

NON-STERILE SINGLE-USE BLUE GOWN WITH CUFFS

Non-sterile single-use gown in light blue Spunbond non-woven fabric with cotton cuffs, particularly suitable for visitors and operators, or for health workers who perform short or outpatient operations. This gown of excellent fit allows for normal movement without risk of tearing the fabric. Used in the post-operative room and in the ward, it offers the same features as a normal fabric gown. The non-woven fabric constitutes a bacteriological barrier but also allows high breathability of the skin, avoiding the rise in body temperature. Being single-use, it eliminates the risk of cross-contamination.

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 120 cm - width 140 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:

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: T0205 (national classification of medical devices)



PRODUCT CLASSIFICATION: CLASS I Medical Device		
NON-STERILE SINGLE-USE BLUE GOWN WITH CUFFS		
DIMENSIONS	PACKAGING	CODE
120 x 140 CM	50 pcs	270426

TECHNICAL SPECIFICATIONS OF THE MATERIALS	
SPUNBOND NON WOVEN FABRIC	
Non-woven fabric made of 100% polypropylene fibres, 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 ² ±5
TENSILE STRENGTH	MD= 80.00 N/5 cm (± 10.0)
TENSILE STRENGTH	CD= 50.50 N/5 cm (± 6.5)
ELONGATION%	MD= 100 (± 15.0)

