595400 Mepilex Border Flex

Self-adherent soft silicone foam dressing

Product details

Product group name :	Mepilex Border Flex
Size :	15 x 15cm
Descriptive feature :	5-layer, All-in-one, Border, Flexible wound pad, Foam, Soft silicone
Sterile :	Sterile
Brand :	Mepilex®

Product descriptions

Short description : Self-adherent soft silicone foam dressing

Long description : Mepilex Border Flex is a self-adherent, absorbent dressing that maintains a moist wound environment. The waterproof outer layer protects the wound from dirt and bacteria. The dressing has a Safetac® wound contact layer that is a unique adhesive technology. It minimises pain to patients and trauma to wounds and the surrounding skin at dressing removal.

Images

Delivered items

595400-50

Sales released in: Argentina, Australia, Austria, Bahrain, Belgium, Bolivia (Plurinational State of), Brazil, Bulgaria, Chile, Colombia, Croatia, Cuba, Cyprus, Czechia, Denmark, Ecuador, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, India, Ireland, Italy, Japan, Korea (the Republic of), Latvia, Lebanon,

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Liechtenstein, Lithuania, Luxembourg, Malta, Mexico, Netherlands, Norway, Oman, Peru, Poland, Portugal, Puerto Rico, Qatar, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, United States of America
Country of origin: United States of America
Shelf life: 3 years
Sterilization method: EtO
Production Responsibility: Mölnlycke Manufacturing US LLC, 192 Admiral Fitch Avenue, Brunswick, ME 04011, USA
Packing information: First packaging layer is a peel open sterile barrier, paper/plastic. Once opened the sterile barrier cannot be closed again. Second layer is a cardboard dispenser box. Third layer is a corrugated board transport box.
Is suitable for Tray: No

Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Piece	1	7323190173914		228x280x212 mm	270.682 cm3	33.62 g / -
Consumer pack	1	7323190197804	7323190197804			
Dispenser box	5	7323190173945	7323190173945	26x195x215 mm		
Transport box	50	7323190173938	7323190173938	228x280x212 mm	13.534 dm3	1.681 / 0.741 kg
Pallet	5600	7323190173921		800x1200x1840 mm		

595400-03

Sales released in: Algeria, Argentina, Australia, Austria, Bahrain, Belgium, Bosnia and Herzegovina, Brazil, Bulgaria, Chile, China, Colombia, Croatia, Cyprus, Czechia, Denmark, Ecuador, Egypt, Estonia, Faroe Islands, Finland, France, Georgia, Germany, Gibraltar, Greece, Hong Kong, Hungary, Iceland, India, Indonesia, Iraq, Ireland, Italy, Japan, Jordan, Kazakhstan, Kenya, Korea (the Republic of), Kuwait, Latvia, Lebanon, Libya, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Netherlands, New Zealand, Norway, Oman, Palestine, State of, Peru, Poland, Portugal, Puerto Rico, Qatar, Romania, Rwanda, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan (Province of China), Thailand, Turkey, United Arab Emirates, United States of America, Viet Nam
Country of origin: Finland
Shelf life: 3 years
Sterilization method: EtO
Packing information: First packaging layer is a peel open sterile barrier, paper/plastic. Once opened the sterile barrier cannot be closed again. Second layer is a cardboard dispenser box. Third layer is a corrugated board transport box.
Is suitable for Tray: Yes

Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Piece	1	7323190173914			361.845 cm3	34.16 g / -
Consumer pack	1	7323190185665	7323190185665	208x185x0 mm		
Dispenser box	5	07333350206864	07333350206864	30x190x225 mm		
Transport box	25	07333350480400	07333350480400	215x255x165 mm	9.046 dm3	0.854 / 0.366 kg
Pallet	3750	7313661541885		800x1200x1803 mm	1730.88 dm3	156.4 kg / -

595400-00

Sales released in: Algeria, Argentina, Australia, Austria, Bahrain, Belgium, Bosnia and Herzegovina, Brazil, Bulgaria, Chile, China, Colombia, Croatia, Cyprus, Czechia, Denmark, Ecuador, Estonia, Faroe Islands, Finland, France, Georgia, Germany, Greece, Hong Kong, Hungary, Iceland, India, Indonesia, Iraq, Ireland, Italy, Japan, Jordan, Kazakhstan, Kenya, Korea (the Republic of), Kuwait, Latvia, Lebanon, Libya, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Netherlands, New Zealand, Norway, Oman, Palestine, State of, Peru, Poland, Portugal, Puerto Rico, Qatar, Romania, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan (Province of China), Thailand, Turkey, Uganda, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, United States of America
Country of origin: Finland
Shelf life: 3 years
Sterilization method: EtO
Production Responsibility: Mölnlycke Health Care Oy, PO Box 76, Saimaankatu 6, FI-50101 Mikkeli 10, Finland
Packing information: First packaging layer is a peel open sterile barrier, paper/plastic. Once opened the sterile barrier cannot be closed again. Second layer is a cardboard dispenser box. Third layer is a corrugated board transport box.
Is suitable for Tray: Yes

Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Piece	1	7323190173914		225x282x246 mm	312.174 cm3	32.98 g / -
Consumer pack	1	7323190185665	7323190185665	208x185x0 mm		
Dispenser box	5	7323190174379	7323190174379	26x191x225 mm		

Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Transport box	50	7323190174362	7323190174362	225x282x246 mm	15.609 dm3	1.649 / 0.732 kg
Pallet	4900	7323190174355		800x1200x1872 mm		

Material

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

Product Composition Bordered Products

Product Component	Composition
Backing material	Polyurethane film
Wound pad Absorption layer	Polyacrylate fibres, Cotton fibres, Polyethylene/Polyester fibres
Wound pad Spreading layer	Polyester/Viscose nonwoven
Wound pad Acquisition layer	Polyurethane foam
Wound contact layer	Polyurethane film
Wound contact layer	Silicone
Protective release liner	Polyethylene film

Product Performance Wound Dressing

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Waterproofness	EN 13726-3:2003	T-1083	Pass/Fail	>500 mm H_2O for 300 s	pass
Conformability-Extensibility, CD	EN 13726-4:2003	T-1086	N/cm	Not specified	1,5 single lot value

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6	N/A
Conformability-Extensibility, MD	EN 13726-4:2003	T-1086	N/cm	Not specified	3 single lot value
Viral penetration	ASTM F 1671	N/A	Pass/Fail	29 out of 32 samples	Pass
Conformability-Permanent Set, CD	EN 13726-4:2003	T-1086	%	Not specified	1,4 single lot value
Conformability-Permanent Set, MD	EN 13726-4:2003	T-1086	%	Not specified	0,9 single lot value
Fluid Handling Capacity	EN 13726:2023 Annex E (normative) – Moisture Vapour Loss	T-2182	g/cm²/24h	Not specified	0,84
Fluid Handling Capacity	EN 13726:2023 Annex E (normative) – Absorption	T-2182	g/cm²/24h	Not specified	0,76
Fluid Handling Capacity	EN 13726:2023 Annex E (normative) – Total Fluid Handling	T-2182	g/cm²/24h	Not specified	1,60
Free Swell Absorptive Capacity	EN 13726:2023 Annex B (normative)	T-2191	g/cm² or g/g for rope/ribbon type	Not specified	0.77

Technical

Dimension

Dimension text	Dimension value
Product	15 cm x 15 cm
Product	6 in x 6 in
Wound pad	11 cm x 11 cm
Wound pad	4.3 in x 4.3 in

Instructions

Precautions :

• Do not use on patients with known hypersensitivity to the ingoing materials/components of the product.
• Do not use together with oxidising agents such as hypochlorite solutions or hydrogen peroxide.
• If you see signs of infection e.g. fever or the wound or surrounding skin becoming red, warm or swollen, consult a health care professional for appropriate treatment.
• The use of dressings as part of a prophylactic therapy does not preclude the need to continue to develop and follow a comprehensive pressure ulcer prevention protocol, i.e. support surfaces, positioning, nutrition, hydration, skin care and mobility.
• Do not reuse. If reused performance of the product may deteriorate, cross contamination may occur.
• Sterile. Do not use if sterile barrier is damaged or opened prior to use. Do not re-sterilise.

Warnings :

The polyurethane foam used in the product may change colour to more yellow when it is exposed to light, air and/or heat. The colour change has no influence on product properties when used before expiry date.
If any serious incident has occurred in relation to the use of Mepilex Border Flex it should be reported to Mölnlycke Health Care and to your local competent authority.

Classifications

Regulation type(s)	MDR Class IIb	MDR Class IIb	CFR Class I	AU Class IIb
CE Certificate Number :				MDR 722028

Regulation type(s)	MDR Class IIb	MDR Class IIb	CFR Class I	AU Class IIb
Intended Purpose :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.		Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Notified body medical devices/PPE :	BSi 2797	BSi 2797	FDA CDRH	TGA (Australia)
FDA Regulation Number :			878.4018	
510(k) clearance number :				

Regulation type(s)	MDR Class IIb	MDR Class IIb	CFR Class I	AU Class IIb
Intended use CFR :			Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	

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Indication for use FDA :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.

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Regulation type(s)	MDR Class IIb	MDR Class IIb	CFR Class I	AU Class IIb
Regulatory Released :	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland	Puerto Rico, United States of America	Australia

Classifications

Regulation type(s)	Class III	Class III	Class III	Class III
CE Certificate Number :				

Regulation type(s)	Class III	Class III	Class III	Class III
Intended Purpose :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Notified body medical devices/PPE :	Anvisa (Brazil)	PMDA (Japan)	PMDA (Japan)	Anvisa (Brazil)
FDA Regulation Number :				
510(k) clearance number :	1677313242			
Intended use CFR :				

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Regulation type(s)	Class III	Class III	Class III	Class III
Indication for use FDA :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Regulatory Released :	Brazil	Japan	Japan	Brazil

Classifications

Regulation type(s)	Class III	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :				

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Regulation type(s)	Class III	Locally Regulated	Locally Regulated	Locally Regulated
Intended Purpose :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Notified body medical devices/PPE :	PMDA (Japan)	Local Authority Mexico	Local Authority India	Local Authority Kuwait
FDA Regulation Number :				
510(k) clearance number :	5130678006619	Not provided		NA
Intended use CFR :				

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Indication for use FDA :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Regulatory Released :	Japan	Mexico	India	Kuwait

Classifications

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Notified body medical devices/PPE :	Saudi Authority	Local Authority South Korea	Local Authority APAC	Local Authority Indonesia
FDA Regulation Number :				
510(k) clearance number :		N&A		
Intended use CFR :				

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Regulatory Released :	Saudi Arabia	Korea (the Republic of)	Hong Kong, New Zealand, Viet Nam	Indonesia

Classifications

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Notified body medical devices/PPE :	Local Authority Bosnia	Local Authority Americas	Local Authority Bolivia	Local Authority Ecuador
FDA Regulation Number :				
510(k) clearance number :	06-07.4-1-5229/21		411502	
Intended use CFR :				

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Regulatory Released :	Bosnia and Herzegovina	Chile, Colombia, Cuba, Ecuador, Peru	Bolivia (Plurinational State of)	Chile, Colombia, Cuba, Ecuador, Peru

Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :				

Mölnlycke Health Care AB, Box 6, SE-431 21 Mölndal, Sweden. Phone +46 31 722 30 00.

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Intended Purpose :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Notified body medical devices/PPE :	Local Authority Thailand	Local Authority Mexico	Local Authority Jordan	Saudi Authority
FDA Regulation Number :				
510(k) clearance number :	NA	23330022030715	NA	
Intended use CFR :				

Mölnlycke Health Care AB, Box 6, SE-431 21 Mölndal, Sweden. Phone +46 31 722 30 00.

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Indication for use FDA :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Regulatory Released :	Thailand	Mexico	Jordan	Saudi Arabia

Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :				

Mölnlycke Health Care AB, Box 6, SE-431 21 Mölndal, Sweden. Phone +46 31 722 30 00.

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Intended Purpose :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Notified body medical devices/PPE :	Local Authority Mexico	Local Authority MEA	Local Authority South Korea	Local Authority Kuwait
FDA Regulation Number :				
510(k) clearance number :	213300401E0223	NA		
Intended use CFR :				

Mölnlycke Health Care AB, Box 6, SE-431 21 Mölndal, Sweden. Phone +46 31 722 30 00.

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Indication for use FDA :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Regulatory Released :	Mexico	Palestine, State of	Korea (the Republic of)	Kuwait

Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :				

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Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Intended Purpose :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Notified body medical devices/PPE :	Local Authority Indonesia	Local Authority Malaysia	Local Authority Thailand	Local Authority Malaysia
FDA Regulation Number :				
510(k) clearance number :				NA
Intended use CFR :				

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Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Indication for use FDA :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Regulatory Released :	Indonesia	Malaysia	Thailand	Malaysia

Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :				

Mölnlycke Health Care AB, Box 6, SE-431 21 Mölndal, Sweden. Phone +46 31 722 30 00.

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Intended Purpose :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Notified body medical devices/PPE :	Local Authority Indonesia	Local Authority South Korea	Local Authority Singapore	Local Authority Argentina
FDA Regulation Number :				
510(k) clearance number :		20240190852	NA	
Intended use CFR :				

Mölnlycke Health Care AB, Box 6, SE-431 21 Mölndal, Sweden. Phone +46 31 722 30 00.

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Indication for use FDA :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Regulatory Released :	Indonesia	Korea (the Republic of)	Singapore	Argentina

Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :				

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Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
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Notified body medical devices/PPE :	Local Authority Americas	Local Authority Argentina	Local Authority China	Local Authority Peru
FDA Regulation Number :				
510(k) clearance number :	20231136193			NA
Intended use CFR :				

Mölnlycke Health Care AB, Box 6, SE-431 21 Mölndal, Sweden. Phone +46 31 722 30 00.

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Indication for use FDA :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Regulatory Released :	Colombia	Argentina	China	Peru

Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :				

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Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Intended Purpose :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Notified body medical devices/PPE :	Local Authority Singapore	Local Authority United Arab Emirates	Local Authority Rwanda	Local Authority Peru
FDA Regulation Number :				
510(k) clearance number :	NA		NA	Not provided
Intended use CFR :				

Mölnlycke Health Care AB, Box 6, SE-431 21 Mölndal, Sweden. Phone +46 31 722 30 00.

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Indication for use FDA :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Regulatory Released :	Singapore	United Arab Emirates	Rwanda	Peru

Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :				

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Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
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Notified body medical devices/PPE :	Local Authority Taiwan	Local Authority South Korea	Local Authority Taiwan	Local Authority Bosnia
FDA Regulation Number :				
510(k) clearance number :			1140703402	NA
Intended use CFR :				

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Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Indication for use FDA :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Regulatory Released :	Taiwan (Province of China)	Korea (the Republic of)	Taiwan (Province of China)	Bosnia and Herzegovina

Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :				

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Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
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Notified body medical devices/PPE :	Local Authority Singapore	Local Authority South Korea	Local Authority MEA	Local Authority APAC
FDA Regulation Number :				
510(k) clearance number :		20240010972		
Intended use CFR :				

Mölnlycke Health Care AB, Box 6, SE-431 21 Mölndal, Sweden. Phone +46 31 722 30 00.

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Indication for use FDA :	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.	Mepilex Border Flex is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Mepilex Border Flex can also be used on dry/necrotic wounds in combination with gels. Mepilex Border Flex reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Regulatory Released :	Singapore	Korea (the Republic of)	Algeria, Bahrain, Georgia, Iraq, Kenya, Lebanon, Libya, Mauritius, Oman, Qatar, South Africa, Turkey	Hong Kong, New Zealand, Viet Nam

Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :				

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Notified body medical devices/PPE :	Local Authority India	Local Authority CIS	Local Authority India	Local Authority China
FDA Regulation Number :				
510(k) clearance number :				
Intended use CFR :				

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Regulatory Released :	India	Kazakhstan	India	China

Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :				

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Notified body medical devices/PPE :	Local Authority China	Local Authority Egypt	Local Authority India	Local Authority Mexico
FDA Regulation Number :				
510(k) clearance number :		NA	NA	Not provided
Intended use CFR :				

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Regulatory Released :	China	Egypt	India	Mexico

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

EN 1041, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-7, EN ISO 11607-1, EN ISO 11607-2, EN ISO 15223-1, EN ISO 10993-11, EN ISO 10993-10, EN ISO 10993-18, ISO 14001

Removable label

No

GMDN Code (Global Medical Device Nomenclature)

46854 Wound - nonadherent dressing, absorbent, sterile

EMDN Code (European Medical Device Nomenclature)

M04040701 SILICONE DRESSINGS, NON-COMBINED

UNSPSC

42311510 Foam dressings

Mölnlycke Health Care AB, Box 6, SE-431 21 Mölndal, Sweden. Phone +46 31 722 30 00.

Commodity Code

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

CE Responsibility / Legal Manufacturer

Molnlycke Health Care AB, Entreprenorsstraket 21, SE-431 53 Molndal Sweden

Basic UDIDI

733243000000000036JV

Codice RDM (Italy)

2509287/R

Codice CND (Italy)

M04040602