

## STERILE GOWN IN LIGHT BLUE SPUNBOND NONWOVEN WITH CUFF

Disposable gown made of light blue Spunbond nonwoven fabric, particularly suitable for visitors, operands or health workers for short or outpatient operations. Being disposable eliminates the risk of cross contamination. Coat with excellent fit, allows normal movements without causing tears in the fabric. Used in the postoperative room and in the ward, it offers the same characteristics as a normal fabric gown. The non-woven fabric used constitutes a bacteriological barrier allowing at the same time a high breathability of the skin avoiding the rise in body temperature.

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

- Coat made of Spunbond non-woven fabric in light blue polypropylene
- Coat with adjustable belt in TNT applied in the front
- Overall size: length 110 cm - width 130 cm
- Neck closure with rear laces
- Collar edged in T.N.T.
- Cuffs in polyester and cotton jersey

### 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.

### CND: T0205 (national classification of medical devices)

### PRODUCT CLASSIFICATION: CLASS IS Medical Device

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DIMENSIONS	PACKAGING	CODE
110 x 130 CM	50 pcs	270414



<b>TECHNICAL SPECIFICATIONS OF THE MATERIALS</b>	
<b>SPUNBOND NON WOVEN FABRIC</b>	
Non-woven fabric made of 100% polypropylene fibers, made up of tightly woven non-orderly fibres that do not allow bacteria to penetrate but allow free air circulation. It is soft, provides good resistance in dry and wet conditions.	
COLOR	LIGHT BLUE
WEIGHT	30 g/m <sup>2</sup> ± 5 (DIN 53854)
TENSION	MD= 45 N/5 cm CD= 50 N/5 cm (TEST = DIN 5358)
ELONGATION	MD=45 - 60 % CD= 45 - 60 % ( TEST=DIN 53857)
TENSILE STRENGTH	MD= 12N CD=12N (TEST=DIN 54301)
AIR PERMEABILITY	550 [l/min/dm <sup>2</sup> ] 1,0 mbar (TEST=DIN53887)

