



**EU Declaration of Conformity
according to MDR**

Document ID: PD-583976 Rev:02
Created by: Pia Malmberg
State: Released
Approved by: Christina Lewing
Release date: 2022-03-01 15:21:19

Title: Mefix

Dates and times in Greenwich Mean Time, 24 hours format

We, Mölnlycke Health Care AB, Gamlestadvägen 3C, Box 13080, SE-402 52 Göteborg, 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
Common Specification: No CS is applicable

Certificate number:	Not Applicable	
Issued by:	Not Applicable	Id No:
	(Notified Body Name)	
<i>NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.</i>		

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: Göteborg, Sweden

Date: 2022-03-01 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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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

Product References Covered by this Declaration:	Product Descriptor:
310250	Self-adhesive fabric
310276	Self-adhesive fabric
310299	Self-adhesive fabric
310500	Self-adhesive fabric
310570	Self-adhesive fabric
310576	Self-adhesive fabric
310584	Self-adhesive fabric
310586	Self-adhesive fabric
310599	Self-adhesive fabric
311000	Self-adhesive fabric
311040	Self-adhesive fabric
311070	Self-adhesive fabric
311076	Self-adhesive fabric
311084	Self-adhesive fabric
311086	Self-adhesive fabric
311090	Self-adhesive fabric
311099	Self-adhesive fabric
311500	Self-adhesive fabric
311570	Self-adhesive fabric
311576	Self-adhesive fabric



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311586	Self-adhesive fabric
311590	Self-adhesive fabric
311599	Self-adhesive fabric
312000	Self-adhesive fabric
312076	Self-adhesive fabric
313000	Self-adhesive fabric
313076	Self-adhesive fabric