1922 Protective Gown

Isolation Gown

Product details

Product group name : Protective gown

Size : XL

Colour : Blue

Sterile : Non-sterile

Brand : BARRIER®

Images

Delivered items

1922-31

Sales released in: Australia, Austria, Bahrain, Belgium, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Japan, Latvia, Lithuania, Luxembourg, Mauritius, Mexico, Morocco, Netherlands, Norway, Poland, Portugal, Qatar, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland
Country of origin: Cambodia
Shelf life: 5 years
Sterilization method: Non-sterile
Packing information: First packaging layer is a plastic liner/bag. Second 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	7332430448750			601.9 cm3	56.8 g / -
Transport box	50	7323190306541	7323190306541	304x330x300 mm	30.1 dm3	2.8 / 2.4 kg

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Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Pallet	1500	7313661085778		800x1200x1644 mm	1578.2 dm3	110.2 kg / -

1922-20

Sales released in: Australia, Austria, Bahrain, Belgium, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Japan, Latvia, Lithuania, Luxembourg, Mauritius, Morocco, Netherlands, Norway, Oman, Poland, Portugal, Qatar, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland
Country of origin: Cambodia
Shelf life: 5 years
Sterilization method: Non-sterile
Production Responsibility: Copious (Cambodia) International Inc., National Road 2, Kilometer 68, Rung Village, Lum Chong Commune, Somrorng District, Takeo Province, Cambodia
Packing information: First packaging layer is a plastic liner/bag. Second 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
Transport box	50	7323190049813	7323190049813	304x330x381 mm	38.2 dm3	4.1 / 3.5 kg
Pallet	1200	7323190049806		800x1200x1674 mm		

Material

Animal tissues : No
Human blood derivatives : No
Natural rubber latex : No
Medicinal substances : No
Phthalates : No
Polyvinyl chloride : No

Product Composition Wearing Apparel

Product Component	Composition
Main material	Variant -31: Polypropylene SMMS nonwoven 18 g/m², Variant -20: Polypropylene Spunbond nonwoven 28 g/m²

Product Component	Composition
Neck band	Variant -31: Polypropylene SMMS nonwoven 18 g/m², Variant -20: Polypropylene Spunbond nonwoven 28 g/m²
Elastic	Polyurethane, Polyamide (Nylon)
Tie bands	Variant -31: Polypropylene SMMS nonwoven 18 g/m², Variant -20: Polypropylene Spunbond nonwoven 28 g/m²
Sewing thread	Polyurethane, Polyamide (Nylon)

Technical

Dimension

Dimension reference	Dimension text	Dimension value
A	Length, highest point at shoulder	127 cm
B	Center front	113 cm
C	Chest width	75 cm
D	Top sleeve	61 cm
E	Armhole width	32 cm

Disposal instructions

Non-hazardous waste used BARRIER products and sterility 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. BARRIER products do not contain any hazardous substances that can leach out if the products are land filled. Transport boxes are designed to fit existing recovery systems. The new BARRIER packaging system complies with the Packaging Waste Directive of the European Union.

Storage instructions

Mölnlycke Health Care recommends that BARRIER 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 sterility 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 package is opened and the product is used.

Classifications

Regulation type(s)	MDR Class Ins	MDR Class Ins	Locally Regulated	Locally Regulated

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Regulation type(s)	MDR Class I ns	MDR Class I ns	Locally Regulated	Locally Regulated
Intended Purpose :	The intended use is to reduce contamination in a non-sterile environment within health care.	The intended use is to reduce contamination in a non-sterile environment within health care.	The intended use is to reduce contamination in a non-sterile environment within health care.	The intended use is to reduce contamination in a non-sterile environment within health care.
MDR Classification Rule :	1			
Conformity Annexes :	IV			
Measuring Function :	No			
Notified body medical devices/PPE :	MPA	MPA	Local Authority Mexico	Local Authority Mexico
510(k) clearance number :				223330022030063
Regulatory Released :	Austria, Belgium, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland	Austria, Belgium, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland	Mexico	Mexico

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Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Intended Purpose :	The intended use is to reduce contamination in a non-sterile environment within health care.	The intended use is to reduce contamination in a non-sterile environment within health care.	The intended use is to reduce contamination in a non-sterile environment within health care.	The intended use is to reduce contamination in a non-sterile environment within health care.
MDR Classification Rule :				
Conformity Annexes :				
Measuring Function :				
Notified body medical devices/PPE :	Local Authority Mexico	Local Authority Mexico	Local Authority Mexico	Local Authority Mexico
510(k) clearance number :	213300401J0021	22330022030070	22330022030068	
Regulatory Released :	Mexico	Mexico	Mexico	Mexico

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Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Intended Purpose :	The intended use is to reduce contamination in a non-sterile environment within health care.	The intended use is to reduce contamination in a non-sterile environment within health care.	The intended use is to reduce contamination in a non-sterile environment within health care.	The intended use is to reduce contamination in a non-sterile environment within health care.
MDR Classification Rule :				
Conformity Annexes :				
Measuring Function :				
Notified body medical devices/PPE :	Local Authority Mexico	Local Authority MEA	Local Authority Mexico	Local Authority Mexico
510(k) clearance number :	223300226B1708			22330022030065
Regulatory Released :	Mexico	Bahrain, Mauritius, Morocco, Qatar	Mexico	Mexico

Classifications

Regulation type(s)	AU Class I ns	Non Medical Device
Intended Purpose :	The intended use is to reduce contamination in a non-sterile environment within health care.	The intended use is to reduce contamination in a non-sterile environment within health care.
MDR Classification Rule :		
Conformity Annexes :		
Measuring Function :		
Notified body medical devices/PPE :	TGA (Australia)	PMDA (Japan)
510(k) clearance number :		
Regulatory Released :	Australia	Japan

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

EN 1041, EN 62366, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 10993-5, EN ISO 15223-1, ISO 15223-2, EN ISO 10993-10, ISO 14001

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GMDN Code (Global Medical Device Nomenclature)

35492 Isolation gown, single-use

UNSPSC

42131612 Medical staff isolation or cover gowns

Commodity Code

6210109200 Wearing apparel mainly made of nonwovens

CE Responsibility / Legal Manufacturer

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Basic UDIDI

733243000000000096KF

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