

Title: Mepitel Film

Page 1(3)

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:	Mepitel Film
------------------------------	---------------------

Product classification: **Ila**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 (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 Care

Date: **2020-07-01**Function: **Regulatory Affairs Director**Name: **Christina Lewing**

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
296170	Ultra thin, transparent, breathable soft silicone film dressing	58316 Synthetic polymer semi-permeable film dressing, wound - nonadherent
296270	Ultra thin, transparent, breathable soft silicone film dressing	58316 Synthetic polymer semi-permeable film dressing, wound - nonadherent
296470	Ultra thin, transparent, breathable soft silicone film dressing	58316 Synthetic polymer semi-permeable film dressing, wound - nonadherent
296500	Ultra thin, transparent, breathable soft silicone film dressing	58316 Synthetic polymer semi-permeable film dressing, wound - nonadherent
296550	Ultra thin, transparent, breathable soft silicone film dressing	58316 Synthetic polymer semi-permeable film dressing, wound - nonadherent
Document template: Declaration of Conformity EU Rev: 05		
296670	Ultra thin, transparent, breathable soft silicone film dressing	58316 Synthetic polymer semi-permeable film dressing, wound - nonadherent

Product Reference:	Product Descriptor:	GMDN Code:
296700	Ultra thin, transparent, breathable soft silicone film dressing	58316 Synthetic polymer semi-permeable film dressing, wound - nonadherent
296750	Ultra thin, transparent, breathable soft silicone film dressing	58316 Synthetic polymer semi-permeable film dressing, wound - nonadherent
296900	Ultra thin, transparent, breathable soft silicone film dressing	58316 Synthetic polymer semi-permeable film dressing, wound - nonadherent
296950	Ultra thin, transparent, breathable soft silicone film dressing	58316 Synthetic polymer semi-permeable film dressing, wound - nonadherent