



Document ID: Created by: Approved by: Approval date: **PD-531904 Rev: 15** Kristin Ödling Karin Darle Olsson 2019-07-09

Title: Mepilex Border Flex / Mepilex Border Comfort

Page 1(5)

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.

Product classification: IIb

Sterility Status: Sterile

Measuring function: No

This declaration is supported by a conformity assessment procedure in accordance with

Annex/es:

Certificate number: CE 01965

Issued by: **BSI (2797)**

For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

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:

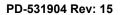


Page 2(5)

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
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







Page 3(5)

Product Reference:	Product Descriptor:	GMDN Code:
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

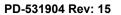




Page 4(5)

Product Reference:	Product Descriptor:	GMDN Code:
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







Page 5(5)

Product Reference:	Product Descriptor:	GMDN Code:
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