

# 313000 Mefix

Self-adhesive fabric

## Product details

Size :	30cm x 10m
Descriptive feature :	Self-adhesive fixation
Sterile :	Non-sterile
Brand :	Mefix

## Images



## Delivered items

313000-30

**Sales released in:** Australia, Austria, Bahrain, Belgium, Bosnia and Herzegovina, Brazil, Bulgaria, Canada, China, Croatia, Czechia, Denmark, Egypt, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Italy, Japan, Jordan, Kazakhstan, Korea (the Republic of), Kuwait, Latvia, Lithuania, Luxembourg, Netherlands, New Zealand, Norway, Oman, 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, 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 transport box.

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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Is suitable for Tray: No

Packing level	Quantity	GS1 Code / UDI-DI	Width x Length x Height	Vol	Weight gross / net
Piece	1	7332430082541			
Consumer pack	1	7323190203468			
Dispenser box	1	7323190195992	75x306x70 mm		
Transport box	10	7323190195985	320x390x157 mm	19.6 dm <sup>3</sup>	5.3 / 4.5 kg
Pallet	660	7323190195978	800x1200x1871 mm	1796.2 dm <sup>3</sup>	389.3 / 297.0 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	12 in x 11 yd
Product	30 cm x 10 m

Classifications

Regulation type(s)	MDR Class I ns	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 :	1			
Conformity Annexes :	IV			
Measuring Function :	No			
Notified body medical devices/PPE :	MPA	Local Authority Thailand	Local Authority EU Non EEC	Local Authority Thailand
510(k) clearance number :		NA		
Regulatory Released :	Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland	Thailand	Bosnia and Herzegovina, Serbia	Thailand

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MDR Classification Rule :				
Conformity Annexes :				
Measuring Function :				
Notified body medical devices/PPE :	Local Authority India	Local Authority MEA	Local Authority Egypt	Local Authority South Korea
510(k) clearance number :				
Regulatory Released :	India	Bahrain, Oman, Ukraine	Egypt	Korea (the Republic of)

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

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MDR Classification Rule :				
Conformity Annexes :				
Measuring Function :				
Notified body medical devices/PPE :	Local Authority MEA	Local Authority Jordan	Saudi Authority	Local Authority India
510(k) clearance number :	NA			
Regulatory Released :	Qatar	Jordan	Saudi Arabia	India

Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	AU Class I ns
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	TGA (Australia)
510(k) clearance number :		NA	NA	
Regulatory Released :	New Zealand, Singapore	Bahrain, Oman, Ukraine	Kazakhstan	Australia

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Classifications

Regulation type(s)	Class I	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	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 :	Health Canada	Anvisa (Brazil)	PMDA (Japan)
510(k) clearance number :			
Regulatory Released :	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

**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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