

**STERILE SINGLE-USE GREEN GOWN WITH CUFFS**

Sterile single-use gown in green 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  $\pm 5\%$

- Dimensions of gown: length 120 cm - width 140 cm
- Gown with adjustable belt in non-woven fabric at the front
- Neck closure with laces at the back
- Collar with hem in non-woven fabric

**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 in protective wrapping, individually packaged in bags/blisters for peel-open sterilization marked with the sterilization batch and 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.

**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 devices listed in this document, consisting of non-woven fabric (NWF), can be disposed of as non-hazardous waste in authorized plants, including incineration, in accordance with current regulations.

However, if the devices used during surgical procedures in the operating room are exposed to contact with the patient's biological fluids, they 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

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|--|------------------|---------------|
| <b>CND: T0205 (national classification of medical devices)</b> |                  |               |
| <b>PRODUCT CLASSIFICATION: CLASS IS Medical Device</b>         |                  |               |
| <b>STERILE SINGLE-USE GREEN GOWN WITH CUFFS</b>                |                  |               |
| <b>DIMENSIONS</b>  | <b>PACKAGING</b> | <b>CODE</b>   |
| <b>120 x 140 CM</b>  | <b>50 pcs</b>    | <b>270427</b> |

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| <b>TECHNICAL FEATURES OF THE MATERIALS</b>   |  |
| <b>GREEN SPUNBOND NON-WOVEN FABRIC</b>   |  |
| Non-woven fabric composed of 100% polypropylene fibres, made up of non-ordered intertwined fibres that do not allow bacteria to penetrate but allow for free circulation of air. It is soft, drapable and has good resistance when dry and when wet. |  |
| COLOUR   | GREEN  |
| DENSITY  | 30 g/m <sup>2</sup> ±5                                   |
| 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 = 12 N CD = 12 N (TEST = DIN 54301)                   |
| AIR PERMEABILITY   | 550 [l/min/dm <sup>2</sup> ] 1,0 mbar (TEST = DIN 53887) |

