

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 Ag / Mepilex Heel Ag
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Product classification: **III**

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;CE 514235**

Issued by: **BSI (0086)**

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: **2019-01-22**

Function: **Regulatory Affairs Manager
Compliance**

Name: **Karin Darle Olsson**

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
287021	Antimicrobial soft silicone foam dressing	47042
287050	Antimicrobial soft silicone foam dressing	47042
287110	Antimicrobial soft silicone foam dressing	47042
287121	Antimicrobial soft silicone foam dressing	47042
287210	Antimicrobial soft silicone foam dressing	47042
287221	Antimicrobial soft silicone foam dressing	47042
287310	Antimicrobial soft silicone foam dressing	47042
287321	Antimicrobial soft silicone foam dressing	47042
287410	Antimicrobial soft silicone foam dressing	47042
287510	Antimicrobial soft silicone foam dressing	47042
388100	Antimicrobial soft silicone foam dressing	47042
388300	Antimicrobial soft silicone foam dressing	47042