

Declaration of Conformity EU

Document ID: Created by: Approved by: Approval date:

Title: Mepore film and Pad

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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 Film and Pad			
Product classification:	lla			
Sterility Status:	Sterile			
Measuring function:	Νο			
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 AB Care

Date: 2021-05-05

Function:

Regulatory Affairs Manager Compliance

Name:

Karin Darle Olsson

Signature:

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Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
275100	Absorbent adhesive film dressing	34864 Adhesive bandage
275110	Absorbent adhesive film dressing	34864 Adhesive bandage
275200	Absorbent adhesive film dressing	34864 Adhesive bandage
275210	Absorbent adhesive film dressing	34864 Adhesive bandage
275300	Absorbent adhesive film dressing	34864 Adhesive bandage
275310	Absorbent adhesive film dressing	34864 Adhesive bandage
275400	Absorbent adhesive film dressing	34864 Adhesive bandage
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275600	Absorbent adhesive film dressing	34864 Adhesive bandage
275610	Absorbent adhesive film dressing	34864 Adhesive bandage
275700 Absorbent adhesive film dressing Document template: Declaration of Conformity EU Rev: 05		34864 Adhesive bandage



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Product Reference:	Product Descriptor:	GMDN Code:
275800	Absorbent adhesive film dressing	34864 Adhesive bandage
275900	Absorbent adhesive film dressing	34864 Adhesive bandage