

310500 Mefix

Self-adhesive fabric

Product details

Size :	5cm x 10m
Descriptive feature :	Self-adhesive fixation
Sterile :	Non-sterile
Brand :	Mefix

Images



Delivered items

310500-30

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, Mauritius, Morocco, Netherlands, New Zealand, Norway, Oman, Pakistan, Poland, Portugal, Qatar, Réunion, Romania, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan (Province of China), 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

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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	7332430130020			
Consumer pack	1	7323190203314			
Dispenser box	1	7323190195206	74x56x70 mm		
Transport box	40	7323190195190	236x395x157 mm	14.6 dm ³	3.7 / 3 kg
Pallet	4400	7323190195183	800x1200x1871 mm	1796.2 dm ³	436.4 / 330.0 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 ² /24 h	Not specified	3448

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Technical

Dimension

Dimension text	Dimension value
Product	5 cm x 10 m
Product	2 in x 11 yd

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 CDRH	Local Authority EU Non EEC	Local Authority India
510(k) clearance number :				
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, Netherlands, Norway, Poland, Portugal, Réunion, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland	United States of America	Serbia	India

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MDR Classification Rule :				
Conformity Annexes :				
Measuring Function :				
Notified body medical devices/PPE :	Local Authority MEA	Local Authority Egypt	Local Authority South Korea	Local Authority Taiwan
510(k) clearance number :				
Intended use CFR :				
Regulatory Released :	Algeria, Bahrain, Iraq, Lebanon, Mauritius, Morocco, Oman, South Africa, Ukraine	Egypt	Korea (the Republic of)	Taiwan (Province of China)

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

Classifications

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

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MDR Classification Rule :				
Conformity Annexes :				
Measuring Function :				
Notified body medical devices/PPE :	Local Authority India	Local Authority APAC	Local Authority MEA	Local Authority CIS
510(k) clearance number :			NA	NA
Intended use CFR :				
Regulatory Released :	India	Hong Kong, Malaysia, New Zealand, Singapore	Algeria, Bahrain, Iraq, Lebanon, Mauritius, Morocco, Oman, South Africa, Ukraine	Kazakhstan

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 :			
Intended use CFR :			
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

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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

Mölnlycke Health Care AB, Gamlestadsvägen 3c, Box 13080, SE-402 52 Goteborg Sweden

Basic UDIDI

733243000000000012JF

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