

63048 C-Arm Drape

Allows sterile handling of equipment that cannot be sterilised

Product details

Product group name :	Equipment drapes
Size :	117 x 183cm
Descriptive feature :	1-part half coverage
Colour :	Transparent
Sterile :	Sterile
Brand :	BARRIER®

Product descriptions

Short description : Allows sterile handling of equipment that cannot be sterilised

Long description : BARRIER® equipment drapes provide a transparent and sterile draping solution for equipment in the operating room.

- Allows sterile handling of equipment that cannot be sterilised.
- Impermeable materials.
- Easy to drape.

Images



Delivered items

63048-00

Country of origin: China

Shelf life: 5 years

Sterilization method: EtO

Production Responsibility: Xuchang Zhengde Environstar Medical Products Co. Ltd., Area B, Baihua Road East, South Side of Erji river, Industry Cluster District, Yanling County, 461200 Xuchang, Henan, China

Packing information: First packaging layer is a peel-open sterile barrier, paper/plastic. Once opened the sterile

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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	7313661500905			1105.263 cm ³	207.5 g / -
Consumer pack	1	6931747835942	6931747835942	225x298x0 mm		
Dispenser box	38	6931747835959	6931747835959	290x380x330 mm		
Transport box	76	6931747835966	6931747835966	400x600x350 mm	84 dm ³	15.77 / 14.79 kg
Pallet	1520	7313661507928		800x1200x1880 mm	1804.8 dm ³	328 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
Primary Packaging	Top web: Paper, Base web:PE/PA Laminate
RET box	Corrugated board, 100% recycled pulp
TRP box	Corrugated board, 100% recycled pulp

Product Composition Drapes

Product Component	Composition
Drape material	Polyethylene film 40 µm, transparent

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
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	-
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm ²	≤300	≤300	N/A - no critical product area	28
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	>150
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	N/A - no critical product area	78
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	N/A - no critical product area	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	N/A - no critical product area	38
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	N/A - no critical product area	-

Technical

Dimension

Dimension text	Dimension value
Outer dimension	117 cm x 183 cm

Instructions

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How product works :

The surgical equipment drapes are intended to be used as a protective equipment coverings, and to create a sterile field during the surgical procedure.

Classifications

Regulation type(s)	MDR Class IS
Intended Purpose :	Equipment Cover is intended to be used in the operation room and as a barrier to cover the medical equipment (e.g., C-arm, surgical laser/camera/microscope, examination table/chair), to protect the patients from the transfer of contamination and infectious agents by the medical equipment.
Notified body medical devices/PPE :	Notified Body (see CE certificate)

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

EN ISO 13485, EN ISO 15223-1, EN ISO 14971, EN 13795-1

Removable label

Yes

GMDN Code (Global Medical Device Nomenclature)

12535 Medical equipment drape, single-use

EMDN Code (European Medical Device Nomenclature)

T030201 MECHANICAL ARMS COVERS

UNSPSC

42295415 Surgical equipment covers

Commodity Code

3926909790 Plastics and articles thereof

CE Responsibility / Legal Manufacturer

Xuchang Zhengde Environstar Medical Products Co., Ltd. Area B, Baihua Road East, South Side of Erji river, Industry Cluster District, Yanling County, 461200 Xuchang, Henan, China

Basic UDIDI

69317478EC0000027K

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