



Surgical Line

Technical Data Sheet – rev.03 – 07.03.2013

## Teli chirurgici sterili TNT + Polietilene

### 1. Identificazione del prodotto/Product identificatin → Teli chirurgici sterili / sterile surgical drape

Classificati nella Classe I secondo la Regola 1 dell'Allegato IX della Direttiva 93/42/CEE e sono marcati CE 0546

Products are classified in Class I in accordance with Rule 1 of Annex IX to Directive 93 /42/EEC and are CE marked 0546

CND = T020102 TELI PER CHIRURGIA SPECIALISTICA

### 2. Identificazione del fabbricante/Manufacturer

Omnia Spa - Via Francesco Delnevo 190 - 43036 Fidenza – Parma

Tel. 0524.527453 – Fax. 0524.525867 - www.omniaspa.eu

### 3. Codici/Codes

Codice/Code	Dimensioni/Dimensions	Descrizione/Description	Materiale/ Material	Colore/ Color
12.T1387.00	50x50 cm	Telo assorbente/impermeabile	TNT + Polietilene  Total nominal grammage 54 gsm	Azzurro
12.T1386.00	50x75 cm			
12.T1354.00	75x90 cm			
12.T1355.00	100x150 cm			
12.T1357.00	150x200 cm			

### Specifiche del materiale/Material specifications:

Physical properties	Test Method		Unit	EN13795-3 [1]	Values [2]
Tensile strength - dry	EN 29073-3	(*)	N / 50 mm	>=20	46.00
Tensile strength - wet	EN 29073-3	(*)	N / 50 mm	>=20	30.00
Cleanliness	EN 11737-1:2006 - Part 1 EN 11737-1:2006 - Part 1	Microbial Particulate matter	Log(10)cfu/dm2 IPM	<=2 <=3,5	0.00 1.40
Resistance to microbial penetration	ISO 22610 - 07-2006	wet	Ib	6.00	6.00
Resistance to liquid penetration	EN 20811 (**)		cm H2O	>100	>991
Bursting strength	EN 13938-1	Dry Wet	KPa KPa	>=40 >=40	105.00 83.00
Peeling (film - substrate A)	Exten		N / 50 mm	not required	1.00
Linting	ISO 9073-10-2003	Particles size >= 3 my	Log(10)	<=4,0	1.60
Absorption (NW side)	Exten (rev.2)		--	not required	IVA
Antibacterial effectiveness [3]	ISO 20743 2007 - Part 2:transfer method (***)	Staphylococcus Aureus Klebsiella Pneumoniae	Log CFU Log CFU	not required not required	0.10 0.00
(*) mean MD - CD values (**) Performed with a supporting tissue to avoid burst opening on non-woven side (***) Absolute values [FYI EMPA 100% cotton values: Staphylococcus Aureus = 2,3 Log CFU - Klebsiella Pneumoniae = 4,4 Log CFU]					
Biocompatibility requirements	Referring Norms		Analysis results		
Cytotoxicity	ISO 10993		not citotoxic		
Skin irritating	ISO 10993		not skin irritating		
Allergenic sensitivisation	ISO 10993		not giving allergenic sensitivisation		
Organotin content	Edana Dic.2002		much below the acceptable levels		
Animal origin materials	1774/2002/EC - 2000/418/EC - 2001/2/EC		conform to the referring norms		
Natural rubber latex content	--		natural rubber latex free		
Heavy metal content (intentionally added)	--		heavy metal free		
Toxicity requirements	Referring Norms		Declarations		
Foodstuffs contact [3]	2002/72/EEC		compliance		
Personal hygiene rules [3]	BGVV statement 3/96		compliance		
USA FDA regulations [3]	21CFR177		compliance		
OEKO-Tex standard 100 [4]	EN 45014		compliance		
[1] High performance requirements for surgical drapes - Part 3:Table 2 - critical product area					
[2] The above figures are an estimate of the expected mean values based on Centexbel laboratories test after EO sterilization in accordance with EN13795-2:2004+A1:2009					

**4. Sterilizzazione/Sterilization**

Il prodotto è sterile fino ad apertura della confezione /*product sterilization until the open of the envelope*

Metodo di sterilizzazione: ossido di etilene/ *sterilized to ethylene oxide in the manner defined in the process of validation*

Il periodo di scadenza è indicato nella forma aaaa-mm / *expiry date in the form yyyy-mm*

**5. Confezionamento/Packaging**

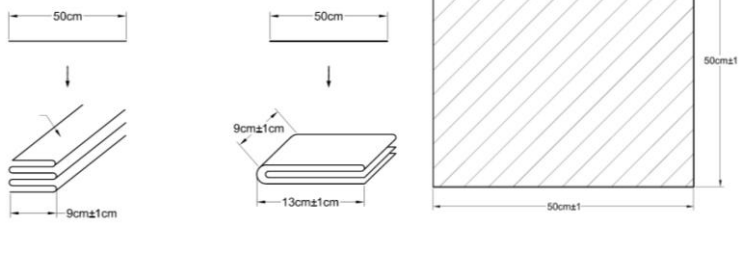
I dispositivi sono confezionati in imballo sterile etichettato con le informazioni relative al codice, lotto, data di scadenza, fabbricante e marchio CE.

*Products are packaged in specific envelope labelled with all information about code, lot, expiry date, manufacturer and CE mark.*

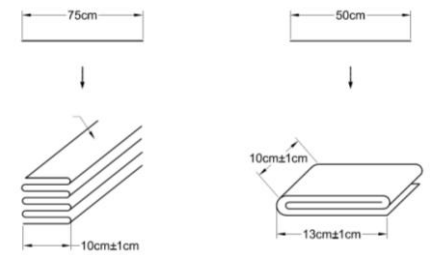
**6. N° di repertorio:**

12.T1387.00 → 228987/R
12.T1386.00 → 231875/R
12.T1354.00 → 231876/R
12.T1355.00 → 231877/R
12.T1357.00 → 229658/R

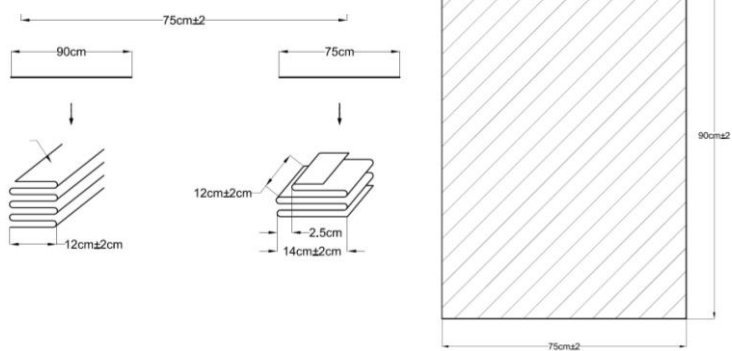
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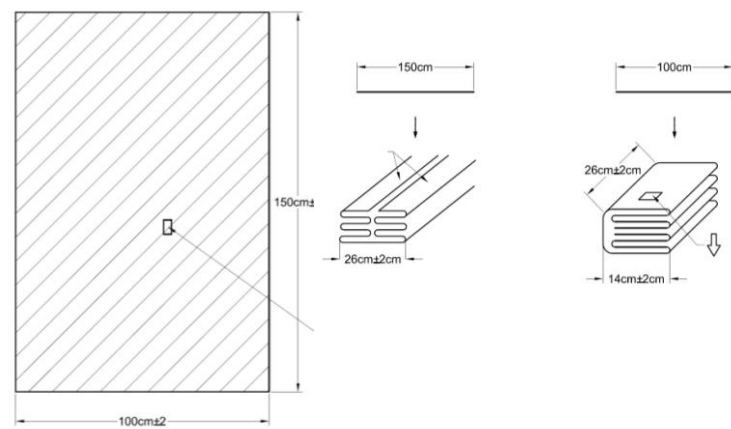
**12.T1386.00**



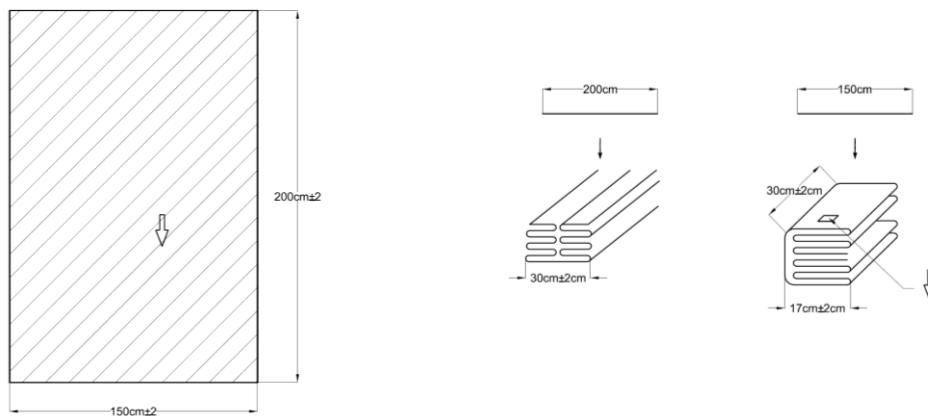
**12.T1354.00**



**12.T1355.00**



**12.T1357.00**



Rev.02 – Inserimento n° di repertorio  
 Rev.03 - Inserimento specifiche del materiale