

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:	Mepilex Lite Products / Mepilex EM Products
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Product classification: **IIb**

Sterility Status: **Sterile**

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**

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: **2014-09-04**

Function: **RA Director Operations**

Name: **Anders Edner**

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
284000	Absorbent soft silicone dressing	46854
284010	Absorbent soft silicone dressing	46854
284021	Absorbent soft silicone dressing	46854
284022	Absorbent soft silicone dressing	46854
284040	Absorbent soft silicone dressing	46854
284090	Absorbent soft silicone dressing	46854
284100	Absorbent soft silicone dressing	46854
284110	Absorbent soft silicone dressing	46854
284122	Absorbent soft silicone dressing	46854
284140	Absorbent soft silicone dressing	46854
284190	Absorbent soft silicone dressing	46854
284221	Absorbent soft silicone dressing	46854
284300	Absorbent soft silicone dressing	46854
284310	Absorbent soft silicone dressing	46854
284321	Absorbent soft silicone dressing	46854
284322	Absorbent soft silicone dressing	46854
284340	Absorbent soft silicone dressing	46854
284390	Absorbent soft silicone dressing	46854
284500	Absorbent soft silicone dressing	46854
284599	Absorbent soft silicone dressing	46854