

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.

<b>Trade name/ Product name:</b>	<b>Mepilex / Mepilex Heel / Mepilex Talon</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	
<b>Annex/es:</b>	<b>II</b>

<b>Certificate number:</b>	<b>CE 01965</b>
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<b>Issued by:</b>	<b>BSI (2797)</b>
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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:** **2020-12-04**

**Function:**

**Regulatory Affairs Manager  
Compliance**

**Name:** **Karin Darle Olsson**

**Signature:**





## Declaration of Conformity EU

Document ID: PD-394574 Rev: 13  
Created by: Anu-Maria Hokkanen  
Approved by: Karin Darle Olsson  
Approval date: 2020-12-04

**Title:** Mepilex / Mepilex Heel / Mepilex Talon

Page 2(6)

**Document template:** Declaration of Conformity EU Rev: 05

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

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
288100	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
288200	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
288220	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
288240	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
288300	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
288320	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
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294000	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294015	Soft silicone foam dressing	46854 Wound - nonadherent

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
		dressing, absorbent, sterile
294050	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294090	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294100	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294150	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294160	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294177	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294199	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294200	Soft silicone foam dressing	46854 Wound - nonadherent

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
		dressing, absorbent, sterile
294201	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294250	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294260	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294299	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294300	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294310	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294350	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294377	Soft silicone foam dressing	46854 Wound - nonadherent

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<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
		dressing, absorbent, sterile
294399	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294400	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294410	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294450	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294460	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294499	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile
294500	Soft silicone foam dressing	46854 Wound - nonadherent dressing, absorbent, sterile