

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</b>
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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:	<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: **2019-10-21**Function: **Regulatory Affairs Manager  
Compliance**Name: **Karin Darle Olsson**

Signature:



**Product(s) covered by this declaration:**

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
290500	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
290510	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
290520	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
290599	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
290700	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
290710	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
290720	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
290799	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
291000	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
291010	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
291020	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
291099	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
292005	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
292010	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
292021	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
292030	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable