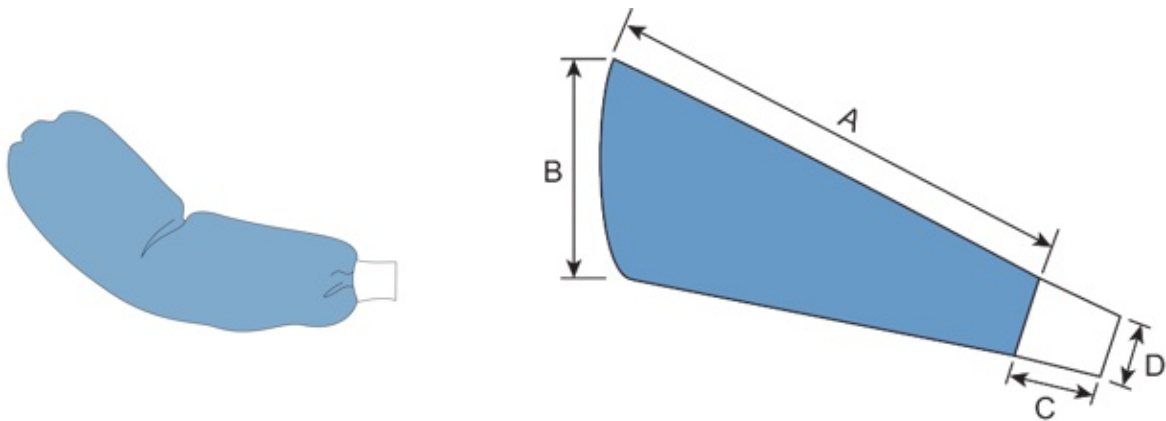


623501 Arm Sleeve

Product details

**Product group name :** Arm sleeve  
**Size :** One Size  
**Descriptive feature :** High performance, Impermeable  
**Colour :** Ocean  
**Sterile :** Sterile  
**Brand :** BARRIER®

Images



Delivered items

623501-09

**Country of origin:** Thailand

**Shelf life:** 5 years

**Sterilization method:** Irradiation

**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
Piece	1	7323190257386			511.546 cm3	39.75 g / -
Consumer pack	1	07333350501020	07333350501020			

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
Dispenser box	40	07333350632847	07333350632847	206x321x267 mm		
Transport box	80	07333350359508	07333350359508	332x428x288 mm	40.924 dm3	3.18 / 1.507 kg
Pallet	2880	7313661197273		800x1200x1872 mm	1797.12 dm3	140.49 kg / -

623501-08

**Country of origin:** Thailand**Shelf life:** 5 years**Sterilization method:** Irradiation

**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
Piece	1	7323190257386			568.384 cm3	42.778 g / -
Consumer pack	1	7323190302185	7323190302185			
Dispenser box	36	7323190300600	7323190300600			
Transport box	72	7323190300594	7323190300594	332x428x288 mm	40.924 dm3	3.08 / 2.15 kg

623501-07

**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**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	7323190257386			451.675 cm3	41.728 g / -
Consumer pack	1	7332551136802	7332551136802			
Dispenser box	30	7332551084295	7332551084295			
Transport box	180	7332551084288	7332551084288	366x753x295 mm	81.301 dm3	7.511 / 3.6 kg
Pallet	3240	7332551084271		800x1200x1914 mm		

## 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

## Product Composition Arm Sleeve

Product Component	Composition
Main material	2-ply laminate 62 g/m <sup>2</sup> : Polyethylene film/polypropylene nonwoven
Cuffs	Polyester
Elastic band	Polyamide (Nylon), Rubber

## Packaging Composition

Product Component	Composition
Primary Packaging	Top web: 85gsm PE, 100% virgin, Base web: 100gsm PE/PA 100% virgin
RET box	100% corrugated cellulose board, >70% recycle content
TRP box	100% corrugated cellulose board, >90% recycle content, FSC A000523

## Product Performance Surgical Gowns, EN 13795 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
Resistance to microbial penetration - Dry	ISO 22612	T-1004	CFU	Not required	≤300	N/A
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6	Not required	6
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm <sup>2</sup>	≤300	≤300	17.5
Linting	EN ISO 9073-10	T-1006	Log <sub>10</sub> (lint count)	≤4.0	≤4.0	log <sub>10</sub> (lint count) 3.0
Resistance to liquid penetration	EN ISO 811	T-280	cm H <sub>2</sub> O	≥100	≥10	200
Bursting strength - Dry	EN ISO 13938-1	T-233	kPa	≥40	≥40	132.7
Bursting strength - Wet	EN ISO 13938-1	T-233	kPa	≥40	Not required	83.3
Tensile strength - Dry , MD	EN 29073-3	T-229	N	≥20	≥20	N/A
Tensile strength - Dry , CD	EN 29073-3	T-229	N	≥20	≥20	35.10
Tensile strength - Wet, MD	EN 29073-3	T-229	N	≥20	Not required	N/A
Tensile strength - Wet, CD	EN 29073-3	T-229	N	≥20	Not required	37.29

### Product Performance Surgical Gowns AAMI level 3

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance Critical Product Area
Spray impact	WSP 080.3/AATCC 42	T-1025	g	≤1	0

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Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance Critical Product Area
Hydro head	WSP 080.6/AATCC 127	T-1030	cm H <sub>2</sub> O	≥50	51

**Product Performance Surgical Gowns Additional tests**

Characteristics	Test Method	Unit	Product Performance Critical Product Area
Flammability	16 CFR 1610.4	sec	>3.5

## Technical

**Dimension**

Dimension reference	Dimension text	Dimension value
A	Length, sleeve	48 cm
B	Armhole width, relaxed	24 cm
C	Cuff length	6 cm
D	Cuff width	7 cm

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## Classifications

Regulation type(s)	MDR Class IS	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :	MDR 722028			
Intended Purpose :	The Arm sleeve is intended to be used sterile by operating room personnel during surgical procedures to protect both the patient and the operating room personnel (users) from the transfer of microorganisms, body fluids and particulate material. The Arm sleeve is a single use, disposable and fluid repellent garment accessory that provides extra fluid protection covering the gown sleeve when high amount of fluids are expected or when the user needs extra layer of protection to ensure barrier integrity.	The Arm sleeve is intended to be used sterile by operating room personnel during surgical procedures to protect both the patient and the operating room personnel (users) from the transfer of microorganisms, body fluids and particulate material. The Arm sleeve is a single use, disposable and fluid repellent garment accessory that provides extra fluid protection covering the gown sleeve when high amount of fluids are expected or when the user needs extra layer of protection to ensure barrier integrity.	The Arm sleeve is intended to be used sterile by operating room personnel during surgical procedures to protect both the patient and the operating room personnel (users) from the transfer of microorganisms, body fluids and particulate material. The Arm sleeve is a single use, disposable and fluid repellent garment accessory that provides extra fluid protection covering the gown sleeve when high amount of fluids are expected or when the user needs extra layer of protection to ensure barrier integrity.	The Arm sleeve is intended to be used sterile by operating room personnel during surgical procedures to protect both the patient and the operating room personnel (users) from the transfer of microorganisms, body fluids and particulate material. The Arm sleeve is a single use, disposable and fluid repellent garment accessory that provides extra fluid protection covering the gown sleeve when high amount of fluids are expected or when the user needs extra layer of protection to ensure barrier integrity.
MDR Classification Rule :	1			
Conformity Annexes :	IX			
Measuring Function :	No			
Notified body medical devices/PPE :	BSi 2797	Local Authority Americas	Local Authority APAC	Local Authority United Arab Emirates
510(k) clearance number :				MoH approval

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## Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated
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MDR Classification Rule :			
Conformity Annexes :			
Measuring Function :			
Notified body medical devices/PPE :	Local Authority APAC	Local Authority MEA	Local Authority EU Non EEC
510(k) clearance number :			

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

ANSI/AAMI PB70, EN 1041, EN 556-1, EN 13795, EN 62366, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 10993-5, EN ISO 11607-1, EN ISO 11607-2, EN ISO 15223-1, ISO 15223-2, EN ISO 10993-10, ISO 14001

## Removable label

No

## GMDN Code (Global Medical Device Nomenclature)

35091 Operating room gown, single-use

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### EMDN Code (European Medical Device Nomenclature)

T020499 SURGICAL GOWNS - OTHER

### UNSPSC

42131601 Medical staff aprons or bibs

### Commodity Code

3926200000 Wearing apparel mainly plastic film, plastic gloves

### CE Responsibility / Legal Manufacturer

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

### Basic UDIDI

733243000000000074K5

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