



EU Declaration of Conformity according to MDR

Title: Mefix

We, Mölnlycke Health Care AB, Entreprenörstråket 21, SE-431 53, Mölndal, Sweden, SRN SE-MF-000014042, 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 the 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: MDR Class I ns

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

Certificate number:	Not Applicable
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Issued by:	Not Applicable
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Id No:

(Notified Body Name)

NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Mölndal, Sweden

Date: 2025-05-06

Function:

Regulatory Affairs Excellence
Director

Name: Karin Darle Olsson

Signature:

Title: Mefix

Generic product information	
Intended Purpose:	Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas
Basic UDI-DI:	733243000000000012JF
GMDN Code:	16866 Basic adhesive tape
EMDN Code:	M04010201 NON-WOVEN FIXING DRESSINGS

Product References Covered by this Declaration:	Product	Product Descriptor:
310250	Mefix 2,5cm x 10m	Self-adhesive fabric
310276	Mefix 2,5cm x 5m	Self-adhesive fabric
310299	Mefix 2,5cm x 10m, US	Self-adhesive fabric
310500	Mefix 5cm x 10m	Self-adhesive fabric
310570	Mefix 5cm X 2.5m	Self-adhesive fabric
310576	Mefix 5cm X 5m	Self-adhesive fabric
310584	Mefix 5cm X 10m, PH FR	Self-adhesive fabric
310586	Mefix 5cm X 5m, PH FR	Self-adhesive fabric
310599	Mefix 5cm x 10m, US	Self-adhesive fabric
311000	Mefix 10cm x 10m	Self-adhesive fabric
311040	Mefix 10cm x 10m, ph ES	Self-adhesive fabric
311070	Mefix 10cm X 2.5m	Self-adhesive fabric
311076	Mefix 10cm x 5m	Self-adhesive fabric
311084	Mefix 10cm x 10m, PH FR	Self-adhesive fabric
311086	Mefix 10cm x 5m, PH FR	Self-adhesive fabric
311090	Mefix 10cm x 11m, DE	Self-adhesive fabric
311099	Mefix 10cm x 10m, US	Self-adhesive fabric
311500	Mefix 15cm x 10m	Self-adhesive fabric
311570	Mefix 15cm x 2.5m	Self-adhesive fabric

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311576	Mefix 15cm x 5m	Self-adhesive fabric
311586	Mefix 15cm X 5m, PH FR	Self-adhesive fabric
311590	Mefix 15cm x 11m, DE	Self-adhesive fabric
311599	Mefix 15cm x 10m, US	Self-adhesive fabric
312000	Mefix 20cm x 10m	Self-adhesive fabric
312076	Mefix 20cm X 5m	Self-adhesive fabric
313000	Mefix 30cm x 10m	Self-adhesive fabric
313076	Mefix 30cm X 5m	Self-adhesive fabric