

# 906693 Adhesive Aperture Drape

## Product details

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**Size :** 50cm x 60cm, Aperture 6 cm x 8 cm  
**Descriptive feature :** Adhesive, Centered ellipse aperture  
**Sterile :** Sterile  
**Brand :** BARRIER

## Images

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## Delivered items

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906693-60

**Sales released in:** Algeria, Austria, Belgium, Bosnia and Herzegovina, Chile, Colombia, Croatia, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, French Polynesia, Germany, Gibraltar, Greece, Hong Kong, Hungary, Iceland, Ireland, Italy, Jordan, Kuwait, Latvia, Lebanon, Lithuania, Luxembourg, Malaysia, Monaco, Montenegro, Morocco, Netherlands, Norway, Oman, Pakistan, Poland, Portugal, Qatar, Réunion, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Tunisia, Turkey, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland

**Country of origin:** Thailand

**Shelf life:** 5 years

**Sterilization method:** Gamma

**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 corrugated board dispenser box. Third layer is a corrugated board transport box.

**Is suitable for Tray:** No

Packing level	Quantity	GS1 code	WxLxH (mm)	Vol (dm3)	Weight gross/net (kg)
Consumer pack	1	7323190272587			



Packing level	Quantity	GS1 code	WxLxH (mm)	Vol (dm3)	Weight gross/net (kg)
Dispenser box	75	7323190262267	206x321x267	17.7	
Transport box	150	7323190262250	332x428x288	40.9	5.0 / 4.0
Pallet	5400	7323190262243	800x1200x1872	1797.1	204.3 / 145.8

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**Sales released in:** Algeria, Austria, Belgium, Bosnia and Herzegovina, Chile, Colombia, Croatia, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, French Polynesia, Germany, Gibraltar, Greece, Hong Kong, Hungary, Iceland, Ireland, Italy, Jordan, Kuwait, Latvia, Lebanon, Lithuania, Luxembourg, Malaysia, Mexico, Monaco, Montenegro, Morocco, Netherlands, Norway, Oman, Pakistan, Poland, Portugal, Qatar, Réunion, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Tunisia, Turkey, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland

**Country of origin:** Thailand

**Shelf life:** 5 years

**Sterilization method:** Beta;Gamma

**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 corrugated board dispenser box. Third layer is a corrugated board transport box.

**Is suitable for Tray:** No

Packing level	Quantity	GS1 code	WxLxH (mm)	Vol (dm3)	Weight gross/net (kg)
Consumer pack	1	7323190179732			
Dispenser box	100	7323190178636	284x378x215		
Transport box	400	7323190178629	398x594x444	105.0	12.8 / 7.2
Pallet	6400	7323190178612	800x1200x1920		

Material

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

Product Composition Drapes

Product Component	Composition
Drape material	Viscose nonwoven 23 g/m <sup>2</sup>
Drape material	Polyethylene film 27.5 µm



Product Component	Composition
Adhesive material	Synthetic rubber based

Product Performance Surgical Drapes, EN 13795-1:2019 Standard 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	N/A - only less critical product area	0
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	≥2.8	Not required	N/A - only less critical product area	-
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm <sup>2</sup>	≤300	≤300	N/A - only less critical product area	0
Particle release	EN ISO 9073-10	T-1006	Log <sub>10</sub> (lint count)	≤4.0	≤4.0	N/A - only less critical product area	2.7
Resistance to liquid penetration	EN ISO 811	T-280	cm H <sub>2</sub> O	≥30	≥10	N/A - only less critical product area	> 153
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	N/A - only less critical product area	54
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	N/A - only less critical product area	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥15	≥15	N/A - only less critical product area	21
Tensile strength - Wet	EN 29073-3	T-229	N	≥15	Not required	N/A - only less critical product area	-

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	50 cm x 60 cm
Aperture	6 cm x 8 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.

### Classifications

Regulation type(s)	MDD Class IS
CE Certificate Number :	CE 01966
Intended use MDD :	Surgical drapes, when sterilised, are intended to minimise the spread of micro-organisms, in order to reduce the risk for post operative wound infection.
MDD Classification Rule :	1
Conformity Annexes :	V;VII
Measuring Function :	No
Notified body medical devices/PPE :	BSI (2797)
Regulatory Released :	Austria, Belgium, Croatia, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Monaco, Netherlands, Norway, Poland, Portugal, Réunion, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland



**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, sterile

### **UNSPSC**

42131701 Surgical drapes

### **Commodity Code**

3005905000 Articles of Wadding, Gauze, Dressings, drapes singlepacked and Sets - textile

