Declaration o	Absorbent shower proof adhesive dressing	34864 Adhesive bandage
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





Title: Mepore Pro and Ultra Page 4(4)

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

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