

63814 OP-Towel, PRIMARY

Impermeable drapes without adhesive edges

Product details

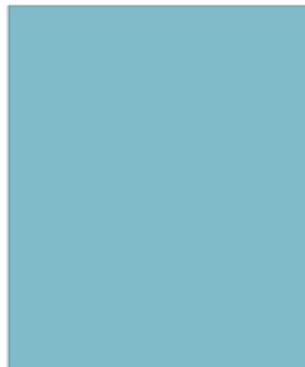
Product group name:	Non-adhesive OP-towels and OP-sheets
Size:	37,5x45 cm
Descriptive feature:	Absorbent
Sterile:	Sterile
Brand:	BARRIER®
Equivalences:	93908

Product descriptions

Short description: Impermeable drapes without adhesive edges

Long description: Non-adhesive OP-towels and OP-sheets are available in various sizes for general applications, contributing to a sterile working area.

Images



Delivered items

63814-00

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

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

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

Find out more at www.molnlycke.com

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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				134.4 cm ³	19 g / -
Consumer pack	1	6931747848003	6931747848003	150x290x0 mm		
Dispenser box	125	6931747848010	6931747848010	140x300x330 mm		
Transport box	250	6931747848027	6931747848027	300x320x350 mm	33.6 dm ³	4.75 / 4.23 kg
Pallet	10000	7313662167121		800x1200x1880 mm	1804.8 dm ³	215 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 content, FSC certified -C180555
TRP box	Corrugated board, 100% recycled content, FSC certified -C180555

Product Composition Drapes

Product Component	Composition
Drape material	Polypropylene nonwoven 28 g/m ²
Drape material	Polyethylene film 27 µm

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	-	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 ²	≤300	≤300	8.4	14.4
Particle release	EN ISO 9073-10	T-1006	Log ₁₀ (lint count)	≤4.0	≤4.0	2.04	2.04
Resistance to liquid penetration	EN ISO 811	T-280	cm H ₂ O	≥100	≥10	>153	>153
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	184	184
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	177	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	85	85
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	92.9	-

Product Performance Drapes, Additional Tests

Characteristics	Test Method	Internal Test Method	Unit	Product Performance
Absorption	ISO 9073-12	T-1158	g/dm ²	1.1
Flammability	16 CFR 1610.4	N/A	s	Class I, > 3.5s

Technical

Dimension

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Dimension text	Dimension value
Outer dimension	37.5 cm x 45 cm

Instructions

How product works:

The surgical patient drapes are intended to be used as protective patient coverings to create a sterile field for a surgical procedure.

Classifications

Regulation type(s)	MDR Class IS
Intended Purpose:	Used as a protective covering or a barrier to isolate a site of surgical incision or a surgical field from contamination found in operating theatre or catheterization laboratory e.g. on instruments or tables.
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 15223-1, EN ISO 13485, EN 13795-1, EN ISO 14971

Removable label

No

GMDN Code (Global Medical Device Nomenclature)

47783 Patient surgical drape, single-use

EMDN Code (European Medical Device Nomenclature)

T020199 SURGICAL DRAPES - OTHER

UNSPSC

42132103 Patient barrier drapes

Commodity Code

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

Basic UDIDI

69317478SD000003GG

Find out more at www.molnlycke.com