

BASE SET

Disposable sterile set for oral implantology surgery. Device used for preparing the sterile field and for covering the dentist, assistants and the patient.

DEVICE CLASSIFICATION

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

PACK: 10 Kits

CODE: 270106

Kit composition:

UNITS	DESCRIPTION	MEASURES
N. 1	LIGHT BLUE NON-WOVEN FABRIC GOWN WITH CUFFS	115x135 CM
N. 2	LIGHT BLUE NON-WOVEN FABRIC GOWN WITH ELASTICS	120x140 CM
N. 1	SURGICAL CAP WITH FIXED TIES	
N. 2	ROUND CAPS WITH ELASTIC	Ø 53 CM
N. 1	FACEMASK WITH TIES	
N. 2	MONOART FACEMASK PTC3	
N. 1	TWO LAYERS DRAPE WITH U CUT WITH ADHESIVE (TNT+ PE)	75x90/cut 11x9
N. 2	TWO LAYERS SURGICAL DRAPE (TNT+ PE)	50x75 CM
N. 2	TUBING SLEEVE WITH ELASTICS	50x50 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

The set is sterilized with ethylene oxide.

PACKAGING

Sterile set, whose components are individually folded and wrapped in the medical grade paper that acts as a wrapper. The set is packaged in peel-open bags made of a plastic film and medical paper. The single sets are packed in cardboard boxes, internally protected by 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:

- trade name of the product
- product code number
- name of the manufacturer
- sterilization method
- production batch number
- Expiration date
- sterile symbol
- disposable symbol



- production place
- 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.

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 skin manifestation.



DETAILED TECHNICAL FEATURES OF SET COMPONENTS

LIGHT BLUE NONWOVEN FABRIC GOWN WITH CUFFS		
Disposable gown made of blue Spunbond nonwoven fabric, suitable for short or ambulatory operations. It eliminates the risk of cross contamination. The gown has an excellent fit, allowing normal movements without causing tears to the fabric.		
TECHNICAL FEATURES: (Dimensional tolerance) $\pm 5\%$		
<ul style="list-style-type: none"> Gown made of Spunbond non-woven fabric in light blue polypropylene Gown length: 115 cm Gown width: 135 cm Gown with adjustable belt in T.N.T. applied in the front Neck closure with back straps Gown with cuffs 		
UNITS	DESCRIPTION	MEASURES
N. 1	LIGHT BLUE NONWOVEN FABRIC GOWN WITH CUFFS	115x135 CM
MATERIAL TECHNICAL FEATURES		
BLUE NONWOVEN FABRIC		
Non-woven fabric composed of 100% polypropylene fibers, made of tightly woven fibers that allow free air circulation. It is soft, drapable and has good dry and wet resistance.		
COLOUR	Light Blue	
WEIGHT	30 g/m ² ± 5	

LIGHT BLUE NON WWOVEN FABRIC GOWN WITH ELASTICS		
Disposable gown made of blue Spunbond nonwoven fabric, suitable for short or ambulatory operations. It eliminates the risk of cross contamination. The gown has an excellent fit, allowing normal movements without causing tears to the fabric.		
TECHNICAL FEATURES: (Dimensional tolerance) $\pm 5\%$		
<ul style="list-style-type: none"> Gown made of Spunbond non-woven fabric in light blue polypropylene Gown length: 120 cm Gown width: 140 cm Gown with adjustable belt in T.N.T. applied in the front Neck closure with back straps Gown with elastics 		
UNITS	DESCRIPTION	MEASURES
N. 2	LIGHT BLUE NON WWOVEN FABRIC GOWN WITH ELASTICS	115x135 CM
MATERIAL TECHNICAL FEATURES		
BLUE NONWOVEN FABRIC		
Non-woven fabric composed of 100% polypropylene fibers, made of tightly woven fibers that allow free air circulation. It is soft, drapable and has good dry and wet resistance.		
COLOR	Light Blue	
WEIGHT	30 g/m ² ± 5	

LIGHT BLUE NON WOVEN FABRIC SURGICAL CAP WITH FIXED LACES		
Disposable cap for surgeons with fixed laces made of non-woven fabric, shaped and sized such as to completely isolate the head and hair. Especially recommended in the operating room, even for long-term operations as the perforated absorbent non-woven fabric of which it is made allows excellent breathability. The non-woven fabric acts as a bacteriological barrier while allowing a high breathability of the skin and avoiding a rise in body temperature. It eliminates the risk of cross contamination.		
TECHNICAL FEATURES: (Dimensional tolerance) $\pm 5\%$		
The cap is made of 3 sewn parts: <ul style="list-style-type: none"> An oval-shaped upper part 24.5x16 cm Two side bands 8x31 cm Two fixed rear laces 24.5 cm each 		
UNITS	DESCRIPTION	
N. 1	LIGHT BLUE NONWOVEN FABRIC SURGICAL CAP WITH FIXED LACES	



MATERIAL TECHNICAL FEATURES	
BLUE SPUNBOND NONWOVEN FABRIC	
Non-woven fabric made of of 100% polypropylene fibers. It is soft, drapable and has good dry and wet resistance.	
COLOR	Light Blue
WEIGHT	35 g/m ² ± 5

LIGHT BLUE NON-WOVEN FABRIC CAPS WITH ELASTIC	
"Charlotte" round cap in blue Spunbond nonwoven fabric, particularly suitable for visitors, staff and operands. It eliminates the risk of cross contamination. The non-woven fabric used constitutes a bacteriological barrier while allowing a high breathability of the skin and avoiding a rise in body temperature. It is a soft, resistant, air permeable and highly extensible cap.	

TECHNICAL FEATURES: (Dimensional tolerance) ± 5%	
<ul style="list-style-type: none"> • Circular cap with a diameter of 53 cm • Cap with hypoallergenic elastic on the whole diameter • Cap of a shape and size such as to completely hold thick hair 	

UNITS	DESCRIPTION	MEASURES
N. 2	ROUND CAP WITH ELASTIC	Ø 53 CM

MATERIAL TECHNICAL FEATURES	
BLUE SPUNBOND NONWOVEN FABRIC	
Non-woven fabric made of of 100% polypropylene fibers that do not allow bacteria to penetrate but allow free air circulation. It is soft, drapable and has good dry and wet resistance.	
COLOR	Light Blue
WEIGHT	15 g/m ² ± 5 (DIN 53854)

FACEMASK WITH TIES	
Intended Use: Non sterile medical device used by medical or paramedical staff in operating room; this medical device protect the patient from the microbial agent transmission.	
Surgical mask with elastics for the bacteriological safety, the materials are made to confer a high degree of lightness. Composed of 3 layers of nonwoven fabric, each structured differently for specific function and protective. (EU Standard Class IR)	

TECHNICAL FEATURES: (Dimensional tolerance) ± 5%	
<ul style="list-style-type: none"> • Surgical Mask conformed to EN 14683 "SURGICAL MASKS: REQUIREMENT AND TEST METHODS" Bacterial filtration efficiency: ≥ 95% approx.. (BFE) (Testing performed by Nelson Laboratories Inc. - Salt Lake City, U.S.A.) • Breathing Resistance: $\Delta P \leq 5,0 \text{ mm. H}_2\text{O/cm}^2$ (Testing performed by Nelson Laboratories Inc. - Salt Lake City, U.S.A.) • Splash resistance: >120 mmhg (Testing performed by Nelson Laboratories Inc. - Salt Lake City, U.S.A.) • Mask dimensions: Height: folded 95 mm – open 187 mm; Length: 178 mm 	

PIECES	DESCRIPTION
N. 1	SURGICAL FACEMASK WITH TIES

LAYER	DESCRIPTION	COMPOSITION
I° (outer)	Layer of water repellent blue Nonwovens	Nonwovens: 100% polypropylene SPUNBOND Weight: 34 g/m ²
II° (central)	Filter in Nonwovens (smooth fibre free filter), white color and with power filter (BFE) ≥ 95% and $\Delta P \leq 5,0 \text{ mm H}_2\text{O/cm}^2$	Nonwovens: 100% polypropylene MELTBLOWN weight: 25 g/m ²
III° (internal)	Layer of Nonwovens soft white and smooth, devoid of free fibers. This material is tested and certified that does not cause skin irritation.	Nonwovens: 100% polypropylene SPUNBOND Weight: 14 g/m ²
CLIPS	Clips encapsulated inside the mask in extra pure aluminum lightweight Dimensions 4 x 125 mm	Molded alluminum thick 0,6 mm PE covered.
TIES	Four white ties dimensions : 11x433 mm	Nonwovens: 100% polypropylene SPUNBOND Weight:: 40 g/m ²



- Material: NON-TOXIC, ANALLERGIC, ANTISTATIC and ODORLESS
- TOTAL ABSENCE OF GLASS FIBERS
- Does not disperse fibers
- Does not contain adhesives, chemical agents or resins often responsible for allergic reactions.
- LATEX FREE (absence of rubber latex)
- Mask made of material that in case of incineration at normal temperatures does not release toxic or polluting residues
- WATER-REPELLENT mask externally
- LIGHT BLUE mask
- Anti-fog mask
- Anti-glare color mask

THREELAYERS NON-WOVEN FABRIC MASKS WITH ELASTICS

Mask with three layers of non-woven fabric: soft colored TNT, anti-particulate and antibacterial PFE and BFE filter, comfortable TNT inside.
Light blue mask with white elastic bands and built-in nose clip.

TECHNICAL FEATURES: (Dimensional tolerance) $\pm 5\%$

- **Filtering capacity:** $\geq 99\%$ (BFE)
- Mask size: Height: folded 90 mm - Length: 175 mm

UNITS	DESCRIPTION
N. 1	THREELAYERS NONWOVEN FABRIC MASKS WITH ELASTICS

TWOLAYERS DISPOSABLE DRAPES

Disposable drapes made of absorbent waterproof double-layered light blue material.
The double-layered material allows a total bacteriological barrier both in wet and dry conditions; consists of 2 layers:

- Light blue tissue layer with absorbing power
- Waterproof layer in transparent polyethylene

TECHNICAL FEATURES: (Dimensional tolerance) $\pm 5\%$

PIECES	DESCRIPTION	MEASURES
N. 2	TWOLAYERS DRAPES	50x75 CM
N. 1	TWOLAYERS DRAPES	75x90 CM

MATERIAL TECHNICAL FEATURES

BI-COUPLED WATERPROOF AND ABSORBENT DRAPE

High absorbency material composed of 100% cellulose coupled with a waterproof PE layer.

- Absorbent layer in pure light blue cellulose (100%)
- Waterproof layer in transparent polyethylene (100%)

GRAMMAGE	g/m ²		54
COLOUR	Light blue		
TEST EN 13795	MEASUREMENT UNIT	VALUE	METHOD
RESISTANCE TO TRACTION - DRY	N/50 mm	45.00	EN 29073-3
RESISTANCE TO TRACTION - HUMID	N/50 mm	30.00	EN 29073-3
MICROBIAL CLEANING	Log (10) cfu/dm ²	1.18	EN 11737
RESISTANCE TO MICROBIC - DRY PENETRATION	Log (10) cfu	< 1	ISO 22612
RESISTANCE TO MICROBIAL - HUMID PENETRATION	BI	6.00	ISO 22610
RESISTANCE TO PENETRATION OF LIQUIDS	Cm H ₂ O	160.00	EN 20811
BURST PRESSURE - DRY	KPa	108.00	EN 13938-1
EXPLOSION PRESSURE - WET	KPa	95.00	EN 13938-1
RELEASE OF PARTICLES - LINTING	Log (10)	3.20	ISO 9073-10

TUBING SLEEVE WITH ELASTICS

Transparent low density polyethylene cover with fixing elastics

PIECES	DESCRIPTION	MEASURES
N. 1	TUBING SLEEVE WITH ELASTICS	120x7 CM

