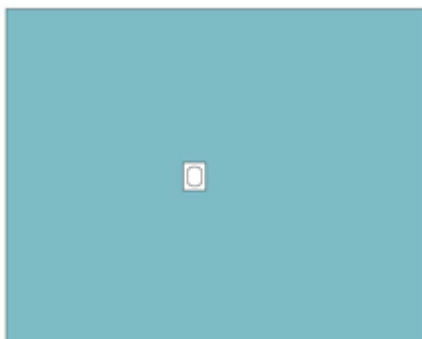


# 935569 Adhesive Aperture Drape

## Product details

Size :	120cm x 150cm, Aperture 5x7cm
Descriptive feature :	Adhesive, Non-centered ellipse aperture
Sterile :	Sterile
Brand :	BARRIER
Equivalences :	904744

## Images



## Delivered items

935569-09

**Sales released in:** Austria, Belgium, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Ireland, Kuwait, Latvia, Lebanon, Lithuania, Malaysia, Martinique, Morocco, Netherlands, Norway, Russian Federation, Saudi Arabia, Slovenia, Sweden, Switzerland, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland

**Country of origin:** Thailand

**Shelf life:** 5 years

**Sterilization method:** Irradiation

**Production Responsibility:** Mölnlycke Health Care (Thailand) Ltd, 160 Moo 17 Bangplee Industrial Estate, Bangna-Trad Road, Km 23 Tambol Bangsaothong, Amphur Bangsaothong, Samutprakarn 10570, Thailand

**Packing information:** First packaging layer is a peel-open sterile barrier, plastic/plastic. Once opened the sterile barrier cannot be closed again. Second layer is a corrugated board dispenser box. Third layer is a corrugated board transport box.

**Is suitable for Tray:** No

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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Packing level	Quantity	GS1 Code / UDI-DI	Width x Length x Height	Vol	Weight gross / net
Consumer pack	1	7332551049317			
Dispenser box	18	7332551899790	191x331x254 mm		
Transport box	108	7332551899783	396x791x348 mm	109.0 dm3	16.4 / 13.9 kg
Pallet	1620	7332551899776	800x1200x1884 mm		

935569-10

**Sales released in:** Austria, Belgium, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hungary, Ireland, Kuwait, Latvia, Lebanon, Lithuania, Malaysia, Martinique, Morocco, Netherlands, Norway, Russian Federation, Saudi Arabia, Slovenia, Spain, Sweden, Switzerland, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland

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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	7332551042400			
Consumer pack	1	7323190248636			
Dispenser box	18	7323190247349	206x321x267 mm		
Transport box	36	7323190247332	332x428x288 mm	40.9 dm3	5.4 / 4.5 kg
Pallet	1296	7323190247325	800x1200x1872 mm	1797.1 dm3	219.4 / 160.9 kg

#### Material

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

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## Product Composition Drapes

Product Component	Composition
Drape material	Viscose nonwoven 23 g/m <sup>2</sup>
Drape material	Polyethylene film 40 µm
Adhesive material	Synthetic rubber based

## Product Performance Surgical Drapes, EN 13795-1:2019 High Performance

Characteristics	Test Method	Internal Test Method	Unit	Requirement Critical Product Area	Requirement Less Critical Product Area	Product Performance Critical Product Area	Product Performance Less Critical Product Area
Resistance to microbial penetration - Dry	ISO 22612	T-1004	CFU	Not required	≤300	-	0
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6.0	Not required	6.0	-
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm <sup>2</sup>	≤300	≤300	0	0
Particle release	EN ISO 9073-10	T-1006	Log <sub>10</sub> (lint count)	≤4.0	≤4.0	2.5	2.5
Resistance to liquid penetration	EN ISO 811	T-280	cm H <sub>2</sub> O	≥100	≥10	127	127
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	67	67
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	45	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	25	25

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Characteristics	Test Method	Internal Test Method	Unit	Requirement Critical Product Area	Requirement Less Critical Product Area	Product Performance Critical Product Area	Product Performance Less Critical Product Area
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	22	-

### Product Performance Drapes, Additional Tests

Characteristics	Test Method	Internal Test Method	Unit	Product Performance
Absorption	ISO 9073-12	T-1158	g/dm <sup>2</sup>	1,10
Flammability	16 CFR 1610.4	N/A	s	Class I, >3.5s

### Technical

#### Dimension

Dimension text	Dimension value
Outer dimension	120 cm x 150 cm
Aperture	5 cm x 7 cm
Aperture placement from top	65 cm

### Disposal instructions

Used Mölnlycke products and sterile barriers should, in the majority of cases, be classified as non-hazardous waste. They contain high amounts of energy and are well suited for incineration. Mölnlycke products do not contain any hazardous substances that can leach out if the products are land filled. Transport- and dispenser boxes are designed to fit existing recovery systems. The Mölnlycke packaging system complies with the EU Directive on packaging and packaging waste.

### Storage instructions

Mölnlycke Health Care recommends that Mölnlycke products are stored under normal storage conditions. All layers of packaging should be kept intact until access to the underlying layers is needed. Storage facilities for products only protected by the sterile barrier should be kept under conditions where low level of particulate air contamination prevail, so that it would not constitute a risk to the patient when the sterile barrier is opened and the product is used.

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## Classifications

Regulation type(s)	MDR Class IS	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :	MDR 722028			
Intended Purpose :	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.
MDR Classification Rule :	1			
Conformity Annexes :	IX			
Measuring Function :	Yes			
Notified body medical devices/PPE :	BSi 2797	Local Authority United Arab Emirates	Local Authority Kuwait	Local Authority Malaysia
Regulatory Released :	Austria, Belgium, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Martinique, Netherlands, Norway, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland	United Arab Emirates	Kuwait	Malaysia

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## Classifications

Regulation type(s)	Locally Regulated
CE Certificate Number :	
Intended Purpose :	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.
MDR Classification Rule :	
Conformity Annexes :	
Measuring Function :	
Notified body medical devices/PPE : Saudi Authority	
Regulatory Released :	Saudi Arabia

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

EN 1041, EN 556-1, EN 13795, EN 62366, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 11607-1, EN ISO 11607-2, EN ISO 15223-1, ISO 15223-2, ISO 14001

**Removable label**

Yes

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

47783 Patient surgical drape, single-use

**UNSPSC**

42131701 Surgical drapes

**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**

733243000000000160JX

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