



EU Declaration of Conformity according to MDR

Document ID: PD-702615 **Rev:**1
Created by: Pia Malmberg
State: Released
Approved by: Christina Lewing
Release date: 2022-07-06 15:13:24

Title: Mepore

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:

Mepore

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

Common Specification: No CS is applicable

Certificate number: MDR 722028

Issued by: BSi

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: 2022-07-06

Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
Intended Purpose:	Self-adhesive sterile absorbent dressing designed for low to moderately exuding wounds, such as surgical wounds, cuts and abrasions.
Basic UDI-DI:	733243000000000003JE
GMDN Code:	34864 Adhesive bandage

Product References Covered by this Declaration:	Product Descriptor:
670700	Adhesive surgical dressing
670800	Adhesive surgical dressing
670840	Adhesive surgical dressing
670860	Adhesive surgical dressing
670880	Adhesive surgical dressing
670900	Adhesive surgical dressing
670940	Adhesive surgical dressing
670960	Adhesive surgical dressing
670970	Adhesive surgical dressing
670980	Adhesive surgical dressing
671000	Adhesive dressing for superficial wounds
671040	Adhesive dressing for superficial wounds
671066	Adhesive dressing for superficial wounds
671070	Adhesive dressing for superficial wounds
671080	Adhesive dressing for superficial wounds
671100	Adhesive surgical dressing
671140	Adhesive surgical dressing
671170	Adhesive surgical dressing
671180	Adhesive surgical dressing
671200	Adhesive surgical dressing



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671299	Adhesive surgical dressing
671300	Adhesive surgical dressing
671400	Adhesive surgical dressing
671500	Adhesive surgical dressing
671600	Adhesive surgical dressing
672000	Adhesive surgical dressing
672100	Adhesive surgical dressing
672200	Adhesive surgical dressing