



**EU Declaration of Conformity
according to MDR**

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Created by: Sofia Horkeby
Approved by: Christina Lewing
Approval date: 2020-09-03

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:	Mepitac
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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:	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:



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:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
298300	Soft silicone tape	73324300000000018JT	58749 Silicone adhesive tape
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