

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 |
|------------------------------|--------------|

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: **2020-11-04**

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 |