



EU Declaration of Conformity according to MDR

Document ID: PD-710372 **Rev:**1
Created by: Maria Ström
State: Released
Approved by: Christina Lewing
Release date: 2022-06-03 14:42:38

Title: Mepitel Film

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 Film
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Product Classification: MDR Class IIa

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: 2022-06-03

Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
Intended Purpose:	Mepitel Film is intended to protect fragile and sensitive skin and minimize risk of skin breakdown. It can be used as secondary dressing, fixating e.g. gauze or non-woven swabs or as a landing zone for aggressive tapes to secure devices to skin. It can be used as a protective dressing over IV sites when the IV device is secured through adhesive tape or sutures.
Basic UDI-DI:	733243000000000021JG
GMDN Code:	58316 Synthetic polymer semi-permeable film dressing, wound - nonadherent

Product References Covered by this Declaration:	Product Descriptor:
296170	Thin, transparent, adhesive, breathable soft silicone film dressing
296270	Thin, transparent, adhesive, breathable soft silicone film dressing
296470	Thin, transparent, adhesive, breathable soft silicone film dressing
296500	Thin, transparent, adhesive, breathable soft silicone film dressing
296550	Thin, transparent, adhesive, breathable soft silicone film dressing
296670	Thin, transparent, adhesive, breathable soft silicone film dressing
296700	Thin, transparent, adhesive, breathable soft silicone film dressing
296750	Thin, transparent, adhesive, breathable soft silicone film dressing
296900	Thin, transparent, adhesive, breathable soft silicone film dressing
296950	Thin, transparent, adhesive, breathable soft silicone film dressing