

GREEN SURGICAL CAP WITH LACES

Non Sterile medical device disposable for hospital use for head protection of operators. Surgical cap in PP Spunbond nonwoven with laces. The non woven material create a bacteriological barrier while, at the same time, allowing the skin to breathe, so that the body temperature does not rise. Its safeguards against cross-contamination

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

- Cap made up of 3 stitched parts:
 - A drop top cap 24,5 x 16 cm
 - Two lateral bands 8 x 31 cm
- 2 laces 24,5 cm each
- Green colour

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:

The packaging consist of a cardboard box in cellulose.

STERILIZATION:

No sterile devices

SHELF LIFE : Best before 5 years from the manufacturing date

QUALITY CONTROL:

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

- **EN ISO 13485:2016**

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

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: T0207 (national classification of medical devices)

PRODUCT CLASSIFICATION: CLASS I Medical Device

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PACK	CODE
100/500 pcs	270503



TECHNICAL SPECIFICATIONS OF THE MATERIALS	
SPUNBOND NON WOVEN FABRIC	
Polypropylene Spunbond nonwoven fabric.	
COLOUR	Green
WEIGHT	35 g/m ² ± 5

