

Title: Mepore

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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
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Product classification: **Ila**

Sterility Status: **Sterile**

Measuring function: **No**

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

Annex/es:	II
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Certificate number:	CE 01965
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Issued by:	BSI (2797)
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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: **2020-10-02**

Function:

**Regulatory Affairs Manager
Compliance**

Name: **Karin Darle Olsson**

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
670700	Adhesive surgical dressing	34864 Adhesive bandage
670800	Adhesive surgical dressing	34864 Adhesive bandage
670840	Adhesive surgical dressing	34864 Adhesive bandage
670860	Adhesive dressing for superficial wounds	34864 Adhesive bandage
670870	Adhesive surgical dressing	34864 Adhesive bandage
670880	Adhesive surgical dressing	34864 Adhesive bandage
670900	Adhesive surgical dressing	34864 Adhesive bandage
670940	Adhesive surgical dressing	34864 Adhesive bandage
670960	Adhesive dressing for superficial wounds	34864 Adhesive bandage
670970	Adhesive surgical dressing	34864 Adhesive bandage
670980	Adhesive surgical dressing	34864 Adhesive bandage
671000	Adhesive surgical dressing	34864 Adhesive bandage
671040	Adhesive surgical dressing	34864 Adhesive bandage

Product Reference:	Product Descriptor:	GMDN Code:
671066	Adhesive dressing for superficial wounds	34864 Adhesive bandage
671070	Adhesive surgical dressing	34864 Adhesive bandage
671080	Adhesive surgical dressing	34864 Adhesive bandage
671100	Adhesive surgical dressing	34864 Adhesive bandage
671140	Adhesive surgical dressing	34864 Adhesive bandage
671170	Adhesive surgical dressing	34864 Adhesive bandage
671180	Adhesive surgical dressing	34864 Adhesive bandage
671200	Adhesive surgical dressing	34864 Adhesive bandage
671299	Adhesive surgical dressing	34864 Adhesive bandage
671300	Adhesive surgical dressing	34864 Adhesive bandage
671400	Adhesive surgical dressing	34864 Adhesive bandage
671500	Adhesive surgical dressing	34864 Adhesive bandage
671600	Adhesive surgical dressing	34864 Adhesive bandage
672000	Adhesive surgical dressing	34864 Adhesive bandage



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Product Reference:	Product Descriptor:	GMDN Code:
672100	Adhesive surgical dressing	34864 Adhesive bandage
672200	Adhesive surgical dressing	34864 Adhesive bandage