

DOCTOR SET

Sterile single-use non-woven set used to clothe the operator/doctor 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: 20 Kits

CODE: 270126

Set composition:

PIECES	DESCRIPTION	MEASURES/SIZE
1	SMS NON-WOVEN FABRIC EXPO MODEL SURGICAL GOWN	SIZE L
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

Sterilisation is carried out with ethylene oxide, the sterilisation process is validated on a regular basis and kept under constant control through routine analyses, the residual sterilising gas is contained within the limits set forth by the laws in force. Sterilisation is carried out by a specialised laboratory.

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

SURGICAL GOWN KIT			
<p>Non-sterile specialist wrap-around gown for operator for surgical procedures, made with water- and alcohol-repellent medical Non-Woven S.M.S Microfibre, uniform non-reflecting light blue. The special wrap-around shape offers excellent fit, making it ideal for long surgical procedures. The anti-static and water-repellent fabric represents a bacteriological barrier which also offers high scalp breathability, preventing the body temperature from rising. As it is single-use, it eliminates the risk of cross-contamination.</p>			
<p>TECHNICAL CHARACTERISTICS: Dimensional tolerance $\pm 5\%$</p>			
<ul style="list-style-type: none"> • Closure of the wrap-around gown, overlapping on the back with 4 ties • The outer closing ties are marked by a non-contagion tag • Gown closure on neck with wraparound and overlapping Velcro. • Ultrasound heat-sealed sleeves • Polyester gown cuffs • 2 hand towels packed with the gown 			
PIECES	DESCRIPTION	SIZE	
1	SMS NON-WOVEN FABRIC EXPO MODEL SURGICAL GOWN	SIZE L	
TECHNICAL CHARACTERISTICS OF THE MATERIALS			
GOWN BODY			
SMS MICROFIBRE ANTISTATIC WATER-REPELLENT NON-WOVEN FABRIC			
<p>S.M.S. Microfibre Non-Woven fabric (Spunbond + Melt-Blown + Spunbond) water/blood repellent. This non-woven fabric features an exceptional "sandwich" multi-layered structure consisting of two external layers of Spunbond non-woven fabric that enclose a layer of Melt-Blown fibres. This heterogeneous structure offers a non-woven fabric with a high level of strength and resistance to friction, while maintaining great softness, exceptional adjustability and considerably convenient use. SMS Non-Woven fabric represents the perfect barrier against liquids and particles, maintaining excellent permeability to air. The long filaments that comprise the external layers of Non-Woven fabric provide this material with excellent mechanical resistance to friction, torsion and abrasion; plus it represents an extremely efficient barrier against bacteria. This Non-Woven fabric improves the safety of the surgical ward thanks to its flame-retardant properties and is a non-irritating product.</p>			
Weight	g/m ²	35	
Colour	Light blue		
TEST EN 13795	UNIT OF MEASURE	VALUE	METHOD
TENSILE STRENGTH MD/CD – DRY	N	70.4/39.2	EN 29073-3
TENSILE STRENGTH MD/CD – WET	N	66/38.7	EN 29073-3
MICROBIAL CLEANING	Log (10) cfu/dm ²	0.0	EN 1174
LINTING	Log (10)	3.30	ISO 9073-10
PARTICULATE CLEANING	IPM	3.10	ISO 9073-10
RESISTANCE TO MICROBIAL PENETRATION – DRY	Log (10) cfu	1.28	ISO 22612
RESISTANCE TO MICROBIAL PENETRATION – WET	BI	4.50	ISO 22610
RESISTANCE TO LIQUID PENETRATION	Cm H ₂ O	38.00	EN 20811
BURSTING PRESSURE – DRY	KPa	110.80	EN 13938-1
BURSTING PRESSURE – WET	KPa	104.00	EN 13938-1
HEAD CAP FOR SURGEON WITH FIXED TIES			
<p>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.</p>			
<p>TECHNICAL CHARACTERISTICS: Dimensional tolerance $\pm 5\%$</p>			
<ul style="list-style-type: none"> • Head cap composed of 3 sewn parts: <ul style="list-style-type: none"> ▪ top oval drop-shaped cap 24.5x16 cm ▪ two dome-shaped side bands 8x31 cm • 2 rear fixed ties 24.5 cm each • Green 			
PIECES	DESCRIPTION		
1	HEAD CAP FOR SURGEON WITH FIXED TIES		
TECHNICAL CHARACTERISTICS OF THE MATERIALS			
GREEN SPUNBOND NON-WOVEN FABRIC			
<p>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.</p>			
COLOUR	Green		
GRAMMAGE	35 g/m ² ± 5		



MASK 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 $\pm 5\%$)

- **Bacterial filtration efficiency: > 99% (BFE)**
- **Particle filtration efficiency: $0.1 \mu > 99\%$ - $\Delta P < 3.0 \text{ mm H}_2\text{O}/\text{cm}^2$ (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 WITH ELASTICS

LIQUID PROOF SHOE COVERS

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.

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

- 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

