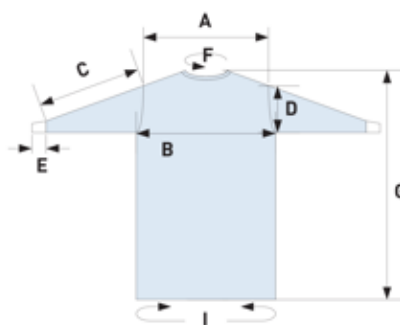


580205 Surgical Gown PRIMARY Plus

Product details

Product group name :	PRIMARY Plus, Standard performance
Size :	XXL-XL
Descriptive feature :	Alcohol repellant, Antistatic treated, Standard performance, Two towels, Wrapped
Colour :	Ocean
Sterile :	Sterile
Brand :	BARRIER®

Images



Delivered items

580205-00

Sales released in: Algeria, Australia, Austria, Bahrain, Belgium, Bulgaria, Chile, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, India, Ireland, Italy, Japan, Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Netherlands, New Zealand, Norway, Oman, Poland, Portugal, Qatar, Romania, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Thailand, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland

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 barrier cannot be closed again. Second layer is a corrugated dispenser board box. Third layer

Find out more at www.molnlycke.com

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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	7323190280278			2625.0 cm3	195.6 g / -
Consumer pack	1	6971004784231	6971004784231	334x242x- mm		
Dispenser box	16	6971004784248	6971004784248	290x380x330 mm		
Transport box	32	6971004784255	6971004784255	400x600x350 mm	84 dm3	6.3 / 4.6 kg
Pallet	640	7323190280285		800x1200x1900 mm	1824.0 dm3	150.2 / 92.2 kg

Material

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

Product Composition Accessories

Product Component	Composition
Hand Towels	65gsm cellulose fibers. Folded 30.5x34cm
Wrapping paper	45gsm Cellulose fibers. 60x60cm

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

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Product Composition Surgical Gowns

Product Component	Composition
Main material	Polypropylene SMS nonwoven 35g/m2 AS & AR
Cuffs	100% Polyester
Outer tie-bands	35g/m2 SMS nonwoven AS & AR
Inner tie-bands	35g/m2 SMS nonwoven AS & AR
Neck band	35g/m2 SMS nonwoven AS & AR
Hook and loop	100% Nylon, Synthetic Resin

Product Performance Surgical Gowns, EN 13795 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	13
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	≥2.8	Not required	4.2	N/A
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm ²	≤300	≤300	19	19
Linting	EN ISO 9073-10	T-1006	Log ₁₀ (lint count)	≤4.0	≤4.0	3.3	3.3
Resistance to liquid penetration	EN ISO 811	T-280	cm H ₂ O	≥20	≥10	42	39
Bursting strength - Dry	EN ISO 13938-1	T-233	kPa	≥40	≥40	125	133
Bursting strength - Wet	EN ISO 13938-1	T-233	kPa	≥40	Not required	129	N/A
Tensile strength - Dry , MD	EN 29073-3	T-229	N	≥20	≥20	73	73
Tensile strength - Dry , CD	EN 29073-3	T-229	N	≥20	≥20	47	47

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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 - Wet, MD	EN 29073-3	T-229	N	≥20	Not required	72	N/A
Tensile strength - Wet, CD	EN 29073-3	T-229	N	≥20	Not required	39	N/A

Product Performance Surgical Gowns AAMI level 2

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Requirement Critical Product Area	Requirement Less Critical Product Area	Product Performance Critical Product Area
Spray impact	WSP 080.3/AATCC 42	T-1025	g	≤1	≤1	Not required	0
Hydro head	WSP 080.6/AATCC 127	T-1030	cm H ₂ O	≥20	≥20	Not required	41

Product Performance Surgical Gowns Additional tests

Characteristics	Test Method	Internal Test Method	Unit	Product Performance Critical Product Area	Product Performance Less Critical Product Area
Alcohol Repellency Rating	WSP 80.8	T-283	1-10	7	7
WVTR (water vapor transmission rate)	WSP 70.4.R3(12)	T-1024	g/m ² /24 h	55125	55125
Flammability	16CFR.1610.4	N/A	s	>3.5	>3.5
Static Decay	IST 40.2 (NFPA 99)	N/A	s	1*10 ¹⁰ ohm	1*10 ¹⁰ ohm

Technical

Dimension

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Dimension reference	Dimension text	Dimension value
A	Shoulder	26,5 cm
B	Chest (most narrow part at front)	65,5 cm
C	Top sleeve	61,5 cm
D	Armhole	30 cm
E	Cuff length	8 cm
F	Neck	71 cm
G	Length, highest point at shoulder	157 cm
H	Circumference	184 cm

Classifications

Regulation type(s)	MDD Class IS	Locally Regulated	Locally Regulated	Locally Regulated
Intended use MDD :	Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.			

Find out more at www.molnlycke.com



Regulation type(s)	MDD Class IS	Locally Regulated	Locally Regulated	Locally Regulated
Intended Purpose :		Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.	Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.	Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.
Notified body medical devices/PPE :	BSi 2797	Local Authority Singapore	Local Authority India	Local Authority India
510(k) clearance number :			IMP/MD/2022/71998	

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Regulation type(s)	MDD Class IS	Locally Regulated	Locally Regulated	Locally Regulated
Regulatory Released :	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland	Singapore	India	India

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Classifications

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
Intended use MDD :				
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Notified body medical devices/PPE :	Local Authority APAC	Saudi Authority	Local Authority Malaysia	Local Authority Thailand
510(k) clearance number :			MDR-20220411-48127	NA
Regulatory Released :	New Zealand	Saudi Arabia	Malaysia	Thailand

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Classifications

Regulation type(s)	Locally Regulated	AU Class IS	Non Medical Device
Intended use MDD :			
Intended Purpose :	Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.	Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.	Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.
Notified body medical devices/PPE :	Local Authority Americas	TGA (Australia)	PMDA (Japan)
510(k) clearance number :		NA	
Regulatory Released :	Chile	Australia	Japan

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

Yes

GMDN Code (Global Medical Device Nomenclature)

35091 Operating room gown, single-use

UNSPSC

42131702 Surgical gowns

Commodity Code

6210109200 Wearing apparel mainly made of nonwovens

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

69317478SSG0000019C

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