

Title: Mepore Roll

Page 1(2)

We, Mölnlycke Health Care AB, Gamlestadsvägen 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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: **Not applicable**

Trade name/ Product name:	Mepore Roll
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Product classification: **I**

MDR Classification Rule: **4**

Sterility: **Non-sterile**

Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with

Annex/es: **IV**

Common Specification: **No CS is applicable**

Certificate number: **Not Applicable**

Issued by: **Not Applicable**

NB. 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 Care

Date: **2020-11-04**

Function: **Regulatory Affairs Director**

Name: **Christina Lewing**

Signature:





**EU Declaration of Conformity
according to MDR**

Document ID: PD-595102 Rev: 00

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Page 2(2)

Intended Purpose: Mepore Roll is a non-sterile, self-adhesive, absorbent dressing for superficial skin damage such as injection sites.

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
331900	Self-adhevised dressing roll	733243000000000002JC	34864 Adhesive bandage
331980	Self-adhevised dressing roll	733243000000000002JC	34864 Adhesive bandage
332000	Self-adhevised dressing roll	733243000000000002JC	34864 Adhesive bandage
332080	Self-adhevised dressing roll	733243000000000002JC	34864 Adhesive bandage