

Title: Mefix

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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:	Mefix
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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
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Common Specification:	No CS is applicable
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Certificate number:	Not Applicable
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Issued by:	Not Applicable
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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: **2020-11-04**

Function: **Regulatory Affairs Director**

Name: **Christina Lewing**

Signature:





**EU Declaration of Conformity
according to MDR**

Document ID: PD-583976 Rev: 00

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Intended Purpose: Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
310250	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
310276	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
310299	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
310500	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
310570	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
310576	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
310580	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
310584	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
310586	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
310599	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311000	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311040	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311070	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311076	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311080	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311084	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311086	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311090	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311099	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
311500	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311570	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311576	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311580	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311586	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311590	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
311599	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
312000	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
312076	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
313000	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape
313076	Self-adhesive fabric	73324300000000012JF	16866 Basic adhesive tape