Title: Mepitel

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:	**Mepitel**

Product classification: **IIb**

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: **2011-03-30** Function: **RA Director Operations**

Name: **Anders Edner** Signature: 

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:
290500	Soft silicone wound contact layer
290510	Soft silicone wound contact layer
290520	Soft silicone wound contact layer
290560	Soft silicone wound contact layer
290580	Soft silicone wound contact layer
290700	Soft silicone wound contact layer
290710	Soft silicone wound contact layer
290720	Soft silicone wound contact layer
290740	Soft silicone wound contact layer
291000	Soft silicone wound contact layer
291010	Soft silicone wound contact layer
291020	Soft silicone wound contact layer
291040	Soft silicone wound contact layer
292005	Soft silicone wound contact layer
292010	Soft silicone wound contact layer
292021	Soft silicone wound contact layer
292030	Soft silicone wound contact layer