

## STERILE DOCTOR SET

Sterile single-use non-woven set used to clothe the operator/doctor 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: 40 Kits**

**CODE: 270102**

Set composition:

PIECES	DESCRIPTION	MEASURES/SIZE
1	WATER-REPELLENT NON-WOVEN GOWN WITH CUFFS	115x135 CM
1	HEAD CAP FOR SURGEON WITH FIXED TIES	
1	SURGICAL MASK WITH ELASTICS	
2	CPE LIQUID PROOF SHOE COVERS WITH ELASTIC OPENING	36 CM

### APPLICABLE STANDARDS

EN ISO 13485; UNI-EN ISO 14644-1

### PRODUCTION ENVIRONMENT

The set is manufactured and packaged in designated controlled clean room. Class ISO 8.

### STERILIZATION

Ethylene oxide sterilized kit.

### PACKAGING

Sterile article, with individually folded components wrapped in bags for peel-open sterilisation, made with plastic film and medical grade paper. The sets, individually packaged, are packed in cardboard boxes, internally protected with a polyethylene sheath. The unopened package is guaranteed resistant to direct and indirect light sources.

**Device equipped with double removable adhesive labeling to facilitate traceability.**

Each peel-open bag is provided with a removable adhesive label to facilitate operators in the operations related to the traceability of the devices used during surgeries.

The removable adhesive label can be detached from the bag and stuck to the medical record or to any other document which, according to the procedures used, is used for traceability.

### EXPIRY

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

### LABELING

Each individual set is provided with an internal label visible through the transparent casing; this label is complete with all the information needed to identify the product:

- product trade name
- product code number
- manufacturer name
- production batch number
- expiry date
- single-use symbol
- place of production
- CE marking
- warnings



## GENERAL PRECAUTIONS AND WARNINGS

This product should only be used by qualified and trained personnel. Always read the label.  
Storage is in the original cardboard boxes, indoors and in a clean environment away from sunlight

## PRODUCT DISPOSAL

The devices listed in this document can be eliminated as non-hazardous waste in authorised plants, including incinerators, complying 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 can cause allergies or any kind of skin rash.



## DETAILED TECHNICAL FEATURES OF SET COMPONENTS

<b>WATER-REPELLENT SPUNBOUND NON-WOVEN GOWN WITH CUFFS</b>		
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 SPUNBOUND 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> $\pm 5$	

<b>HEAD CAP FOR SURGEON WITH FIXED TIES</b>		
Single-use non-woven cap for surgeon with fixed ties, with shape and size that completely isolate the head and hair. Also especially recommended for long procedures in the operating room as the perforated absorbent non-woven fabric offers excellent breathability. The Non-Woven fabric is a bacteriological barrier that also ensures high scalp breathability, preventing the body temperature from rising. As it is single-use, it eliminates the risk of cross-contamination.		
<b>TECHNICAL CHARACTERISTICS:</b> Dimensional tolerance $\pm 5\%$		
<ul style="list-style-type: none"> <li>Head cap composed of 3 sewn parts: <ul style="list-style-type: none"> <li>top oval drop-shaped cap 24.5x16 cm</li> <li>two dome-shaped side bands 8x31 cm</li> </ul> </li> <li>2 rear fixed ties 24.5 cm each</li> <li>Green</li> </ul>		
PIECES	DESCRIPTION	
1	HEAD CAP FOR SURGEON WITH FIXED TIES	
MATERIAL TECHNICAL FEATURES		
GREEN SPUNBOUND 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	Green	
GRAMMAGE	35 g/m <sup>2</sup> $\pm 5$	

<b>MASK WITH ELASTICS</b>		
Mask with elastics and three layers of non-woven fabric: soft coloured non-woven fabric, PFE and BFE anti-particulate and anti-bacterial filter, comfortable non-woven fabric inside. Blue mask with white elastics and incorporated nose clip.		
<b>TECHNICAL CHARACTERISTICS:</b> (Dimensional tolerance $\pm 5\%$ )		
<ul style="list-style-type: none"> <li><b>Bacterial filtration efficiency: &gt; 99% (BFE)</b></li> <li><b>Particle filtration efficiency: 0.1 <math>\mu</math> &gt; 99% - <math>\Delta P</math> &lt; 3.0 mm H<sub>2</sub>O/cm<sup>2</sup> (PFE)</b></li> <li>Mask size: Height: 95 mm – Length: 175 mm – Nose clip: 105 cm</li> <li>Mask compliant with standard EN 14683 Type II</li> <li>External layer 100% PP Spunbond</li> <li>Filtering layer 100% PP Meltblown</li> <li>Internal layer 100% PP Spunbond</li> <li>Blue</li> </ul>		
PIECES	DESCRIPTION	
1	SURGICAL MASK WITH ELASTICS	

<b>LIQUID PROOF SHOE COVERS</b>		
Blue single-use C.P.E. 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, offering effective protection in both wet and dry conditions.		
<b>TECHNICAL CHARACTERISTICS:</b> Dimensional tolerance $\pm 5\%$		



# Euronda | Alle<sup>®</sup> TECHNICAL DATA SHEET

- One-size shoe covers with versatile fit suitable for every type of foot
- Shoe covers with elastic at the ankle
- Blue high purity CPE shoe covers (Chlorinated polyethylene)
- Dimensions: length 36 cm, height 15 cm

PIECES	DESCRIPTION	MEASURES
2	CPE LIQUID PROOF SHOE COVERS WITH ELASTIC OPENING	36 CM

