Product data sheet 5 January 2023

# 310250 Mefix

Self-adhesive fabric

#### Product details

**Size**: 2,5cm x 10m

Descriptive feature: Self-adhesive fixation

Sterile : Non-sterile Brand : Mefix

### **Images**





#### Delivered items

310250-30

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







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transport box.

Is suitable for Tray: Yes

| Packing level | Quantity | GS1 Code /<br>UDI-DI | Width x Length x<br>Height | Vol           | Weight gross /<br>net |
|---------------|----------|----------------------|----------------------------|---------------|-----------------------|
| Piece         | 1        | 7332430082282        |                            |               |                       |
| Consumer pack | 1        | 7323190203246        |                            |               |                       |
| Dispenser box | 1        | 7323190195107        | 31x74x72 mm                |               |                       |
| Transport box | 40       | 7323190195091        | 195x263x157 mm             | 8.1 dm3       | 2 / 1.5 kg            |
| Pallet        | 7920     | 7323190195084        | 800x1200x1871 mm           | 1796.2<br>dm3 | 421.0 / 301.0 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<br>Test<br>Method | Unit         | Requirement      | Product<br>Performance |
|--|---------------------------------------|----------------------------|--------------|------------------|------------------------|
| Adhesion   | ASTM<br>D3330/D3330M-<br>04, method F | T-1082                     | N/25<br>mm   | Not<br>specified | 2.97                   |
| Moisture Vapour Transmission Rate (MVTR) of a wound dressing when in contact with water vapour | EN 13726-2 part<br>3:2                | T-1070                     | g/m²/24<br>h | Not<br>specified | 3448                   |







#### Technical

## Dimension

| Dimension text | Dimension value |
|----------------|-----------------|
| Product        | 1 in x 11 yd    |
| Product        | 2.5 cm x 10 m   |

## Classifications

| Regulation type(s)                  | MDR Class I ns  | Locally<br>Regulated  | Locally<br>Regulated  | Locally<br>Regulated  |
|-------------------------------------|---|---|---|---|
| Intended Purpose :                  | Mefix is a self-adhesive fabric for fixation of dressings, tubes and cannulas   | Mefix is a<br>self-<br>adhesive<br>fabric for<br>fixation of<br>dressings,<br>tubes and<br>cannulas | Mefix is a<br>self-<br>adhesive<br>fabric for<br>fixation of<br>dressings,<br>tubes and<br>cannulas | Mefix is a<br>self-<br>adhesive<br>fabric for<br>fixation of<br>dressings,<br>tubes and<br>cannulas |
| MDR Classification Rule :           | 1   |   |   |   |
| Conformity Annexes :                | IV  |   |   |   |
| Measuring Function :                | No  |   |   |   |
| Notified body medical devices/PPE : | MPA   | Local<br>Authority<br>Thailand  | Local<br>Authority<br>EU Non<br>EEC   | Local<br>Authority<br>Thailand  |
| 510(k) clearance number :           |   | NA  |   |   |
| Regulatory Released :               | Austria, Belgium, Bulgaria, Croatia,<br>Cyprus, Czechia, Denmark, Estonia, Faroe<br>Islands, Finland, France, Germany,<br>Greece, Hungary, Iceland, Ireland, Italy,<br>Latvia, Lithuania, Luxembourg, Malta,<br>Netherlands, Norway, Poland, Portugal,<br>Romania, Slovakia, Slovenia, Spain,<br>Sweden, Switzerland, United Kingdom of<br>Great Britain and Northern Ireland | Thailand  | Serbia  | Thailand  |





## Classifications

| Regulation type(s)                  | Locally Regulated  | Locally Regulated  | Locally Regulated  | Locally Regulated  |
|-------------------------------------|--|--|--|--|
| Intended Purpose :                  | Mefix is a self-<br>adhesive fabric for<br>fixation of<br>dressings, tubes<br>and cannulas | Mefix is a self-<br>adhesive fabric for<br>fixation of<br>dressings, tubes<br>and cannulas | Mefix is a self-<br>adhesive fabric for<br>fixation of<br>dressings, tubes<br>and cannulas | Mefix is a self-<br>adhesive fabric for<br>fixation of<br>dressings, tubes<br>and cannulas |
| MDR Classification Rule :           |  |  |  |  |
| Conformity Annexes :                |  |  |  |  |
| Measuring Function :                |  |  |  |  |
| Notified body medical devices/PPE : | Local Authority<br>MEA   | Local Authority<br>South Korea   | Local Authority<br>Taiwan  | Local Authority<br>United Arab<br>Emirates   |
| 510(k) clearance number :           |  |  |  |  |
| Regulatory Released :               | Algeria, Bahrain,<br>Lebanon,<br>Mauritius, Oman,<br>South Africa,<br>Ukraine              | Korea (the<br>Republic of)   | Taiwan (Province of China)   | United Arab<br>Emirates  |

#### Classifications

| Regulation type(s)                  | Locally Regulated  | Locally Regulated  | Locally Regulated  | Locally Regulated  |  |  |
|-------------------------------------|--|--|--|--|--|--|
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| MDR Classification Rule :           | MDR Classification Rule :  |  |  |  |  |  |
| Conformity Annexes :                | Conformity Annexes :   |  |  |  |  |  |
| Measuring Function :                |  |  |  |  |  |  |
| Notified body medical devices/PPE : | Local Authority<br>China   | Local Authority<br>MEA   | Local Authority<br>Pakistan  | Local Authority<br>Americas  |  |  |
| 510(k) clearance number :           |  | NA   |  |  |  |  |
| Regulatory Released :               | China  | Qatar  | Pakistan   | Chile  |  |  |



#### Classifications

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| MDR Classification Rule :           |  |  |  |  |
| Conformity Annexes :                |  |  |  |  |
| Measuring Function :                |  |  |  |  |
| Notified body medical devices/PPE : | Saudi Authority  | Local Authority<br>Kuwait  | Local Authority<br>APAC  | Local Authority<br>MEA   |
| 510(k) clearance number :           |  |  |  | NA   |
| Regulatory Released :               | Saudi Arabia   | Kuwait   | Hong Kong,<br>Malaysia,<br>Singapore   | Algeria, Bahrain,<br>Lebanon,<br>Mauritius, Oman,<br>South Africa,<br>Ukraine              |

#### Classifications

| Regulation type(s)                  | Locally Regulated  | Class I  | Class I  | Non Medical<br>Device  |  |
|-------------------------------------|--|--|--|--|--|
| Intended Purpose :                  | Mefix is a self-<br>adhesive fabric for<br>fixation of<br>dressings, tubes<br>and cannulas | Mefix is a self-<br>adhesive fabric for<br>fixation of<br>dressings, tubes<br>and cannulas | Mefix is a self-<br>adhesive fabric for<br>fixation of<br>dressings, tubes<br>and cannulas | Mefix is a self-<br>adhesive fabric for<br>fixation of<br>dressings, tubes<br>and cannulas |  |
| MDR Classification Rule :           |  |  |  |  |  |
| Conformity Annexes :                |  |  |  |  |  |
| Measuring Function :                |  |  |  |  |  |
| Notified body medical devices/PPE : | Local Authority<br>CIS   | Health Canada  | Anvisa (Brazil)  | PMDA (Japan)   |  |
| 510(k) clearance number :           | NA   |  |  |  |  |
| Regulatory Released :               | Kazakhstan   | Canada   | 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

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#### 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

Molnlycke Health Care AB, Gamlestadsvagen 3c, Box 13080, SE-402 52 Goteborg Sweden

#### **Basic UDIDI**

733243000000000012JF



