



EU Declaration of Conformity according to MDR

Document ID: PD-720554 **Rev:**1
Created by: Maria Ström
State: Released
Approved by: Christina Lewing
Approval date: 2023-01-11 16:05:16
Release date: 2023-01-11 16:05:21

Title: Mepitel

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, 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
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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

(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: Göteborg, Sweden

Date: 2023-01-11

Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
Intended Purpose:	Mepitel is a meshed non-adherent wound contact layer allowing passage of exudate and providing fixation and protection of tissues. Mepitel is designed for a wide range of exuding wounds such as skin tears, skin abrasions, sutured wounds, partial thickness burns, lacerations, partial and full thickness grafts, diabetic foot ulcers, venous and arterial leg ulcers. Mepitel can also be used as a protective layer on non-exuding wounds, blisters, fragile skin and exposed fragile tissues.
Basic UDI-DI:	733243000000000019JV
GMDN Code:	46855 Wound - nonadherent dressing, permeable

Product References Covered by this Declaration:	Product Descriptor:
290500	Soft silicone wound contact layer
290510	Soft silicone wound contact layer
290520	Soft silicone wound contact layer
290599	Soft silicone wound contact layer
290700	Soft silicone wound contact layer
290710	Soft silicone wound contact layer
290720	Soft silicone wound contact layer
290799	Soft silicone wound contact layer
291000	Soft silicone wound contact layer
291010	Soft silicone wound contact layer
291020	Soft silicone wound contact layer
291099	Soft silicone wound contact layer
292005	Soft silicone wound contact layer
292010	Soft silicone wound contact layer
292021	Soft silicone wound contact layer
292030	Soft silicone wound contact layer