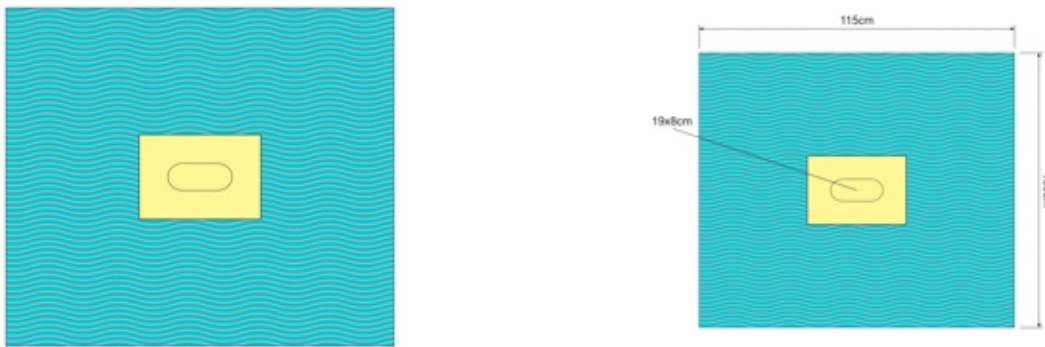


85601 Adhesive Aperture Drape

Product details

Product group name : Ophthalmic drape, SMS
Size : 115x100cm, Incise 8x19cm
Descriptive feature : Incise film, SMS
Sterile : Sterile
Brand : BARRIER®
Equivalences : 95601

Images



Delivered items

85601-00

Country of origin: Thailand

Shelf life: 5 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 corrugated board transport 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
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Find out more at www.molnlycke.com

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Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Piece	1			397x580x329 mm	1893.9 cm ³	106.5 g / -
Consumer pack	1	07333350103811	07333350103811			
Dispenser box	20	07333350055424	07333350055424			
Transport box	40	07333350814298	07333350814298	397x580x329 mm	75.8 dm ³	4.3 / 2.4 kg
Pallet	800	7313661282160		800x1200x1789 mm	1717.4 dm ³	110.2 kg / -

Material

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

Packaging Composition

Product Component	Composition
RET box	Corrugated board, 100% recycled pulp
Primary Packaging	Top web: Cellulose, Base web: PA/PE Laminate
TRP box	Corrugated board, 90-95% recycled content
PE liner	Transparent Polyethylene film 40 µm

Product Composition Drapes

Product Component	Composition
Drape material	Incise film: Polyethylene film 40 µm, transparent
Drape material	Polypropylene nonwoven 40 g/m ²
Adhesive material	Acrylate based

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

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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 - Dry	EN 29073-3	T-229	N	≥20	≥20	44	44
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	47	-
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	-
Resistance to liquid penetration	EN ISO 811	T-280	cm H ₂ O	≥100	≥10	153	53
Particle release	EN ISO 9073-10	T-1006	Log ₁₀ (lint count)	≤4.0	≤4.0	1,5	1,5
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm ²	≤300	≤300	0	0
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	130	-
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	138	138

Product Performance Drapes, Additional Tests (#2)

Characteristics	Test Method	Unit	Product Performance
Flammability	16 CFR 1610.4	s	Class I, >3.5s

Technical

Dimension

Dimension text	Dimension value
Outer dimension	100 cm x 115 cm
Length, drape edge to aperture	45 cm

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Dimension text	Dimension value
Incise	8 cm x 19 cm

Classifications

Regulation type(s)	MDR Class IS	MDR Class IS	Locally Regulated	Locally Regulated
CE Certificate Number :	UKCA 760670			
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 :	V			
Measuring Function :	No			
Notified body medical devices/PPE :	BSi 2797	BSi 2797	Local Authority Thailand	Local Authority MEA

Classifications

Regulation type(s)	Locally Regulated	AU Class IS	Class I
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
MDR Classification Rule :			
Conformity Annexes :			
Measuring Function :			
Notified body medical devices/PPE :	Local Authority New Zealand	TGA (Australia)	PMDA (Japan)

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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

CE Responsibility / Legal Manufacturer

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

Basic UDIDI

733243000000000173K8

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