

**Title:** Mepitel Film

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We, Mölnlycke Health Care AB, Gamlestadvägen 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:	<b>Mepitel Film</b>
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Product classification: **Ila**  
Sterility Status: **Sterile**  
Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
Annex/es:	<b>II</b>

Certificate number:	<b>CE 01965</b>
Issued by:	<b>BSI (2797)</b>
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:**

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
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
<b>Document template:</b> Declaration of Conformity EU Rev: 05		
296670	Ultra thin, transparent, breathable soft silicone film dressing	58316 Synthetic polymer semi-permeable film dressing, wound - nonadherent

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
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