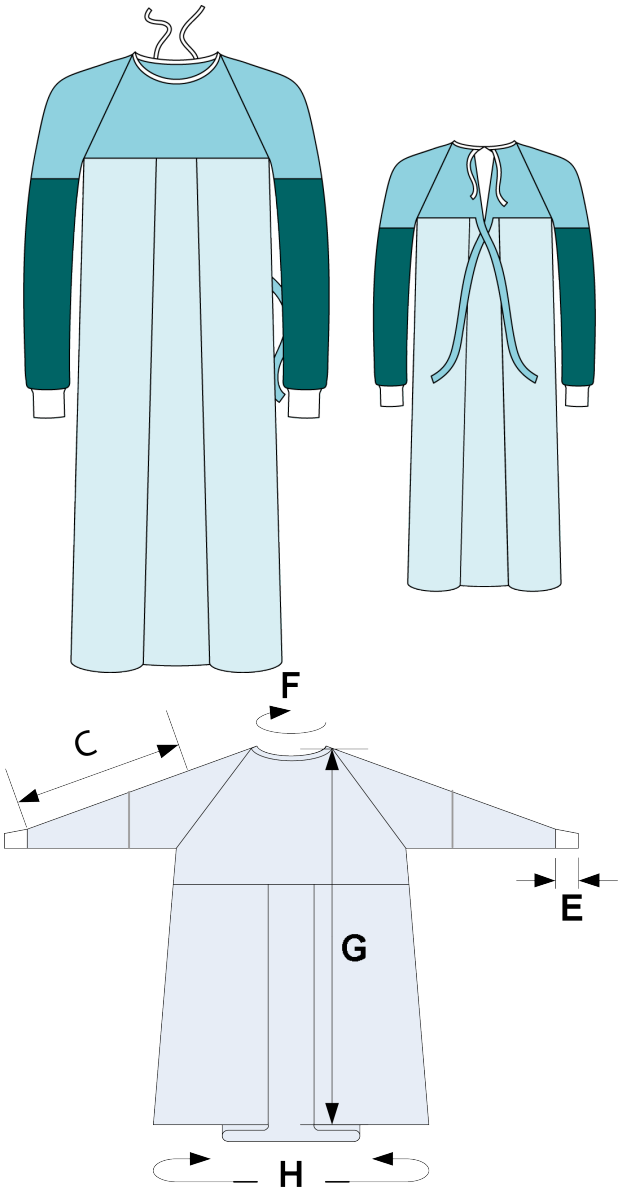
670302 Urology Surgical Gown CLASSIC HP



Size And Description	XL, two towels, wrapped **Dimensions (in cm) see image 2** C Top sleeve: 88 E Sewn cuff: 8 F Neck: 108 G Highest length at shoulder: 160 H Circumference: 180
Other information	Product sheet is available in MRM Removable label
Sterile	Yes
Country Of Origin	Thailand

Sterility barrier quantity	1
Dispenser Box Quantity	16
Transport Box Quantity	32
Pallet Quantity	640
Standard	EN 13795 High Performance EN 13795 ANSI/AAMI PB70:2003 ANSI/AAMI PB70:2003 Level 3 ISO 11607-1 ISO 10993 ISO 14001 ISO 9001 ISO 13485
Label Of Standard	EN 1041 CEE 93/42 ISO 15223

Material data

Material composition

Gown Body (upper part) and Gown Sleeves	A blue 68 g/m2 repellent spunlaced nonwoven material that consists of pulp and polyester.
Gown Body (lower part)	A blue 50 µm impermeable polyethylene film.
Sleeve Reinforcement	An impermeable 2-ply laminate that consists of a blue 27,5 µm polyethylene film and a 30 g/m² spunlaced viscose/polyester nonwoven.
Cuffs	A white soft knitted cuff made of 100% polyester.
Tie-Bands	A blue 68 g/m2 spunlaced nonwoven material that consists of pulp and polyester.
Neckline	A white 68 g/m² spunlaced nonwoven material that consists of pulp and polyester.

Product Performance according to EN 13795

Characteristic	Unit	High 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	-	107 **
Resistance to microbial penetration - Wet	BI	6.0 b, c	Not required	6.0*	-
Cleanliness - Microbial	CFU/100cm2	<300	<300	<300	<300
Cleanliness - Particulate matter	IPM	≤ 3.5	≤ 3.5	3.1**	3.1**
Linting	Log 10 (lint count)	≤ 4.0	≤ 4.0	3.3**	3.3**
Resistance to liquid penetration	cm H2O	≥ 100	≥ 10	Sleeve seam and reinforced front: >110	Shoulder seam: 22, Fabric: 25, Front seam: 22
Bursting strength - Dry	kPa	≥ 40	≥ 40	Plastic film: 61	Fabric: 234
Bursting strength - Wet	kPa	≥ 40	Not required	Fabric: 182*, Plastic film: 62	-
Tensile strength - Dry	N	≥ 20	≥ 20	Fabric 42, Plastic film: 35, Plastic film: 35	Fabric: 42, Front seam: 35
Tensile strength - Wet	N	≥ 20	Not required	Fabric: 41, Sleeves: 44	-

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).
c) BI = 6,0 for the purpose of this standard means no penetration. BI = 6,0 is the maximum achievable value.

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

* For both Critical and Less Critical product area the lowest identified average value for concerned product area has been

reported.
** For both Critical and Less Critical product area the highest identified average value for concerned product area has been reported.

Additional test

Characteristics	Units	Test Method	Product performance/Critical area	Product performance/Less critical area
Repellency				
Spray impact	g *	AATCC 42	Sleeves and film: 0.0	Fabric: 0.1 Front seam: 0.1
Alcohol Repellency Rating	1-10 **	WSP 80.8	Not applicable for film	Fabric: 9
Strength				
Tear, MD	N **	ASTM D5733	Not applicable, film	Fabric: 23
Comfort				
WVTR (water vapor transmission rate)	g/m2/24hrs **	ASTM 6701	Film nonbreathable Sleeves nonbreathable	Fabric: 52
Air Permeability	m/s **	ISO 9237:1995	Film nonbreathable Sleeves nonbreathable	Fabric: 0.3
Air Porosity	ft3/min **	ASTM D737:96	Film nonbreathable Sleeves nonbreathable	Fabric: 59

* < better
** > better

Instruction Intended Use	The product shall, when sterilised, help to create an isolated sterile working area for surgical interventions, thus protecting patient from infection.
Sterilization Method	Irradiation
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