

We, Mölnlycke Health Care AB, Gamlestadvägen 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 Film
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Product classification: **Ila**
Sterility: **EtO**
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 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: **2011-03-02** Function: **RA Director Operations**

Name: **Anders Edner**

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:
270600	Transparent, breathable, adhesive coated polyurethane film
270670	Transparent, breathable, adhesive coated polyurethane film
271500	Transparent, breathable, adhesive coated polyurethane film
271570	Transparent, breathable, adhesive coated polyurethane film
272500	Transparent, breathable, adhesive coated polyurethane film
272570	Transparent, breathable, adhesive coated polyurethane film
273000	Transparent, breathable, adhesive coated polyurethane film
273500	Transparent, breathable, adhesive coated polyurethane film.