

Title: Mestopore and Mestopore S

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:	Mestopore and Mestopore S
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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: **2020-09-03** Function: **Regulatory Affairs Director**

Name: **Christina Lewing** Signature:





**EU Declaration of Conformity
according to MDR**

Document ID: PD-583978 Rev: 00

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Page 2(2)

Intended Purpose: Self-adhesive absorbant dressing for continent stomas.

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
665000	MESTOPORE is a highly absorbent non-irritant, breathable stomacap with a fluid barrier for continent stoma. Do not dispose of in WC.	73324300000000024JN	58854 Absorbent enteric stomal dressing
665100	MESTOPORE S is a highly absorbent non-irritant, breathable dressing with a fluid barrier for continent stoma. Soft silicone adhesive (Safetac technology). Do not dispose of in WC.	73324300000000024JN	58854 Absorbent enteric stomal dressing