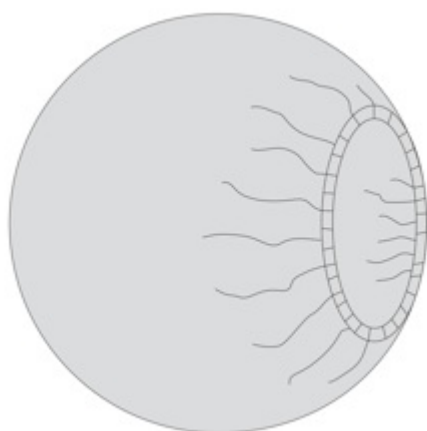


# 903740 Banded Bag

## Product details

<b>Product group name :</b>	Circular banded bag
<b>Size :</b>	90cm
<b>Descriptive feature :</b>	Circular
<b>Colour :</b>	Transparent
<b>Sterile :</b>	Sterile
<b>Brand :</b>	BARRIER®

## Images



## Delivered items

903740-21

**Country of origin:** Thailand

**Shelf life:** 5 years

**Sterilization method:** Irradiation

**Production Responsibility:** Mölnlycke Health Care (Thailand) Ltd, 160 Moo 17 Bangplee Industrial Estate, Bangna-Trad Road, Km 23 Tambol Bangsaothong, Amphur Bangsaothong, Samutprakarn 10570, Thailand

**Packing information:** First packaging layer is a peel-open sterile barrier, plastic/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
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Find out more at [www.molnlycke.com](http://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	7323190258178			787.0 cm <sup>3</sup>	47.3 g / -
Consumer pack	1	7323190292363	7323190292363			
Dispenser box	26	7323190289387	7323190289387			
Transport box	52	7323190289370	7323190289370	332x428x288 mm	40.9 dm <sup>3</sup>	2.5 / 1.5 kg
Pallet	1872	7323190289363		800x1200x1872 mm	1797.1 dm <sup>3</sup>	113.6 / 55.1 kg

903740-15

**Country of origin:** Thailand**Shelf life:** 5 years**Sterilization method:** Irradiation**Production Responsibility:** Mölnlycke Health Care (Thailand) Ltd, 160 Moo 17 Bangplee Industrial Estate, Bangna-Trad Road, Km 23 Tambol Bangsaothong, Amphur Bangsaothong, Samutprakarn 10570, Thailand**Packing information:** First packaging layer is a peel-open sterile barrier, plastic/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:** Yes

Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Piece	1	7323190258178			483.9 cm <sup>3</sup>	41.7 g / -
Consumer pack	1	7310791152967	7310791152967			
Dispenser box	28	7310791219042	7310791219042			
Transport box	168	7310791219059	7310791219059	366x753x295 mm	81.3 dm <sup>3</sup>	7.0 / 5.0 kg
Pallet	3024	7332430434661		800x1200x1914 mm		

**Material****Animal tissues :** NoFind out more at [www.molnlycke.com](http://www.molnlycke.com)

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**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 30 µm, transparent
Aperture material	Elastic material, sewn

### 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 - no critical product area	0
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	≥2.8	Not required	N/A - no critical product area	-
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm <sup>2</sup>	≤300	≤300	N/A - no critical product area	0
Particle release	EN ISO 9073-10	T-1006	Log <sub>10</sub> (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 <sub>2</sub> O	≥30	≥10	N/A - no critical product area	> 100
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	N/A - no critical product area	52
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	N/A - no critical product area	-

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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	≥15	≥15	N/A - no critical product area	22
Tensile strength - Wet	EN 29073-3	T-229	N	≥15	Not required	N/A - no 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>	N/A
Flammability	16 CFR 1610.4	N/A	s	Class 1, >3.5s

### Technical

#### Dimension

Dimension text	Dimension value
Outer dimension	90 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.

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**Classifications**

Regulation type(s)	MDD Class IS	Locally Regulated	Locally Regulated	Locally Regulated
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.			
Intended Purpose :		Surgical drapes, when sterilised, are intended to minimise the spread of micro-organisms, in order to reduce the risk for post operative wound infection.	Surgical drapes, when sterilised, are intended to minimise the spread of micro-organisms, in order to reduce the risk for post operative wound infection.	Surgical drapes, when sterilised, are intended to minimise the spread of micro-organisms, in order to reduce the risk for post operative wound infection.
Conformity Annexes :	V			
Measuring Function :	No			
Notified body medical devices/PPE :	BSi 2797	Local Authority Americas	Local Authority United Arab Emirates	Local Authority APAC

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**Classifications**

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :				
Intended use MDD :				
Intended Purpose :	Surgical drapes, when sterilised, are intended to minimise the spread of micro-organisms, in order to reduce the risk for post operative wound infection.	Surgical drapes, when sterilised, are intended to minimise the spread of micro-organisms, in order to reduce the risk for post operative wound infection.	Surgical drapes, when sterilised, are intended to minimise the spread of micro-organisms, in order to reduce the risk for post operative wound infection.	Surgical drapes, when sterilised, are intended to minimise the spread of micro-organisms, in order to reduce the risk for post operative wound infection.
Conformity Annexes :				
Measuring Function :				
Notified body medical devices/PPE :	Local Authority Thailand	Local Authority Mexico	Local Authority MEA	Saudi Authority

**Classifications**

Regulation type(s)	Locally Regulated
CE Certificate Number :	
Intended use MDD :	
Intended Purpose :	Surgical drapes, when sterilised, are intended to minimise the spread of micro-organisms, in order to reduce the risk for post operative wound infection.
Conformity Annexes :	
Measuring Function :	
Notified body medical devices/PPE : Local Authority Kuwait	

**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**

No

Find out more at [www.molnlycke.com](http://www.molnlycke.com)



## **GMDN Code (Global Medical Device Nomenclature)**

47783 Patient surgical drape, single-use

## **Other specific product information**

Equipment Category: Microscope. Lens, Flat

## **UNSPSC**

42295415 Surgical equipment covers

## **Commodity Code**

3926909790 Plastics and articles thereof

## **CE Responsibility / Legal Manufacturer**

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

## **Basic UDIDI**

73324300000000164K7

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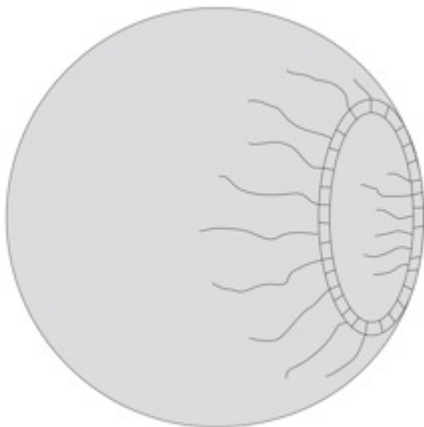


# 63011 Banded Bag

## Product details

<b>Product group name :</b>	Circular banded bag
<b>Size :</b>	90cm
<b>Descriptive feature :</b>	Circular
<b>Colour :</b>	Transparent
<b>Sterile :</b>	Sterile
<b>Brand :</b>	BARRIER®

## Images



## Delivered items

63011-00

**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	7313661143287			763.6 cm <sup>3</sup>	67.5 g / -

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Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Consumer pack	1	6931747819836	6931747819836	150x290x- mm		
Dispenser box	22	6931747819843	6931747819843	140x300x330 mm		
Transport box	44	6931747819850	6931747819850	300x320x350 mm	33.6 dm3	3.0 / 2.4 kg
Pallet	1760	7313661182514		800x1200x1880 mm	1804.8 dm3	118.9 kg / -

## Material

<b>Animal tissues :</b>	No
<b>Human blood derivatives :</b>	No
<b>Natural rubber latex :</b>	No
<b>Medicinal substances :</b>	No
<b>Phthalates :</b>	No
<b>Polyvinyl chloride :</b>	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 micron, 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
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm <sup>2</sup>	≤300	≤300	N/A - no critical product area	0
Particle release	EN ISO 9073-10	T-1006	Log <sub>10</sub> (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 <sub>2</sub> O	≥100	≥10	N/A - no critical product area	155
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

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**Dimension**

Dimension text	Dimension value
Product	90 cm

**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

Find out more at [www.molnlycke.com](http://www.molnlycke.com)



## Removable label

Yes

## GMDN Code (Global Medical Device Nomenclature)

12535 Medical equipment drape, single-use

## UNSPSC

42295415 Surgical equipment covers

## Commodity Code

3926909790 Plastics and articles thereof

## CE Responsibility / Legal Manufacturer

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

## Basic UDIDI

733243000000000307K5

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