DATA SHEET Information

Ref. **2SVAST020715**

Tray Set

DIAGNOSTIC PROCEDURES KIT

Description

The Diagnostic Procedures Kit is a sterile, single-use operating field procedure pack consisting of devices for diagnostic procedures. The kits help to increase productivity in the operating room by shortening preparation time of the operating field and standardising the materials needed for surgery.

Q.TA'	COMPONENTS
1	Trilaminate drape 50x50 cm foldable
1	Laminate drape 40x50 cm
1	Bilaminate drape 150x200 cm
1	Trilaminate coronary angiography drape 240x370 cm
1	Bilaminate drape 100x150 cm foldable
4	Instruments cover diam. 140 cm
2	Instruments cover diam. 80 cm
4	Single-use paper towel 40x50 cm
2	Reinforced surgical gown size XXL
1	Surgical gloves No. 7
3	Surgical gloves No. 8
1	Bowl 120 ml
1	Bowl 1000 ml
1	Transparent bowl 120 ml
1	Sterile urine container 150 ml
1	Blue graded tray 250 ml
1	Thin Tip Clamp 14 cm
1	Iris Scissor str 14 cm
1	Graded bowl 3000 ml
1	Angiographic syringe 12 ml
1	Scalpel No. 11
10	Gauze swabs 10x10 cm 16 ply (10 pcs)
1	Needle 18 G
1	Needle 21 G
1	Needle 22 G
1	Syringe 20 ml LL
1	Syringe 10 ml LL
1	Bowl for tubing

Sterile components contained in the kit:

1	**J guide for angiographic catheter 3 mm 0.035" 150 PTFE**

MATERIAL SPECIFICATIONS

All devices are manufactured from non-toxic and non-pyrogenic materials prescribed and approved by the official pharmacopoeia.

TRILAMINATE DRAPE 50X50 CM FOLDABLE:

Tri-ply nonwoven sheet **(TABLE 1)** 50x50 cm laminated in one piece of 68.8 g/sqm by *Hot Melt Technology*. Excellent resistance to tearing and tensile strength, consisting of a TNT layer with high absorbency, a layer made of waterproof Polyethylene and a PP layer. Excluding weaving, knitting, stitching and traditional felting, as well as paper products, in compliance with the provisions of Directive 93/42/EEC (Legislative Decree no. 46/1997) on medical devices. If several sheets are to be joined, this will be done by continuous welding along the entire length to ensure the continuity of the antibacterial barrier.

TECHNICAL CHARACTERISTICS:

1. **Drapability**: highly drapable and soft drape, such that it conforms naturally to the patients' body; high resistance to tearing;
2. **Absorbent capacity**: The sheet has one side with high absorbency 290 g/sqm (EN 13795), This feature ensures the absorption of liquids during interventions and reduces the cleaning time in the operating theatre;
3. **Resistance in** wet conditions: the sheet ensures maximum sterility even for prolonged wet operations (EN13795);
4. **Impermeability** and resistance to liquid **penetration**: the polyethylene layer guarantees impermeability and resistance to the passage of liquids, such that the sheet is totally impermeable, water and alcohol repellent, creating an antimicrobial barrier (EN 13795-3);
5. **NO linting**: No transmission of microorganisms to the surgical wound. The risk of inflammatory processes is avoided;
6. **No release of particles or dust**;
7. **Folded in accordance with correct aseptic technique, it** avoids contamination when creating the operating field and covering the patient, which can also be performed by a single operator. The drape is provided with graphic indications that allow for correct positioning of the drape as well as easy removal of the *liner*, hence easy application;
8. **It does not contain any substance included in the ECHA SVHC (Substances of Very High Concern) list in an amount exceeding 0.1% by weight** (referring to Art. 57 Reg. *1907/2006 REACH and subsequent amendments*).

Table 1 - *Technical characteristics of three-ply nonwoven*

FEATURE	UNITS OF MEASUREMENT	METHOD	VALUE [1]	EN 13795-3 [2]
GRAMMING	g/m²	M.I.P.1	68.8 +/- 10%	NOT REQUIRED
ABSORBANCE	g/m²	M.I.A.1	290 +/- 10%	NOT REQUIRED
RESISTANCE TO MICROBIAL PENETRATION DRY	Log_{10} (CFU)	ISO 22612	ABSENCE OF PENETRATION	< = 2 [3]
RESISTANCE TO WET MICROBIAL PENETRATION	BI	ISO 22610	6	6
MICROBIAL CLEANING	Log_{10} (CFU/100 cm²)	EN 1174-2	0.9	< 2
MICROBIAL CLEANLINESS UNDER SPECIAL CONDITIONS	Log_{10} (PM)	ISO 9073-10	1.08	< 3.5
LINTING	Log_{10} (Linting)	ISO 9073-10	1.11	< 4
RESISTANCE TO LIQUID PENETRATION	cm H O_2	EN 20811	139	> = 100
DRY BURST PRESSURE RESISTANCE	kPa	ISO 13938-1	125	> = 40
WET BURST PRESSURE RESISTANCE	kPa	ISO 13938-1	113	> = 40
DRY TENSILE STRENGTH	N/50 mm	EN ISO 29073-3	72.6	> = 20
WET TENSILE STRENGTH	N/50 mm	EN ISO 29073-3	53.7	> = 20
COLOUR			LIGHT BLUE	

FEATURES	METHOD	RESULT
CYTOXICITY	ISO 10993	Negative
PRESENCE OF LATEX		LATEX FREE
PRESENCE OF PHTHALATES		FTALATI FREE
FIRE REACTION CLASS		I
ANTI-RFLECT		SI
ANTISTATICITY		SI

[1] Value obtained after sterilisation, except for the microbial cleanliness value
[2] Requirements referring to high performance in critical product areas.
[3] Requirements referring to high performance in the less critical areas of the product.

LAMINATE DRAPE 40X50 CM:

Absorbent non-woven fabric **(TABLE 2)** 40x50 cm laminated in one piece of 121 g/sqm by *Hot Melt Technology*. Excellent tear and tensile strength, consisting of a highly absorbent TNT layer, a waterproof polyethylene layer and a white cellulose middle layer. Excluding weaving, knitting, stitching and traditional felting, as well as paper products, in compliance with the provisions of Directive 93/42/EEC (Legislative Decree no. 46/1997) on medical devices. If several sheets are to be joined, this will be done by continuous welding along the entire length to ensure the continuity of the antibacterial barrier.

Table 2 - *Technical characteristics of absorbent TNT*

FEATURE	UNITS OF MEASUREMENT	METHOD	VALUE [1]	EN 13795-3 [2]
GRAMMING	g/m²	M.I.P.1	121 +/- 10%	NOT REQUIRED
ABSORBANCE	g/m²	M.I.A.1	950 +/- 10%	NOT REQUIRED
RESISTANCE TO MICROBIAL PENETRATION DRY	Log_{10} (CFU)	ISO 22612	ABSENCE OF PENETRATION	< = 2 [3]
RESISTANCE TO WET MICROBIAL PENETRATION	BI	ISO 22610	6	6
MICROBIAL CLEANING	Log_{10} (CFU/100 cm²)	EN 1174-2	0.9	< 2
MICROBIAL CLEANLINESS UNDER SPECIAL CONDITIONS	Log_{10} (PM)	ISO 9073-10	1.08	< 3.5
LINTING	Log_{10} (Linting)	ISO 9073-10	1.11	< 4
RESISTANCE TO LIQUID PENETRATION	cm H O_2	EN 20811	139	> = 100
DRY BURST PRESSURE RESISTANCE	kPa	ISO 13938-1	125	> = 40
WET BURST PRESSURE RESISTANCE	kPa	ISO 13938-1	113	> = 40
DRY TENSILE STRENGTH	N/50 mm	EN ISO 29073-3	67.1	> = 20
WET TENSILE STRENGTH	N/50 mm	EN ISO 29073-3	40.4	> = 20
COLOUR			LIGHT BLUE	

FEATURES	METHOD	RESULT
CYTOXICITY	ISO 10993	Negative
PRESENCE OF LATEX		LATEX FREE
PRESENCE OF PHTHALATES		FTALATI FREE
FIRE REACTION CLASS		I
ANTI-RFLECT		SI
ANTISTATICITY		SI

[1] Value obtained after sterilisation, except for the microbial cleanliness value
[2] Requirements referring to high performance in critical product areas.
[3] Requirements referring to high performance in the less critical areas of the product.

BILAMINATE DRAPE:

TNT+PE sheet **(TABLE 3)** laminated in one piece of 54 g/sqm by *Hot Melt Technology*. Excellent resistance to tearing and traction, composed of a layer of TNT with high absorbent capacity and a layer consisting of waterproof polyethylene coextruded with TNT, excluding weaving, knitting, stitching and traditional felting, as well as paper products, in compliance with the provisions of Directive 93/42/EEC (Legislative Decree no. 46/1997) on medical devices. If several sheets are to be joined, this will be done by continuous welding along the entire length to ensure the continuity of the antibacterial barrier.

- Bilaminate drape 150x200 cm;
- Bilaminate drape 100x150 cm.

TECHNICAL CHARACTERISTICS:

1. **Drapability**: highly drapable and soft drape, such that it conforms naturally to the patients' body; high resistance to tearing;
2. **Absorbent capacity**: The sheet has one side with high absorbency 243 g/sqm (EN 13795), This feature ensures the absorption of liquids during interventions and reduces the cleaning time in the operating theatre;
3. **Resistance in** wet conditions: the sheet ensures maximum sterility even for prolonged wet operations (EN13795);
4. **Impermeability** and resistance to liquid **penetration**: the polyethylene layer guarantees impermeability and resistance to the passage of liquids, such that the sheet is totally impermeable, water and alcohol repellent, creating an antimicrobial barrier (EN 13795-3);
5. **NO linting**: No transmission of microorganisms to the surgical wound. The risk of inflammatory processes is avoided;
6. **No release of particles or dust**;
7. **Folded in accordance with correct aseptic technique, it** avoids contamination when creating the operating field and covering the patient, which can also be performed by a single operator. The drape is provided with graphic indications that allow for correct positioning of the drape as well as easy removal of the *liner*, hence easy application;
8. **It does not contain any substance included in the ECHA SVHC (Substances of Very High Concern) list in an amount exceeding 0.1% by weight** (referring to Art. 57 Reg. *1907/2006 REACH and subsequent amendments*).

Table 3 - *Technical characteristics of TNT+PE*

FEATURE	UNITS OF MEASUREMENT	METHOD	VALUE [1]	EN 13795-3 [2]
GRAMMING	g/m²	M.I.P.1	54 +/- 10%	NOT REQUIRED
ABSORBANCE	g/m²	M.I.A.1	243 +/- 10%	NOT REQUIRED
RESISTANCE TO MICROBIAL PENETRATION DRY	Log_{10} (CFU)	ISO 22612	ABSENCE OF PENETRATION	≤ 2 [3]
RESISTANCE TO WET MICROBIAL PENETRATION	BI	ISO 22610	6	6
MICROBIAL CLEANING	Log_{10} (CFU/100cm²)	EN 1174-2	0.9	< 2
MICROBIAL CLEANLINESS UNDER SPECIAL CONDITIONS	Log_{10} (PM)	ISO 9073-10	1.08	< 3.5
LINTING	Log_{10} (Linting)	ISO 9073-10	1.11	< 4
RESISTANCE TO LIQUID PENETRATION	cm H O_2	EN 20811	139	≥ 100
DRY BURST PRESSURE RESISTANCE	kPa	ISO 13938-1	125	≥ 40
WET BURST PRESSURE RESISTANCE	kPa	ISO 13938-1	113	≥ 40
TENSILE STRENGTH DRY	N/50 mm	EN ISO 29073-3	49	≥ 20
WET TENSILE STRENGTH	N/50 mm	EN ISO 29073-3	31.5	≥ 20
COLOUR			LIGHT BLUE	

FEATURES	METHOD	RESULT
CYTOXICITY	ISO 10993	Negative
PRESENCE OF LATEX		LATEX FREE
PRESENCE OF PHTHALATES		FTALATI FREE
FIRE REACTION CLASS		I
ANTI-RFLECT		SI
ANTISTATICITY		SI

[1] Value obtained after sterilisation, except for the microbial cleanliness value
[2] Requirements referring to high performance in critical product areas.
[3] Requirements referring to high performance in the less critical areas of the product.

TRILAMINATE CORONARY ANGIOGRAPHY DRAPE 240X370 CM:

Angiography drape 240X370 cm made of triacoupled, waterproof and absorbent non-woven fabric for total and abundant patient coverage. There are two femoral holes with incision film and two radial adhesive medical grade holes surrounded by absorbent reinforcement. At the end of the drape there are two transparent PE bands to control the bed and X-ray equipment.

TECHNICAL CHARACTERISTICS:

1. **Adhesive hold**: tested hypoallergenic and liquid-resistant adhesive, it guarantees a high degree of hold with low probability of wrinkling even during prolonged interventions;
2. **Easy positioning:** the drape is highly drapable and soft, so that it conforms to the patients' body and makes positioning quick and easy;
3. **Drapability:** highly drapable and soft drape, such that it conforms naturally to the patients' body; high resistance to tearing;
4. **Absorbent capacity:** The sheet has one side with high absorbency 290 g/sqm (EN 13795). This characteristic guarantees the absorption of liquids during interventions and reduces the cleaning time in the operating theatre;
5. **Resistance in** wet conditions**:** the sheet ensures maximum sterility even for prolonged wet operations (EN13795);
6. **Impermeability and resistance to liquid penetration:** the polyethylene layer guarantees impermeability and resistance to the passage of liquids, such that the sheet is totally impermeable, repellent to water and alcohol, creating an antimicrobial barrier (EN 13795);
7. **Antistaticity:** the sheet has an antistatic treatment that prevents the build-up of electrical charges, which eliminates any inconvenience related to the presence of accumulated charge;
8. **NO linting:** No transmission of microorganisms to the surgical wound. The risk of inflammatory processes is avoided;
9. **Bending in accordance with correct aseptic technique, avoiding contamination during manoeuvring.**

DIMENSIONS:

- Three-ply non-woven cloth **(TABLE 4)** 100x370 cm;
- Two transparent PE sidebands **(TABLE 5)** 70x370 cm;
- Two holes with incision film **(TABLE 6)** for femoral access diameter 10 cm drilled 6 cm;
- Two medical-grade adhesive holes **(TABLE 7)** for radial access diameter 7 cm;
- Reinforcement area in absorbent TNT **(TABLE 8)** 90x140 cm.

Table 4 - *Technical characteristics of **three-ply** nonwoven*

FEATURE	UNITS OF MEASUREMENT	METHOD	VALUE [1]	EN 13795-3 [2]
GRAMMING	g/m²	M.I.P.1	68.8 +/- 10%	NOT REQUIRED
ABSORBANCE	g/m²	M.I.A.1	290 +/- 10%	NOT REQUIRED
RESISTANCE TO MICROBIAL PENETRATION DRY	Log_{10} (CFU)	ISO 22612	ABSENCE OF PENETRATION	< = 2 [3]
RESISTANCE TO WET MICROBIAL PENETRATION	BI	ISO 22610	6	6
MICROBIAL CLEANING	Log_{10} (CFU/100 cm²)	EN 1174-2	0.9	< 2
MICROBIAL CLEANLINESS UNDER SPECIAL CONDITIONS	Log_{10} (PM)	ISO 9073-10	1.08	< 3.5
LINTING	Log_{10} (Linting)	ISO 9073-10	1.11	< 4
RESISTANCE TO LIQUID PENETRATION	cm H O_2	EN 20811	139	> = 100
DRY BURST PRESSURE RESISTANCE	kPa	ISO 13938-1	125	> = 40
WET BURST PRESSURE RESISTANCE	kPa	ISO 13938-1	113	> = 40
DRY TENSILE STRENGTH	N/50 mm	EN ISO 29073-3	72.6	> = 20
WET TENSILE STRENGTH	N/50 mm	EN ISO 29073-3	53.7	> = 20
COLOUR			LIGHT BLUE	

FEATURES	METHOD	RESULT
CYTOXICITY	ISO 10993	Negative
PRESENCE OF LATEX		LATEX FREE
PRESENCE OF PHTHALATES		FTALATI FREE
FIRE REACTION CLASS		I
ANTI-RFLECT		SI
ANTISTATICITY		SI

[1] Value obtained after sterilisation, except for the microbial cleanliness value
[2] Requirements referring to high performance in critical product areas.
[3] Requirements referring to high performance in the less critical areas of the product.

Table 5 - *Technical characteristics of LDPE Polyethylene*

PROPERTIES	UNITS OF MEASURE MENT	TEST METHOD	NOMINAL VALUES	TOLERANCES
DENSITY	g/cm^3	INTERNAL METHOD	0.9220	
THICKNESS	µm	ASTM D374	50	± 5%
MODULUS OF ELASTICITY MD	Mpa	ASTM D882-02	200	± 10%
ELASTIC MODULUS TD	Mpa	ASTM D882-02	220	± 10%
YIELD STRENGTH TD	Mpa	ASTM D882-02	8	± 10%
MAXIMUM LOAD MD	Mpa	ASTM D882-02	19	± 10%
MAXIMUM TD LOAD	Mpa	ASTM D882-02	17	± 10%
ELONGATION AT BREAK MD	%	ASTM D882-02	350	± 10%
ELONGATION AT BREAK TD	%	ASTM D882-02	>550	/
COLOUR			NEUTRAL	

Table 6 - *Technical characteristics of the INCISION* ***FILM***

LINER	135 G WHITE ONE-SIDE COATED PAPER
SUPPORT	25 MICRON PU FILM PROTECTED WITH PE COVER
ADHESIVE	ACRYLIC (PURE ACRYLIC POLYMERS IN WATER DISPERSION) HYPO-ALLERGENIC SELF-CROSSLINKING AGENT

Table 7 - *Technical characteristics of MEDICAL GRADE BIADESIVE*

Hypoallergenic, hypoallergenic and non-toxic adhesive, tested and liquid resistant, with very low probability of wrinkling even during prolonged operations, easily removable when the drape is removed. It leaves no glue residue on the patient's skin of sufficient size to ensure tightness during surgery.

SHEET ADHESIVE EDGE	BIADHESIVE MEDICAL GRADE
SUPPORT	IN POLYPROPYLENE
ADHESIVE	ACRYLIC (PURE ACRYLIC POLYMERS IN WATER DISPERSION) HYPO-ALLERGENIC
PAPER PROTECTION	BISILICONED GLASSINE OF THE ADHESIVE LAYER

Table 8 - *Technical characteristics of the ABSORBENT REINFORCEMENT*

FEATURE	UNITS OF MEASUREMENT	METHOD	VALUE [1]	EN 13795-3 [2]
GRAMMING	g/m²	M.I.P.1	121 +/- 10%	NOT REQUIRED
ABSORBANCE	g/m²	M.I.A.1	950 +/- 10%	NOT REQUIRED
RESISTANCE TO MICROBIAL PENETRATION DRY	Log_{10} (CFU)	ISO 22612	ABSENCE OF PENETRATION	< = 2 [3]
RESISTANCE TO WET MICROBIAL PENETRATION	BI	ISO 22610	6	6
MICROBIAL CLEANING	Log_{10} (CFU/100 cm²)	EN 1174-2	0.9	< 2
MICROBIAL CLEANLINESS UNDER SPECIAL CONDITIONS	Log_{10} (PM)	ISO 9073-10	1.08	< 3.5
LINTING	Log_{10} (Linting)	ISO 9073-10	1.11	< 4
RESISTANCE TO LIQUID PENETRATION	cm H O_2	EN 20811	139	> = 100
DRY BURST PRESSURE RESISTANCE	kPa	ISO 13938-1	125	> = 40
WET BURST PRESSURE RESISTANCE	kPa	ISO 13938-1	113	> = 40
DRY TENSILE STRENGTH	N/50 mm	EN ISO 29073-3	67.1	> = 20
WET TENSILE STRENGTH	N/50 mm	EN ISO 29073-3	40.4	> = 20
COLOUR			LIGHT BLUE	

FEATURES	METHOD	RESULT
CYTOXICITY	ISO 10993	Negative
PRESENCE OF LATEX		LATEX FREE
PRESENCE OF PHTHALATES		FTALATI FREE
FIRE REACTION CLASS		I
ANTI-RFLECT		SI
ANTISTATICITY		SI

[1] Value obtained after sterilisation, except for the microbial cleanliness value
[2] Requirements referring to high performance in critical product areas.
[3] Requirements referring to high performance in the less critical areas of the product.

INSTRUMENTS COVER:

Transparent polyethylene covering system **(TABLE 9) designed to be ready for** use and to give maximum flexibility during preparation; intended for covering equipment in the operating theatre in order to protect it from accidental contact with liquids and to maintain the sterile field.

- 140 cm diameter instrument cover in transparent PE with elastic band;
- 80 cm diameter instrument cover in transparent PE with elastic band.

Table 9 - *Technical characteristics of LDPE Polyethylene*

PROPERTIES	UNITS OF MEASUREMENT	TEST METHOD	NOMINAL VALUES	TOLERANCES
DENSITY	g/cm^3	INTERNAL METHOD	0.9220	
THICKNESS	µm	ASTM D374	50	± 5%
MODULUS OF ELASTICITY MD	Mpa	ASTM D882-02	200	± 10%
ELASTIC MODULUS TD	Mpa	ASTM D882-02	220	± 10%
YIELD STRENGTH TD	Mpa	ASTM D882-02	8	± 10%
MAXIMUM LOAD MD	Mpa	ASTM D882-02	19	± 10%
MAXIMUM TD LOAD	Mpa	ASTM D882-02	17	± 10%
ELONGATION AT BREAK MD	%	ASTM D882-02	350	± 10%
ELONGATION AT BREAK TD	%	ASTM D882-02	>550	/
COLOUR			NEUTRAL	

SINGLE-USE PAPER TOWEL 40X50 CM:

A towel made of high-quality dry paper with double S-embossing, which gives it a high absorbency capacity of up to 6 times its weight.
Resistant, practical and hygienic. Its suitability for skin contact makes it suitable for use in healthcare facilities, both for cleaning patients and for cleansing all kinds of surfaces.

REINFORCED SURGICAL GOWN SIZE XXL:

[2]Surgical gown in 40 g/m 'SMS' triple-layer polypropylene non-woven fabric **(TABLE 10),** water-repellent, breathable and antistatic. Reinforced at the front and on the sleeves by means of antistatic plastic laminates applied without stitching; body made in one piece, without vertical and/or horizontal stitching; back wallet fastening with 4 TNT laces fixed to the body of the gown by seamless heat-sealing and anti-pollution tag; elasticised cotton knit cuffs; adjustable neck fastening with Velcro; no. 2 hand towels.

Each gown is individually bagged.

Table 10 - *Technical characteristics of polypropylene three-layer TNT 'SMS*

PROPERTIES	UNITS OF MEASUREMENT	VALUE	TEST METHOD
THICKNESS	mm	0.40	ASTM D 3776
DRY TENSILE STRENGTH MD	N	54	EN29073-3
DRY TENSILE STRENGTH CD	N	50	EN29073-3
TENSILE STRENGTH A WET MD	N	50	EN29073-3
TENSILE STRENGTH WET CD	N	49	EN29073-3
TEAR RESISTANCE MD	N	48	EN29073-4
TEAR RESISTANCE CD	N	52	EN29073-4
DRY BURST PRESSURE	KPa	210 ÷ 230	EN13938-1
WET BURST PRESSURE	KPa	180 ÷ 220	EN13938-1
CLEANING - CONTAMINATING PARTICLES	log media	3.4	ISO9073-10
LIQUID PENETRATION RESISTANCE	cm	11	EN20811
RESISTANCE PENETR. MICROBIC DRY	log media	2	EN22612
RESISTANCE PENETR. MICROBIC WET	IB	4.5	EN22610
LINTING - PARTICLE RELEASE	log media	3.9	ISO9073-10
DETERMINATION LIQUID CONTROL	%	41	UNI8279
FIRE RESISTANCE CLASS		I	

SURGICAL GLOVES:

Latex glove for exploration and protection, single-use, ambidextrous, micro-roughened surface for easy donning, good protection against chemicals, perfectly adapted to the hand.

- Surgical gloves No. 7;
- Surgical gloves No. 8.

GRADUATED POLYPROPYLENE BOWLS:

Bowls made of polypropylene, a durable and easy-to-clean material.

- Bowl 120 ml;
- Bowl 1000 ml;
- Transparent bowl 120 ml;
- Blue graded tray 250 ml;
- Graded bowl 3000 ml;
- Bowl for tubing.

STERILE URINE CONTAINER 150 ML

Urinalysis container 150 ml volume. Screw cap.

THIN TIP CLAMP 14 CM:

AISI-410 stainless steel pliers **(TABLE 11)**. Length 14 cm.

Table 11 - *Technical characteristics of surgical instruments Pliers*

DESCRIPTION	CARBON	MAGNESIA	PHOSPHORUS	SULPHUR	SILICON	CHROME
AISI 410	0.150	1.00	0.040	0.030	1.00	12.50

IRIS SCISSOR STR 14 CM:

AISI-420 stainless steel scissors **(TABLE 12)**. Length 14 cm.

Table 12 - *Technical characteristics of surgical instruments* ***SCISSORS***

DESCRIPTION	CARBON	MAGNESIA	PHOSPHORUS	SULPHUR	SILICON	CHROME
AISI 420	0.250	1.00	0.040	0.030	1.00	13.00

ANGIOGRAPHIC SYRINGE 12 ML:

12 ml polycarbonate angiography syringe luer lock cone, transparent with rubber piston seals, large support surface for easy aspiration and injection.

SCALPEL NO. 11:

Disposable scalpel Fig. 11 with plastic handle for medical use and blade protection.
Stainless steel blade.

GAUZE SWABS 10X10 CM 16 PLY (10 PCS):

Medical Device in compliance with Annex IX of Directive 93/42/EEC as amended.
The gauze pads are made of pure cotton fibres (100 % cotton in accordance with Directive 96/74/EC transposed into Italian law by Legislative Decree 194/1999) of the highest quality, pure white, with a regular, non-skewed weave. Each fibre has a flattened tubular shape, thick and rounded walls, and consists exclusively of typical cotton fibres approximately 4 cm long. Fray-free, not frayed by bleaching and dried by passing through a calender.
The gauze tablets are packaged in bags of 10.

NEEDLES:
Triple sharpened hypodermic needle in AISI 304 stainless steel, non-toxic and apyrogenic, medical grade polypropylene barrel, transparent polypropylene needle cover.

- Aug 18 G;
- Aug 21 G;
- Aug 22 G.

SYRINGE:
Syringes with non-toxic and non-pyrogenic polypropylene cylinder equipped with a stopper that prevents the piston from falling out. Polypropylene piston, medical rubber plunger (latex free).

- Syringe 20 ml LL;
- Syringe 10 ml LL.

STERILE CONTENTS IN THE KIT:

J GUIDE FOR ANGIOGRAPHIC CATHETER 3 MM 0.035" 150 PTFE:
0.035" guide, consisting of a stainless steel core with PTFE coating designed to minimise friction and aid tracking. J-tip with 3 mm radius. Guide length 150 cm.

Medical Device Class: III
RDM: 1913103/R
CND: C04020202

PACKAGING

The kit is packaged according to UNI EN ISO 11607 reference standards.

PRIMARY PACKAGING

The ready-to-use pack consists of a paper/plastic pouch with Tyvek insert suitable for sterilisation, hermetically sealed. Quantity: 1 kit per pouch.
The label on the packaging presents all the information and features necessary for identification of the device, and traceability is ensured by two detachable adhesive daughter labels.

THE FOLLOWING INDICATIONS APPEAR ON THE PRIMARY PACKAGING:

1. Trade name;
2. Product code;
3. Lot number;
4. Description of the composition of the 'Tray Set' with measurements, dimensions and length (where applicable);
5. Date of Manufacture;
6. Expiry date;
7. Method of sterilisation;
8. Disposable and CE product symbol;
9. Name and address of the manufacturer;

SECONDARY PACKAGING

Sturdy and resistant cardboard box for transport and possible storage, dimensions 79 x 39 x 40 cm type kmfmk/44244/eb grammage 1590 g/sqm suitable for sterilisation containing 4 kits per pack.

THE FOLLOWING INDICATIONS APPEAR ON THE PACKAGING:

10. Trade name;
11. Product code;
12. Lot number;
13. Description of the 'Tray Set';
14. Number of pieces contained;
15. Date of Manufacture;
16. Expiry date;
17. Method of sterilisation;
18. Disposable and CE product symbol;
19. Name and address of the manufacturer.

PRESERVATION

The product should be stored at room temperature and away from heat sources and direct exposure to sunlight.

PRODUCTION

The 'Tray Set' is manufactured in the production workshop of SVAS BIOSANA S.p.a. certified according to UNI EN ISO 9001 and UNI EN ISO 13485.
Production is carried out according to validated standard methods in compliance with the express provisions of Directive 93/42/EC, in the absence of allergy-inducing elements.
The device is disposable.

STERILISATION

The kit is sterilised by ethylene oxide according to a validated cycle that does not alter the characteristics of the components in accordance with the harmonised UNI EN ISO 11135-1 standards.

Sterility is valid for 5 years in an unopened package.

DISPOSAL

Follow the legal regulations on hospital waste disposal.

The Components of the Device:

- **Ensure minimal environmental impact with the possibility of disposal by incineration without the formation and release of toxic residues**
- **They are free of dyes classified as sensitisers, allergens, carcinogens, mutagens or toxic to reproduction**
- **They are free of chlorinated components**
- **They do not contain the following flame retardants: PBB (polybrominated biphenyl) CAS No. 59536-65-1;TRIS (tri (2,3-dibromopropyl) phosphate) CAS No. 126-72-7**
- **The primary packaging used complies with UNI EN 13431:2005 - Packaging - Requirements for packaging recoverable in the form of energy recovery including specification of the minimum lower calorific value, having a lower calorific value greater than or equal to 5 MJ/kg**
- **The secondary packaging used complies with the essential requirements of Annex F of Legislative Decree no. 152 of 3 April 2006, as amended and supplemented, containing Environmental Regulations and with UNI EN 13427:2005 - Packaging - Requirements for the use of European standards in the field of packaging and packaging waste.**

CLASSIFICATION

Class **II/A** sterile according to Annex IX relating to Legislative Decree No. 46 of 24/02/1997 concerning Medical Devices as amended.
The class refers to the most critical device in the kit.
CND number T0202
RDM Number **245357/R**

ANNOTATIONS

THE DEVICE COMPLIES WITH CURRENT LEGAL PROVISIONS ON SAFETY AND QUALITY.

Digitally signed by Nicorici Oleg
Date: 2023.10.16 09:33:45 EEST
Reason: MoldSign Signature
Location: Moldova