

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:	Mepilex Border/Border Sacrum/Border Heel_Talon/ Border Flex
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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: **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: **2020-02-07**

Function: **Regulatory Affairs Manager
Compliance**

Name: **Karin Darle Olsson**

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
282000	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
282044	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
282200	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
282220	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
282400	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
282420	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
282444	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
282500	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile

Product Reference:	Product Descriptor:	GMDN Code:
283220	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
283221	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
283250	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
283270	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
283300	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
283370	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
283400	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
283470	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
283570	Self-adherent soft silicone dressing	46854 Wound - nonadherent dressing, absorbent, sterile

Product Reference:	Product Descriptor:	GMDN Code:
295000	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295066	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295200	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295210	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295255	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295266	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295300	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295355	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295366	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile

Product Reference:	Product Descriptor:	GMDN Code:
295400	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295410	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295455	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295466	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295600	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295610	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295655	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295660	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295800	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile

Product Reference:	Product Descriptor:	GMDN Code:
295850	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295900	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
295920	Self-adherent soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile