

Title: Mepitel One

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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:	Mepitel One
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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
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Issued by:	BSI (2797)
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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 AB Care

Date: 2021-01-26

Function:

**Regulatory Affairs Manager
Compliance**

Name: Karin Darle Olsson

Signature:



Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
289000	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289100	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289110	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289120	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289170	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289200	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289210	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289270	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289300	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable

Product Reference:	Product Descriptor:	GMDN Code:
289320	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289400	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289470	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289500	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289520	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289620	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289670	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289700	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable
289750	Soft silicone wound contact layer	46855 Wound - nonadherent dressing, permeable