

“EXPO” SMS SINGLE-USE GOWN

Specialist non-sterile wrap-around gown for surgical operators, made of non-woven water-repellent and alcohol repellent S.M.S. Microfibre medical fabric, uniform anti-reflection blue colour. The particular wrap-around shape allows for an excellent fit, making it ideal for long operations. The antistatic and water-repellent material constitutes a bacteriological barrier but also allows high breathability of the skin, avoiding a rise in body temperature. Being single-use, it eliminates the risk of cross-contamination.

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

- Wrap-around closure of the gown that overlaps on the back with 4 laces
- The external laces of the closure are identified with an anti-contagion card
- Neck closure of the gown with wrap-around and overlapping velcro
- Ultrasonic heat-sealed sleeves
- Gown with polyester cuffs
- 2 hand towels packed with the gown

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:

Gowns wrapped in protective wrapping, packed in cardboard boxes.

STERILIZATION:

Non sterile item

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)

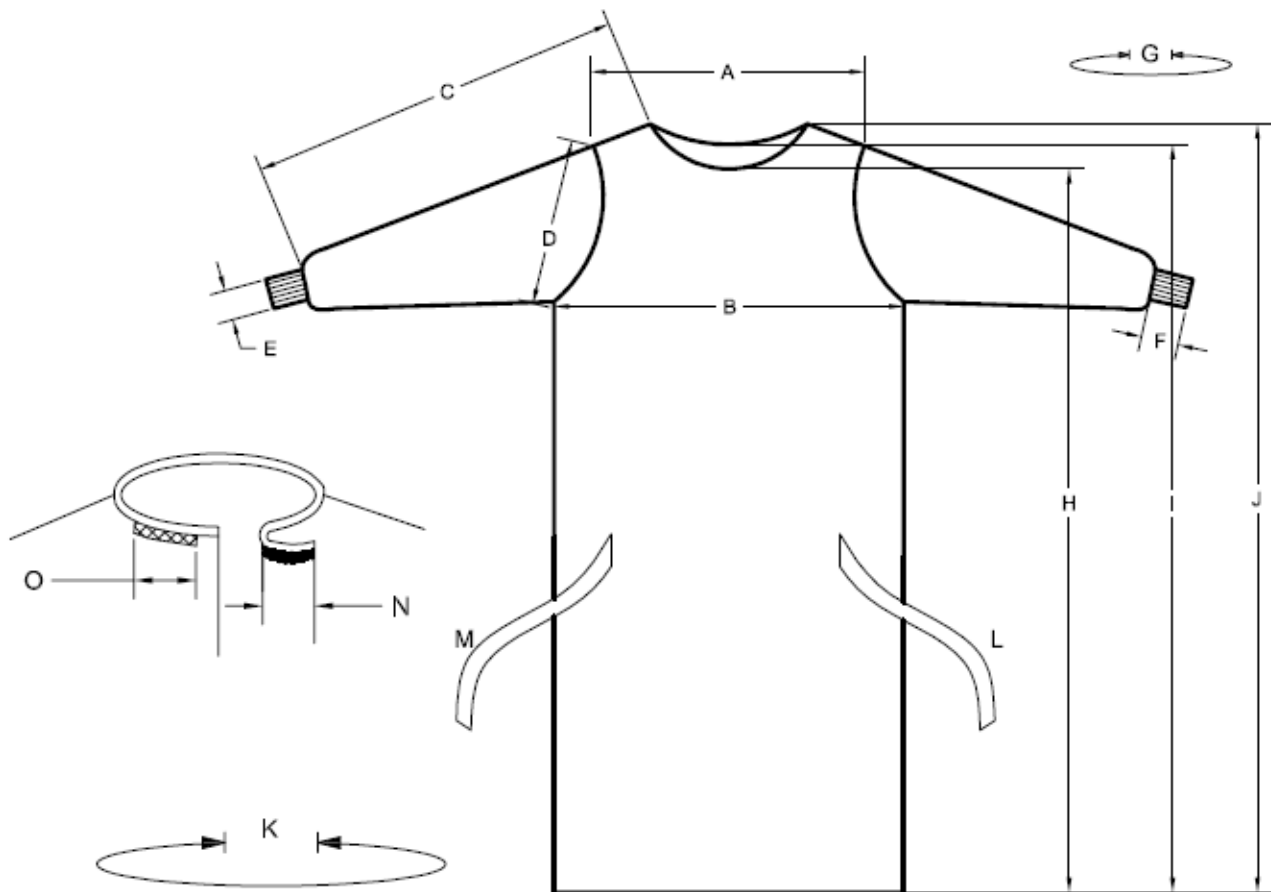
PRODUCT CLASSIFICATION: CLASS I Medical Device



SMS "EXPO" SINGLE-USE GOWN IN NWF		
MEASUREMENTS	PACKAGE	CODE
SIZE XL	12 pcs	270424

TECHNICAL FEATURES OF THE MATERIAL			
GOWN BODY			
SMS MICROFIBRE ANTISTATIC WATER-REPELLENT NWF			
S.M.S. Microfibre Non-Woven Fabric (Spunbond + Melt-Blown + Spunbond) water/blood-repellent. This non-woven fabric has an exceptional multi-layered "sandwich" structure, consisting of a layer of Melt-Blown fibres between two outer layers of Spunbond non-woven fabric. This heterogeneous structure makes for a non-woven fabric with a high level of resistance and tensile strength, while maintaining great softness, excellent drapability and considerable comfort of use. The SMS non-woven fabric forms a perfect barrier against liquids and particles while maintaining excellent air permeability. The long filaments that make up the outer layers of the non-woven fabric offer excellent mechanical resistance to traction, torsion and abrasion, and it also forms an extremely effective barrier to bacteria. This non-woven fabric improves the safety of the operating block due to the delay of flammability over time, and is a non-irritating product.			
Weight	g/m ²		35
Colour	Light blue		
EN 13795 TEST	UNIT OF MEASURE	VALUE	METHOD
CD TENSILE STRENGTH - DRY	N	70.4/39.2	EN 29073-3
CD TENSILE STRENGTH - WET	N	66/38.7	EN 29073-3
MICROBIAL CLEANING	Log (10) cfu/dm ²	0.0	EN 1174
PARTICLE RELEASE – LINTING	Log (10)	3.30	ISO 9073-10
CLEANING PARTICLES	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 THE PENETRATION OF LIQUIDS	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





Dimensions of gown - Measurements in 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	Circumference of neck	71	74	75
H	Length of gown from the centre	120	122	125
I	Length of gown	127	130	131
J	Maximum length of gown	128	133	134
K	Total circumference of the gown	149	148	160
L	Belt length	43	43	43
M	Belt length	66	66	66
N	Velcro rough side	5	5	5
O	Velcro soft side	18	18	18

