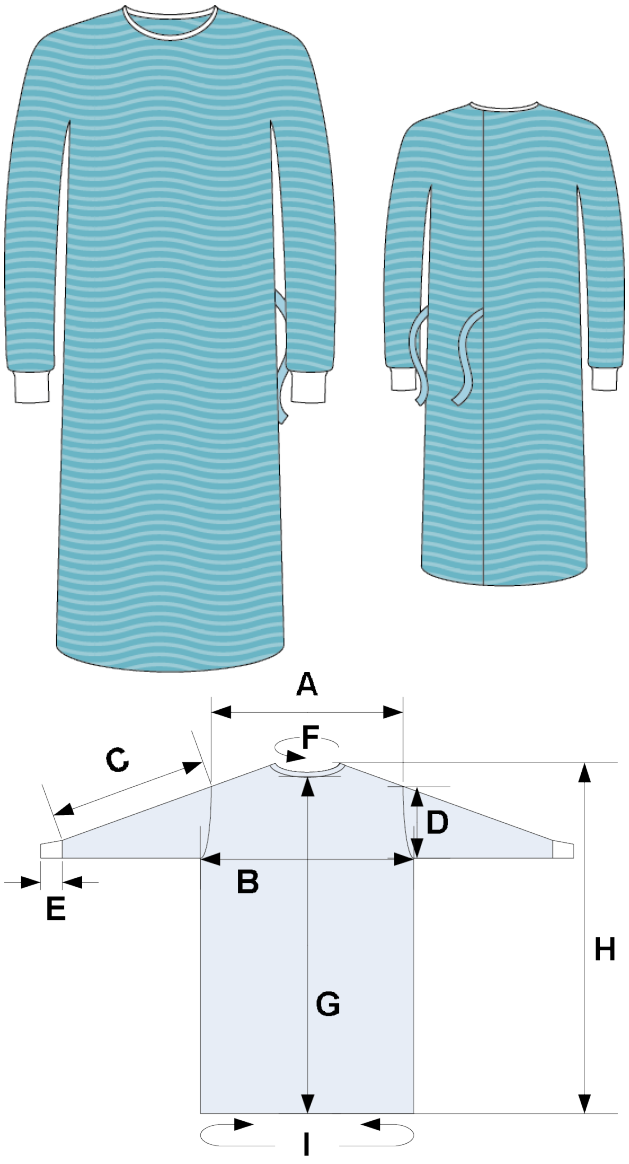
98000623 Surgical Gown PRIMARY SP



Size And Description	L-L, two towels, wrapped **Dimensions (in cm) see image** A Shoulder: 62 B Chest: 67 C Top sleeve: 57 D Armhole: 26 E Sewn cuff: 6 F Neck line: 67 G Centre front: 143 H Highest length at shoulder: 151 I Circumference: 150
Other information	Product sheet is available in MRM
Sterile	Yes
Country Of Origin	Thailand

Transport Box Quantity	42
Pallet Quantity	840
Standard	EN 13795 Standard Performance EN 13795 ISO 11607-1 ISO 10993 ISO 14001 ISO 14971-1 ISO 9001 ISO 13485
Label Of Standard	EN 1041 CEE 93/42 ISO 15223

Material data

Material composition

Gown Body and Sleeves	A blue 35 g/m^2 polypropylene SMS nonwoven material.
Cuffs	A white soft knitted cuff made of 100% polyester.
Outer and Inner Tie-Bands and Neckbinder	A blue 35 g/m^2 polypropylene SMS nonwoven material.

Product Performance according to EN 13795

Characteristic	Unit	Standard Performance			
		Requirement		Product Performance	
		Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration - Dry	CFU	Not required	≤ 300 a	Not required	33
Resistance to microbial penetration - Wet	BI	≥ 2.8 b	Not required	3.8	Not required
Cleanliness - Microbial	CFU/100cm2	<300	<300	<300	<300
Cleanliness - Particulate matter	IPM	≤ 3.5	≤ 3.5	2.7	2.7
Linting	Log 10 (lint count)	≤ 4.0	≤ 4.0	2.9	2.9
Resistance to liquid penetration	cm H2O	≥ 20	≥ 10	Sleeve seam: 56, Fabric: 61	Shoulder seam: 15, Fabric: 61
Bursting strength - Dry	kPa	≥ 40	≥ 40	149	149
Bursting strength - Wet	kPa	≥ 40	Not required	125	Not required
Tensile strength - Dry	N	≥ 20	≥ 20	37 (CD)	37 (CD)
Tensile strength - Wet	N	≥ 20	Not required	Fabric: 37 (CD), Sleeve seam: 34 (CD)	Not required

a) Test conditions: challenge concentration 10^8 CFU/g talc. and 30 minutes vibration time.
b) The Least Significant Difference (LSD) for BI when estimated using EN ISO 22610, was found to be 0,98 at the 95% confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. Thus materials varying by up to 0,98 BI are probably not different, materials varying by more than 0,98 BI probably are different (The 95% confidence levels means that an observer would be correct 19 times out of 20 to accept these alternatives).

Remark:
log (10) CFU ≤ 2 means maximum 300 CFU.

(PD-404100, PD-421053, PD-343182, PD-418082)

Additional test

Characteristics	Units	Test Method	Product performance/Critical area	Product performance/Less critical area
Repellency				
Spray impact	g *	AATCC 42	Fabric: 0.1	Shoulder seam: 0.1
Alcohol Repellency	1-10 **	WSP 80.8	2	2

Rating				
Strength				
Tear, MD	N **	ASTM D5733	Fabric: 17	Fabric: 17
Comfort				
WVTR (water vapor transmission rate)	g/m2/24hrs **	ASTM 6701	67000	67000
Air Permeability	m/s **	ISO 9237:1995	Not available	Not available
Frazier Air Porosity	ft3/min **	ASTM D737:96	44	44

* < better
** > better

Instruction Intended Use	Surgical Gowns are single use, disposable, repellent garments worn by hospital operation room personnel during surgical procedures to protect both the patient and the operating room personnel (users) from the transfer of microorganisms and body fluids.
Sterilization Method	Ethylene Oxide
MDD Classification	Class I Sterile
CEMark Certificate	01966
Instruction Storage	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.
Instruction Disposal Waste	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.
Shelf Life	5 years