

**Title:** Mepiform (non-sterile)

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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:	<b>Mepiform (non-sterile)</b>
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Product classification: **I**  
MDR Classification Rule: **1**  
Sterility: **Non-sterile**  
Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
Annex/es:	<b>IV</b>
Common Specification:	<b>No CS is applicable</b>

Certificate number:	<b>Not Applicable</b>
Issued by:	<b>Not Applicable</b>

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:





Intended Purpose: Mepiform is designed for the management of both old and new hypertrophic and keloid scars. It can also be used as a prophylactic therapy on closed wounds for prevention of hypertrophic or keloid scarring.

**Product(s) covered by this declaration:**

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
293600	Self-adherent soft silicone dressing for scar care	73324300000000017JR	47771 Scar management dressing, single-use, non-sterile
293640	Self-adherent soft silicone dressing for scar care	73324300000000017JR	47771 Scar management dressing, single-use, non-sterile
293700	Self-adherent soft silicone dressing for scar care	73324300000000017JR	47771 Scar management dressing, single-use, non-sterile
293740	Self-adherent soft silicone dressing for scar care	73324300000000017JR	47771 Scar management dressing, single-use, non-sterile
293750	Self-adherent soft silicone dressing for scar care	73324300000000017JR	47771 Scar management dressing, single-use, non-sterile
293770	Self-adherent soft silicone dressing for scar care	73324300000000017JR	47771 Scar management dressing, single-use, non-sterile
293800	Self-adherent soft silicone dressing for scar care	73324300000000017JR	47771 Scar management dressing, single-use, non-sterile