


 <b>STS MEDICAL GROUP</b> <small>IMPROVING HEALTHCARE THROUGH EFFICIENCY</small>		<b>TECHNICAL DATA SHEET</b>		Doc. No: TD 11 Art. 11, acc. MDD	
Code: 28378 Date: 06.06.2022		DRESSING SET KIT MEDICAZIONE		Edition/Revision:01 Page:1/3	
Prepared by: N. Angelova - Labeling		Checked by: M. Apostolova - RA		Approved by: M. Antalavicheva - RA	
Sign: 	Date: 24.06.22	Sign: 	Date: 24.06.2022	Sign: 	Date: 24.06.22






### 1. Photo of the product



### 2. Description

2.1. Description of the product	
Description of the product	DRESSING SET KIT MEDICAZIONE
Weight (g)	37
Intended Use	The device is intended to be used as a mechanical barrier, for compression, or for absorption of exudates. Non-invasive medical device to be used for dressing procedures.
Risk class	Class I sterile, Rule 4
Trademark	SECUTRAY
Basic UDI-DI	N/A
RDM code	2269681
CND code	T0203- MEDICATION AND AID KITS (only with EC certificate)
Method of sterilization	Sterile EO
Legal Manufacturer	STS Medical Group AD Industrial area Sokolovetz 2800 Sandanski- Bulgaria
Produced by	STS Medical Group AD Industrial area Sokolovetz 2800 Sandanski- Bulgaria
Distributor	N/A
Procedure Pack Producer	N/A
Validity	5 years from the date of the sterilization, if the package is not damaged and after proper storage.
Special storage condition	To be stored in a dry place, away from heat and direct sunlight.
CE Mark	0373

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**2.2. Description of components**

PHOTOS OF THE PRODUCTS	QTY	DESCRIPTION, REF., and SIZE	MATERIAL	COMPOSITION AND CHARACTERISTICS
	1pce/ product	<u>REF: 90567-02</u>  Drape Telino  Size (cm): 38x45	Cellulose Polyethylene	Cellulose tissue-20 gsm Polyolefinic film-24 gsm The raw material is resistant to microbial and liquid penetration. It is not cytotoxic and skin irritating. It is not giving allergenic sensitization in contact with the human body.
	2pcs/ product	<u>REF: 64305SF</u>  Gauze swab, 8 plies Compressa di garza, 8 strati  Size (cm): 7,5x7,5	Gauze	100% Cotton bleached gauze cloth
	3pcs/ product	<u>REF: 63431</u>  Gauze ball Tampone rotondo di garza  Size (mm): Ø60	Gauze Elastic ring	100% cotton
	1pce/ product	<u>REF: 90412</u>  Plastic forceps Pinza verde punta fine  Size (cm): 13	Colourant, Reinforced Polypropylene	Green color
	1pce/ product	<u>REF: 90406</u>  Littauer scissors Forbici per sutura littauer  Size (cm): 12	HANDLES ABS or nylon reinforced with glass fibers BLADES stainless steel 430 EYELET stainless steel, or brass nickel plated	Green color stainless steel blades, thermoplastic handles

**2.3. Packaging detail**
**2.3.1 Primary packaging**
**Size (cm): 17x17x2,5**  
**Pcs per carton: 50**

-	-	<u>REF: 92609</u>  Medical paper	Paper	White medical paper with a lacquered sealing side
-	-	<u>REF: 92640</u>  Foil	PP/ PE adhesive solvent less	-
-	1pce/ product	<u>REF: 96206-05</u>  Product label  Size (cm): 90x73	Paper, adhesive, <u>printing ink</u>	SECUTRAY

**2.3.2 Secondary packaging**
**Size (cm):**  
**PE bag – 58/68/1x15cm**  
**Carton – 390/290/280mm**  
**Cartons per pallet: 64**

-	1pce/ carton	<u>REF: 00321B</u>  PE bag	Polyethylene	LDPE
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-	-	<u>REF: 97737</u> Carton	Corrugated carton	5- layer Brown color
-	1pce/ carton	<u>REF: 96211-03</u> Carton label Size (cm): 90x120	Paper, adhesive, printing ink	SECUTRAY

**3. Containing PVC, Latex, and Phthalates**

PVC		LATEX		PHTHALATES	
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

**4. Symbols on the labels**

**Catalogue number**

**Batch code**

**Use by date**

**Date of manufacture**

**CE mark**

**Do not re-use**

**Keep dry**

**Keep away from sunlight**

**Medical device**

**Manufacturer**

**Sterilized using ethylene oxide**

**Single sterile barrier system**

**Recycle symbol**

**Do not use if the package is damaged**
**5. Applied standards- The list of applied standards is a part of TF.**
**6. List of changes**

Issue	Date	Changes	Signed by		
			Prepared by:	Checked by:	Approved by:
01	06.06.22	First issue	N.A.	M.A.	M.A.