

NON STERILE GREEN ROUND CUP WITH ELASTIC

Round headgear "Charlotte" model in light blue Spunbond absorbent non-woven fabric, particularly suitable for visitors, staff and operands. Being disposable eliminates the risk of cross contamination. 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. It is a soft, resistant, air permeable and highly extensible headgear.

Color_ green

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

- Circular shaped cap with 53cm diameter
- Cuff with elastic on the whole diameter
- Cap of shape and size such as to completely retain even thick hair

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**

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

NON STERILE GREEN SURGICAL CAP WITH ELASTIC

SIZE	PACKAGING	CODE
DIAMETER 53 CM	1000 pcs	270505



TECHNICAL SPECIFICATIONS OF THE MATERIALS	
SPUNBOND NON WOVEN FABRIC	
Polypropylene Spunbond non-woven fabric made of 100% polypropylene fibres. Composition allows for free air circulation. It is soft, and performs good resistance both in dry and wet conditions.	
COLOR	Green
WEIGHT	15 g/m ² ± 5

