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## **Declaration of Conformity EU**

Document ID: Created by: Approved by: Approval date: PD-426348 Rev: 00 Roland Sobenius Anders Edner 2011-09-28

Title: Mepore IV Page 1(2)

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being the manufacturer of the following, 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 IV
Product classification:	I
Sterility:	EtO
Measuring function:	No

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

Annex/es: V, VII

Certificate number: CE 01966

Issued by: BSI 0086

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: 2011-09-28 Function: RA Director Operations

Name: Anders Edner Signature:

**Document template:** Declaration of Conformity EU Rev: 05

PD-426348 Rev: 00



Title: Mepore IV Page 2(2)

## Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
274000	Transparent IV film dressing	17428
274200	Transparent IV film dressing	17428
274400	Transparent IV film dressing	17428