



EU Declaration of Conformity according to MDR

Title: Mepitel One

We, Mölnlycke Health Care AB, Entreprenörstråket 21, SE-431 53, Mölndal, Sweden, SRN SE-MF-000014042, 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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product name:	Mepitel One
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Product Classification: MDR Class IIb

MDR Classification Rule: 4

Sterility: Sterile

Measuring Function: No

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IX
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Common Specification: No CS is applicable

Certificate number:	MDR 722028
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Issued by:	BSi
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Id No:	2797
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(Notified Body Name)

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

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Mölndal, Sweden

Date: 2025-05-12

Function:

Regulatory Affairs Excellence
Director

Name: Karin Darle Olsson

Signature:

Title: Mepitel One

Generic product information	
Intended Purpose:	Mepitel One is a wound contact layer designed for the management of a wide range of exuding wounds such as; skin tears, skin abrasions, surgical incisions, partial thickness burns, traumatic wounds, partial and full thickness grafts, radiated skin, leg and foot ulcers. It can also be used as a protective layer on non-exuding wounds, blisters and on areas with fragile skin.
Basic UDI-DI:	733243000000000022JJ
GMDN Code:	46855 Wound - nonadherent dressing, permeable
EMDN Code:	M04010203 SILICONE DRESSINGS

Product References Covered by this Declaration:	Product	Product Descriptor:
289000	Mepitel One 5x7 cm	Soft silicone wound contact layer
289100	Mepitel One 5x7,5 cm	Soft silicone wound contact layer
289110	Mepitel One 6x7cm, Dispenser box	Soft silicone wound contact layer
289120	Mepitel One 5x7,5 cm, FR ph	Soft silicone wound contact layer
289170	Mepitel One 6x7 cm	Soft silicone wound contact layer
289200	Mepitel One 8x10 cm	Soft silicone wound contact layer
289210	Mepitel One 9x10cm, Dispenser box	Soft silicone wound contact layer
289270	Mepitel One 9x10 cm	Soft silicone wound contact layer
289300	Mepitel One 7,5x10 cm	Soft silicone wound contact layer
289320	Mepitel One 7,5x10 cm, FR ph	Soft silicone wound contact layer
289400	Mepitel One 12x15 cm	Soft silicone wound contact layer
289470	Mepitel One 13x15 cm	Soft silicone wound contact layer
289500	Mepitel One 10x18 cm	Soft silicone wound contact layer



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289520	Mepitel One 10x18 cm, FR ph	Soft silicone wound contact layer
289620	Mepitel One 24x27,5 cm, FR ph	Soft silicone wound contact layer
289670	Mepitel One 24x27,5 cm	Soft silicone wound contact layer
289700	Mepitel One 17x25 cm	Soft silicone wound contact layer
289750	Mepitel One 27,5x50cm	Soft silicone wound contact layer