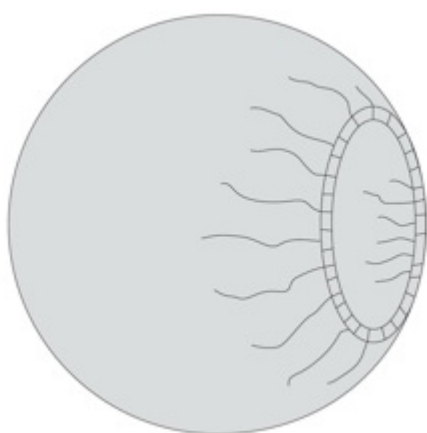


63012 Banded Bag

Product details

Size :	140cm
Descriptive feature :	Circular
Colour :	Transparent
Sterile :	Sterile
Brand :	BARRIER

Images



Delivered items

63012-00

Country of origin: China

Shelf life: 5 years

Sterilization method: EtO;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 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	7313661143607			1527.3 cm ³	125.1 g / -
Consumer pack	1	6931747819867	6931747819867	150x290x- mm		

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Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Dispenser box	11	6931747819874	6931747819874	140x300x330 mm		
Transport box	22	6931747819881	6931747819881	300x320x350 mm	33.6 dm3	2.8 / 2.2 kg
Pallet	880	7313661182521		800x1200x1880 mm	1804.8 dm3	110.1 kg / -

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	Polyethylene film 40 micron, transparent

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
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm ²	≤300	≤300	N/A - no critical product area	0
Particle release	EN ISO 9073-10	T-1006	Log ₁₀ (lint count)	≤4.0	≤4.0	N/A - no critical product area	N/A, 1-ply PE-film
Resistance to liquid penetration	EN ISO 811	T-280	cm H ₂ O	≥100	≥10	N/A - no critical product area	155

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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
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	N/A - no critical product area	54
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	N/A - no critical product area	43
Resistance to microbial penetration - Dry	ISO 22612	T-1004	CFU	Not required	≤300	N/A - no critical product area	0
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6.0	Not required	N/A - no critical product area	-
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	N/A - no critical product area	-
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	N/A - no critical product area	-

Product Performance Drapes, Additional Tests

Characteristics	Test Method	Unit	Product Performance	Product Performance Critical Product Area
Flammability	16 CFR 1610.4	s	Class I, > 3.5s	N/A - no critical product area

Technical

Dimension

Dimension text	Dimension value
Product	140 cm

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Classifications

Regulation type(s)	MDD Class IS	Locally Regulated	Locally Regulated
Intended use MDD :	Equipment Cover is intended as a protective covering or a barrier to protect the medical equipment (e.g., C-arm, surgical laser/camera/microscope, examination table/chair) and/or equipment components (e.g., cables, tubes, headrest) from soiling and contamination when used in the operation room or other hygiene area.		
Intended Purpose :		Equipment Cover is intended as a protective covering or a barrier to protect the medical equipment (e.g., C-arm, surgical laser/camera/microscope, examination table/chair) and/or equipment components (e.g., cables, tubes, headrest) from soiling and contamination when used in the operation room or other hygiene area.	Equipment Cover is intended as a protective covering or a barrier to protect the medical equipment (e.g., C-arm, surgical laser/camera/microscope, examination table/chair) and/or equipment components (e.g., cables, tubes, headrest) from soiling and contamination when used in the operation room or other hygiene area.
Notified body medical devices/PPE :	Notified Body (see CE certificate)	Local Authority Mexico	Local Authority Singapore
510(k) clearance number :		NA	

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

EN 556-1, EN 13795, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-7, EN ISO 11607-1, EN ISO 11607-2, EN ISO 10993-10, ISO 11135

Removable label

Yes

GMDN Code (Global Medical Device Nomenclature)

12535 Medical equipment drape, single-use

Find out more at www.molnlycke.com



UNSPSC

42295415 Surgical equipment covers

Commodity Code

3926909790 Plastics and articles thereof

CE Responsibility

Xuchang Zhengde Environstar Medical Products Co. Ltd, NO. 3 Weilai Road, Industry Cluster District, Yanling Country, Xuchang City, Henen Province, China

Basic UDIDI

73324300000000307K5

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