

STERILE ASSISTANT SET	
Sterile single-use non-woven set used to clothe the operator/assistant during surgical or in-office procedures.	

DEVICE CLASSIFICATION		
Class Is	Disposable	STERILE
CND: T0202 - SURGICAL KITS (National classification of medical devices IT)		
GMDN: Not applicable		

PACK: 40 Kits	CODE: 270103	
Kit composition:		
PIECES	DESCRIPTION	MEASURES
1	BLUE NON-WOVEN OPERATOR GOWN WITH CUFFS	115x135 CM
1	PERFORATED NON-WOVEN HEAD CAP	Ø 53 CM
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:
<ul style="list-style-type: none"> • product trade name • product code number • manufacturer name • sterilisation method • production batch number • expiry date • sterile symbol • single-use 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.
Storage is in the original cardboard boxes, indoors and in a clean environment away from sunlight

PRODUCT DISPOSAL

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

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

BLUE SPUNBOND NON-WOVEN GOWN WITH CUFFS		
Single-use gown in light blue Non-Woven Spunbond fabric, particularly suitable for surgeons 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.		
TECHNICAL CHARACTERISTICS: (Dimensional tolerance $\pm 5\%$)		
<ul style="list-style-type: none"> Gown made with Spunbond Non-Woven blue polypropylene Gown length: 115 cm Gown width: 135 cm Gown with Non-Woven adjustable belt applied at the front Closure of the collar with ties at the back Gown with cuffs 		
PIECES	DESCRIPTION	MEASURES
1	BLUE NON-WOVEN OPERATOR GOWN WITH CUFFS	115x135 CM
MATERIAL TECHNICAL FEATURES		
LIGHT BLUE 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 ² ± 5	

PERFORATED NON-WOVEN HEAD CAP		
Round "Charlot" model protective cap with elastic along the entire diameter. Cap made with absorbent perforated and breathable Non-Woven fabric. Cap with shape and size that completely isolate the head and hair. Also recommended for long procedures as the perforated non-woven fabric offers excellent breathability. 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.		
TECHNICAL CHARACTERISTICS: (Dimensional tolerance $\pm 5\%$)		
<ul style="list-style-type: none"> Cap composed of a single piece of \varnothing 50 cm Cap with elastic along the entire diameter Blue cap Cap with shape and dimensions that adapt to every size 		
PIECES	DESCRIPTION	MEASURES
1	PERFORATED NON-WOVEN HEAD CAP	\varnothing 53 CM
MATERIAL TECHNICAL FEATURES		
PERFORATED NON-WOVEN FABRIC		
Perforated non-woven fabric, it is soft, adjustable and features good resistance, both dry and wet. It does not have any unpleasant odours, it does not cause allergies, it is physiologically safe.		
Colour	Light blue	
Grammage	15 g/m ² ± 5 (DIN 53854)	
Tensile strength	MD 28 N-CD 5 N (dry)	

SURGICAL MASK PTC3 WITH ELASTICS		
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.		
TECHNICAL CHARACTERISTICS: (Dimensional tolerance $\pm 5\%$)		
<ul style="list-style-type: none"> Bacterial filtration efficiency: > 99% (BFE) Particle filtration efficiency: 0.1 μ > 99% - ΔP < 3.0 mm H₂O/cm² (PFE) Mask size: Height: 95 mm – Length: 175 mm – Nose clip: 105 cm Mask compliant with standard EN 14683 Type II External layer 100% PP Spunbond Filtering layer 100% PP Meltblown Internal layer 100% PP Spunbond Blue 		
PIECES	DESCRIPTION	
1	SURGICAL MASK PTC3 WITH ELASTICS	



IMPERMEABLE 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.		
TECHNICAL CHARACTERISTICS: (Dimensional tolerance $\pm 5\%$)		
<ul style="list-style-type: none"> • 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

