

**Title:** Mepitac

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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>Mepitac</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>
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Common Specification:	<b>No CS is applicable</b>
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Certificate number:	<b>Not Applicable</b>
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Issued by:	<b>Not Applicable</b>
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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:** Mepitac is intended for fixation of medical devices such as drains, tubes, probes, electrodes, IV cannula, and dressings. Mepitac offers gentle skin protection when used under devices such as tubes.

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

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>Basic UDI-DI:</b>	<b>GMDN Code:</b>
298300	Soft silicone tape	73324300000000018JT	58749 Silicone adhesive tape
298400	Soft silicone tape	73324300000000018JT	58749 Silicone adhesive tape