

STERILE STANDARD SURGICAL GOWN “EXPO” MODEL IN NON WOVEN SMS MEDICAL FABRICS

Specialist gown for surgical operators made of medical non-woven microfiber S.M.S. water repellent and repellent alcohol of uniform blue color. The particular wrap-around shape allows an excellent fit making it ideal for long-lasting interventions. The particular antistatic and water-repellent material constitutes a bacteriological barrier while allowing a high breathability of the skin avoiding the rise in body temperature. Being disposable eliminates the risk of cross-contamination.

TECHNICAL FEATURES: Dimensional tolerance $\pm 5\%$

- Medical non-woven gowns Microfiber S.M.S. water-repellent and anti-reflective blue repellent alcohol
- Closure of the enveloping gown and superimposed on the back with 4 laces
- The external closing laces are marked with an anti-contagion card
- Closure of the lab coat on the neck with wrap-around and overlapping velcro
- Ultrasonic heat sealed sleeves
- Shirts with polyester cuffs
- 2 towel wipes packed with shirts
- Double protection packaged gown, wrapped in medical paper

PRODUCTION:

The product is produced and packaged in a special **clean room with a controlled environment**

CLEAN ROOM WITH CONTROLLED ENVIRONMENT:

Class ISO 8 – Standard UNI-EN ISO 14644-1.

Environment with constant temperature and humidity; by means of special ventilation and filtering systems, the presence of the bacterial load is kept controlled and at low levels.

PACKAGING:

Sterile gown, packed in bag for sterilization with peel-open opening and sterilization indication, packed in cardboard boxes.

STERILIZATION:

Sterilization is carried out with ethylene oxide; the sterilization process is regularly validated and kept under constant control by routine analysis; and the residue of the sterilizing gas is kept within the limits established by the current legislation. Sterilization is performed by a specialized laboratory.

SHELF LIFE :

This product is valid for 59 months from the sterilisation date (MONTH-YEAR). The expiry date indicated refers to the product in its unopened and correctly preserved packaging.

QUALITY CONTROL:

The quality system adopted by ALLE complies with the following regulations:

- **EN ISO 13485**

Checks are carried out at all stages of processing: entry, production, packaging.

GENERAL PRECAUTIONS AND WARNINGS

This product should only be used by qualified and trained personnel. Always read the label.

STORAGE:

- The items are stored in the original cardboard boxes, in a closed and clean environment protected from sunlight
- The integral sales package is guaranteed impermeable to direct and indirect light sources.

PRODUCT DISPOSAL:

The device listed in this document can be disposed of as non-hazardous waste in authorized plants, including incineration, in accordance with current regulations.

However, if the device used during surgical procedures in the operating room is exposed to contact with the patient's biological fluids, it must be treated and disposed of as hospital waste.

LATEX AND PHTHALATE-FREE:

- The device does not contain natural rubber latex (Latex free)
- The device does not contain phthalates (PVC free)
- The device does not contain elements (adhesives, chemicals, etc.) that could cause allergies or any skin reaction.

LABELLING:

Each individual package is provided with an internal label visible through the transparent packaging; this label is complete with all the information necessary to identify the product:

- trade name of the product
- product code number
- manufacturer's name
- production batch number



- expiry date
- single-use symbol
- production area
- CE marking
- warnings

There is an adhesive label on the transport packaging bearing all the information required to identify the product as indicated above and the no. of kits per pack

CND: T020401 (National classification of medical devices)

PRODUCT CLASSIFICATION: CLASS IS Medical Device

STERILE STANDARD SURGICAL GOWN "EXPO" MODEL IN NON WOVEN SMS MEDICAL FABRICS

DIMENSIONS	PACKAGING	CODE
LARGE SIZE	12 pcs	270406

TECHNICAL SPECIFICATIONS OF THE MATERIALS

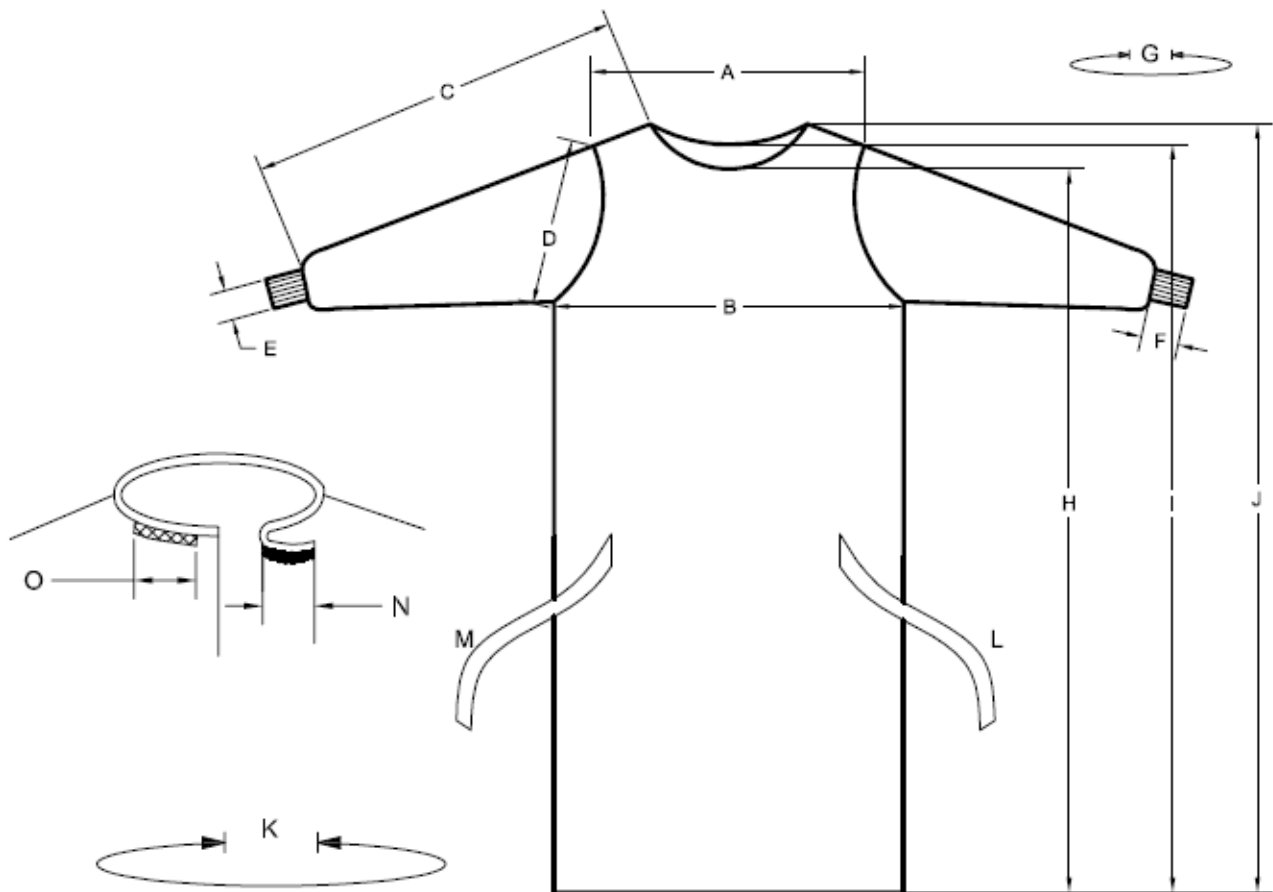
SMS NON WOVEN FABRIC

S.M.S. Microfibre Non-Woven fabric (Spunbond + Melt-Blown + Spunbond) water/blood repellent.

This non-woven fabric features an exceptional "sandwich" multi-layered structure consisting of two external layers of Spunbond non-woven fabric that enclose a layer of Melt-Blown fibres. This heterogeneous structure offers a non-woven fabric with a high level of strength and resistance to friction, while maintaining great softness, exceptional adjustability and considerably convenient use. SMS Non-Woven fabric represents the perfect barrier against liquids and particles, maintaining excellent permeability to air. The long filaments that comprise the external layers of Non-Woven fabric provide this material with excellent mechanical resistance to friction, torsion and abrasion; plus it represents an extremely efficient barrier against bacteria. This Non-Woven fabric improves the safety of the surgical ward thanks to its flame-retardant properties and is a non-irritating product.

WEIGHT	g/m ²	35	
COLOR	Light Blue		
TEST EN 13795	UNIT	VALUES	TEST METHOD
TENSILE STRENGTH MD/CD – DRY	N	70.4/39.2	EN 29073-3
TENSILE STRENGTH MD/CD – WET	N	66/38.7	EN 29073-3
MICROBIAL CLEANING	Log (10) cfu/dm ²	0.0	EN 1174
LINTING	Log (10)	3.30	ISO 9073-10
PARTICULATE CLEANING	IPM	3.10	ISO 9073-10
RESISTANCE TO MICROBIAL PENETRATION – DRY	Log (10) cfu	1.28	ISO 22612
RESISTANCE TO MICROBIAL PENETRATION – WET	BI	4.50	ISO 22610
RESISTANCE TO LIQUID PENETRATION	Cm H ₂ O	38.00	EN 20811
BURSTING PRESSURE – DRY	KPa	110.80	EN 13938-1
BURSTING PRESSURE – WET	KPa	104.00	EN 13938-1





GOWN DIMENSION – Measures cm		M	L	XL
A	Shoulder width	57	57	66
B	Chest width	63	65	75
C	Total arm length	76	79	88
D	Sleeve width	29	29	29
E	Cuff width	6	6	6
F	Cuff length	7	7	7
G	Neck circumference	71	74	75
H	Overall length from the center	120	122	125
I	Overall length	127	130	131
J	Maximum overall length	128	133	134
K	Total circumference of the lab coat	149	148	160
L	Belt length	43	43	43
M	Belt length	66	66	66
N	Male velcro	5	5	5
O	Female velcro	18	18	18

