

# 311500 Mefix

Self-adhesive fabric

## Product details

|                       |                        |
|-----------------------|------------------------|
| Size :                | 15cm x 10m             |
| Descriptive feature : | Self-adhesive fixation |
| Sterile :             | Non-sterile            |
| Brand :               | Mefix                  |

## Images



## Delivered items

311500-30

**Sales released in:** Algeria, Austria, Bahrain, Belgium, Brazil, Bulgaria, Canada, Chile, China, Croatia, Cyprus, Czechia, Denmark, Egypt, Estonia, Faroe Islands, Finland, France, Germany, Gibraltar, Greece, Guadeloupe, Hong Kong, Hungary, Iceland, India, Iran (Islamic Republic of), Iraq, Ireland, Italy, Japan, Jordan, Kazakhstan, Korea (the Republic of), Kuwait, Latvia, Lebanon, Lithuania, Luxembourg, Malaysia, Malta, Martinique, Morocco, Netherlands, New Zealand, Norway, Oman, Pakistan, Poland, Portugal, Qatar, Romania, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Taiwan (Province of China), Thailand, Ukraine, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, United States of America, Viet Nam

**Country of origin:** Thailand

**Shelf life:** 3 years

**Sterilization method:** Non-sterile

**Production Responsibility:** Mölnlycke Health Care (Thailand) Ltd, Amata Nakorn (Bang Pakong), Industrial Estate, 700/461 Moo 7 Bangna-Trad Road, Km 57 Tambol Donhuaroh, Amphur Muang Chonburi 20000, Thailand

**Packing information:** First packaging layer is a cardboard dispenser box. Second layer is a corrugated board

Find out more at [www.molnlycke.com](http://www.molnlycke.com)

Mölnlycke Health Care AB, Box 13080, Gamlestadsvägen 3 C, SE-402 52 Göteborg, Sweden. Phone +46 31 722 30 00.  
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transport box.

Is suitable for Tray: Yes

| Packing level | Quantity | GS1 Code / UDI-DI | Width x Length x Height | Vol                    | Weight gross / net |
|---------------|----------|-------------------|-------------------------|------------------------|--------------------|
| Piece         | 1        | 7332430082459     |                         |                        |                    |
| Consumer pack | 1        | 7323190203291     |                         |                        |                    |
| Dispenser box | 1        | 7323190195701     | 74x156x75 mm            |                        |                    |
| Transport box | 15       | 7323190195695     | 236x395x172 mm          | 16.0 dm <sup>3</sup>   | 4.0 / 3.4 kg       |
| Pallet        | 1500     | 7323190195688     | 800x1200x1872 mm        | 1797.1 dm <sup>3</sup> | 427.1 / 338.0 kg   |

#### Material

|                           |    |
|---------------------------|----|
| Animal tissues :          | No |
| Human blood derivatives : | No |
| Natural rubber latex :    | No |
| Medicinal substances :    | No |
| Phthalates :              | No |
| Polyvinyl chloride :      | No |

#### Product Composition Film Products and Fixation Products

| Product Component        | Composition                    |
|--------------------------|--------------------------------|
| Backing material         | Hydrophobic polyester nonwoven |
| Adhesive                 | Polyacrylate                   |
| Protective release liner | Siliconised paper              |

#### Product Performance Fixation Products

| Characteristics  | Test Method                    | Internal Test Method | Unit                   | Requirement   | Product Performance |
|--|--------------------------------|----------------------|------------------------|---------------|---------------------|
| Adhesion   | ASTM D3330/D3330M-04, method F | T-1082               | N/25 mm                | Not specified | 2.97                |
| Moisture Vapour Transmission Rate (MVTR) of a wound dressing when in contact with water vapour | EN 13726-2 part 3:2            | T-1070               | g/m <sup>2</sup> /24 h | Not specified | 3448                |

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Technical

Dimension

| Dimension text | Dimension value |
|----------------|-----------------|
| Product        | 6 in x 11 yd    |
| Product        | 15 cm x 10 m    |

Classifications

| Regulation type(s)                  | MDR Class I ns  | CFR Class I   | Locally Regulated   | Locally Regulated   |
|-------------------------------------|---|---|---|---|
| Intended Purpose :                  | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas |   | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas |
| MDR Classification Rule :           | 1   |   |   |   |
| Conformity Annexes :                | IV  |   |   |   |
| Measuring Function :                | No  |   |   |   |
| Notified body medical devices/PPE : | MPA   | FDA<br>CDRH   | Local Authority<br>Thailand   | Local Authority<br>EU Non EEC   |
| 510(k) clearance number :           |   |   | NA  |   |
| Intended use CFR :                  |   | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas |   |   |

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| Regulation type(s)    | MDR Class I ns   | CFR Class I              | Locally Regulated | Locally Regulated |
|-----------------------|--|--------------------------|-------------------|-------------------|
| Regulatory Released : | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Gibraltar, Greece, Guadeloupe, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Martinique, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland | United States of America | Thailand          | Serbia            |

Classifications

| Regulation type(s) | Locally Regulated   | Locally Regulated   | Locally Regulated   | Locally Regulated   |
|--------------------|---|---|---|---|
| Intended Purpose : | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas |

MDR Classification Rule :

Conformity Annexes :

Measuring Function :

|                                     |                          |                       |                     |                       |
|-------------------------------------|--------------------------|-----------------------|---------------------|-----------------------|
| Notified body medical devices/PPE : | Local Authority Thailand | Local Authority India | Local Authority MEA | Local Authority Egypt |
|-------------------------------------|--------------------------|-----------------------|---------------------|-----------------------|

510(k) clearance number :

Intended use CFR :

|                       |          |       |   |       |
|-----------------------|----------|-------|---|-------|
| Regulatory Released : | Thailand | India | Algeria, Bahrain, Iraq, Lebanon, Morocco, Oman, Ukraine | Egypt |
|-----------------------|----------|-------|---|-------|

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| MDR Classification Rule :           |   |   |   |   |
| Conformity Annexes :                |   |   |   |   |
| Measuring Function :                |   |   |   |   |
| Notified body medical devices/PPE : | Local Authority South Korea   | Local Authority Taiwan  | Local Authority United Arab Emirates  | Local Authority India   |
| 510(k) clearance number :           |   |   |   |   |
| Intended use CFR :                  |   |   |   |   |
| Regulatory Released :               | Korea (the Republic of)   | Taiwan (Province of China)  | United Arab Emirates  | India   |

Classifications

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| MDR Classification Rule :           |   |   |   |   |
| Conformity Annexes :                |   |   |   |   |
| Measuring Function :                |   |   |   |   |
| Notified body medical devices/PPE : | Local Authority China   | Local Authority MEA   | Local Authority Pakistan  | Local Authority Jordan  |
| 510(k) clearance number :           |   | NA  |   |   |
| Intended use CFR :                  |   |   |   |   |
| Regulatory Released :               | China   | Qatar   | Pakistan  | Jordan  |

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| MDR Classification Rule :           |   |   |   |   |
| Conformity Annexes :                |   |   |   |   |
| Measuring Function :                |   |   |   |   |
| Notified body medical devices/PPE : | Local Authority Americas  | Saudi Authority   | Local Authority Kuwait  | Local Authority India   |
| 510(k) clearance number :           |   |   |   |   |
| Intended use CFR :                  |   |   |   |   |
| Regulatory Released :               | Chile   | Saudi Arabia  | Kuwait  | India   |

Classifications

| Regulation type(s)                  | Locally Regulated   | Locally Regulated   | Locally Regulated   | Class I   |
|-------------------------------------|---|---|---|---|
| Intended Purpose :                  | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas |
| MDR Classification Rule :           |   |   |   |   |
| Conformity Annexes :                |   |   |   |   |
| Measuring Function :                |   |   |   |   |
| Notified body medical devices/PPE : | Local Authority APAC  | Local Authority MEA   | Local Authority CIS   | Health Canada   |
| 510(k) clearance number :           |   | NA  | NA  |   |
| Intended use CFR :                  |   |   |   |   |
| Regulatory Released :               | Hong Kong, Malaysia, New Zealand, Singapore                                   | Algeria, Bahrain, Iraq, Lebanon, Morocco, Oman, Ukraine                       | Kazakhstan  | Canada  |

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Classifications

| Regulation type(s)                  | Class I   | Non Medical Device  |
|-------------------------------------|---|---|
| Intended Purpose :                  | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas |
| MDR Classification Rule :           |   |   |
| Conformity Annexes :                |   |   |
| Measuring Function :                |   |   |
| Notified body medical devices/PPE : | Anvisa (Brazil)   | PMDA (Japan)  |
| 510(k) clearance number :           |   |   |
| Intended use CFR :                  |   |   |
| Regulatory Released :               | Brazil  | Japan   |

**Applied standards :** The standards presented below is a selection of the most essential standards that are adhered to.

EN ISO 20417, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, EN ISO 10993-18, ISO 14001

**Removable label**

No

**GMDN Code (Global Medical Device Nomenclature)**

16866 Basic adhesive tape

**UNSPSC**

42311552 Medical and surgical adherent tapes for general use

**Commodity Code**

3005100000 Wadding, Gauze, Dressings, drapes singlepacked - adhesive articles, Sets mainly consisting thereof

**CE Responsibility**

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**Basic UDIDI**

733243000000000012JF

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