

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>Mepilex Border Flex / Mepilex Border Comfort</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: **2019-07-09**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>
583300	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
583320	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
583400	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
583420	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
583500	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
583520	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
583620	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595000	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
595011	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595021	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595200	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595211	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595221	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595277	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595300	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595311	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595377	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
595400	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595411	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595421	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595477	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595600	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595611	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595621	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595800	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
595850	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
595900	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
596011	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
596211	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
596311	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
596411	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
596611	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
596800	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
596900	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile