

## STERILE SET FOR PATIENT

Sterile single-use non-woven set used to clothe the patient during surgical or in-office procedures.

### DEVICE CLASSIFICATION

<b>Class Is</b>	<b>Disposable</b>	<b>STERILE</b>
<b>CND:</b> T0202 - SURGICAL KITS (National classification of medical devices IT)		
<b>GMDN:</b> Not applicable		

**PACK: 50 Kits**

**CODE: 270101**

Kit composition:

PIECES	DESCRIPTION	MEASURES
No. 1	BLUE NON-WOVEN OPERATOR GOWN WITH CUFFS	115x135 CM
No. 1	PERFORATED NON-WOVEN HEAD CAP WITH ELASTIC	Ø 53 CM
No. 2	CPE LIQUID PROOF SHOE COVERS WITH ELASTIC OPENING	36 CM

### APPLICABLE STANDARDS

EN ISO 13485; UNI-EN ISO 14644-1

### MANUFACTURING ENVIRONMENT

The product is manufactured and packaged in a controlled environment clean room. Class ISO 8.

### STERILIZATION

Ethylene oxide sterilized kit.

### PACKAGING

Sterile article, the components of which are individually folded and wrapped in medical-grade drapes. Kit packed in peel-open sterilization pouches in plastic film material and medical paper. The sets in single packaging are packed in cardboard boxes protected internally by a polyethylene sheath. End-product packaging is sealed and impermeable to direct and indirect light sources.

#### Device with removable double adhesive labelling to facilitate traceability.

Each bag is provided with a removable adhesive label to make it easier for operators to trace the devices used during operations. The removable parts of the label can be detached from the envelope and attached to the medical record or any other document that - depending on the procedures used - is necessary for traceability.

### EXPIRY

This product is valid for 59 months from the sterilization date (MONTH-YEAR). The expiry date indicated refers to the product in its unopened and correctly stored packaging.

### LABELING

Each individual package has an inner label visible through the transparent wrapping; this label is complete with all the information necessary to identify the product:

- commercial name of the product
- product code number
- manufacturer's name
- sterilization method
- batch number
- expiry date
- sterile symbol
- disposable symbol
- place of production
- CE marking and number of the notified body
- warnings



## GENERAL PRECAUTIONS AND WARNINGS

This product should only be used by qualified and trained personnel. Always read the label.

## DISPOSAL

The devices listed in this document must be disposed of as hospital waste and may not be sent to the incinerator.

## LATEX AND PHTHALATE FREE

- This is a latex free product
- This is a PVC free product
- This product does not contain substances (glues, chemical substances etc.) that can cause allergies or skin rashes of any kind.



## DETAILED TECHNICAL CHARACTERISTICS OF SET COMPONENTS

WATER-REPELLENT SPUNBOND NON-WOVEN GOWN WITH CUFFS		
Single-use gown in white Non-Woven Spunbond fabric, particularly suitable for patients during brief or in-office procedures. As it is single-use, it eliminates the risk of cross-contamination. Excellent fitting gown, allows normal movements without causing the fabric to tear.		
<b>TECHNICAL CHARACTERISTICS:</b> (Dimensional tolerance $\pm 5\%$ )		
<ul style="list-style-type: none"> <li>Gown made with Spunbond Non-Woven white polypropylene</li> <li>Gown length: 115 cm</li> <li>Gown width: 135 cm</li> <li>Gown with Non-Woven adjustable belt applied at the front</li> <li>Closure of the collar with ties at the back</li> </ul>		
PIECES	DESCRIPTION	MEASURES
1	WATER-REPELLENT NON-WOVEN GOWN WITH CUFFS	115x135 CM
MATERIAL TECHNICAL FEATURES		
WATER-REPELLENT SPUNBOND NON-WOVEN FABRIC		
100% polypropylene fibre non-woven fabric, composed of tightly non-woven fibres that allow air to circulate freely. It is soft, adjustable and features good resistance, both dry and wet.		
COLOUR	Light blue	
GRAMMAGE	30 g/m <sup>2</sup> $\pm 2$	

PERFORATED NON-WOVEN HEAD CAP		
Round "Charlotte" model head cap in light blue Non-Woven Spunbond fabric, particularly suited for visitors, staff and operators. As it is single-use, it eliminates the risk of cross-contamination. The Non-Woven fabric is a bacteriological barrier that also ensures high scalp breathability, preventing the body temperature from rising. It is a soft, resistant, air-permeable, high-stretch head cap.		
<b>TECHNICAL CHARACTERISTICS:</b> (Dimensional tolerance $\pm 5\%$ )		
<ul style="list-style-type: none"> <li>Round cap shape <math>\varnothing</math> 53 cm</li> <li>Anallergic cap with elastic along entire diameter</li> <li>Cap shape and size able to retain even thick hair</li> </ul>		
PIECES	DESCRIPTION	MEASURES
1	HEAD CAP WITH ELASTIC	$\varnothing$ 53 CM
MATERIAL TECHNICAL FEATURES		
LIGHT BLUE SPUNBOND NON-WOVEN FABRIC		
100% polypropylene fibre non-woven fabric, composed of tightly non-woven fibres that do not allow bacteria to penetrate, but do allow air to circulate freely. It is soft, adjustable and features good resistance, both dry and wet.		
COLOUR	Light blue	
GRAMMAGE	15 g/m <sup>2</sup> $\pm 5$ (DIN 53854)	

LIQUID PROOF SHOE COVERS		
Single-use blue C.P.E. shoe covers, for effective protection in wet or dry conditions. Shoe covers used in the room as protection for the operator against infected liquids and to avoid polluting the operating field or sterile and sanitised environments.		
<b>TECHNICAL CHARACTERISTICS:</b> (Dimensional tolerance $\pm 5\%$ )		
<ul style="list-style-type: none"> <li>One-size shoe covers with versatile fit suitable for every type of foot</li> <li>Shoe covers with elastic at the ankle</li> <li>Blue high purity CPE shoe covers (Chlorinated polyethylene)</li> <li>Dimensions: length 36 cm, height 15 cm</li> </ul>		
PIECES	DESCRIPTION	MEASURES
2	CPE LIQUID PROOF SHOE COVERS WITH ELASTIC OPENING	36 CM

