

LOTTO 9

SCHEDA TECNICA / TECHNICAL DATA SHEET

NOLINT®
COMPRESSA DI GARZA CON FILO RADIOPACO
 20 FILI CM/Q, DEL PESO DI 28 G/MQ (FILATO N.E. 32/40)
 GAUZE SWAB WITH X-RAY THREAD
 20 THREADS/CM² - WEIGHT 28 G/SQM (YARN N.E. 32'S/40'S)
NON STERILE

Numero di Repertorio Dispositivi Medici: 48557/R – CND: M0201020202

DESCRIZIONE/ DESCRIPTION

NOLINT, COMPRESSA DI GARZA IDROFILA DI PURO COTONE DA 20 FILI CM/Q, DEL PESO DI 28 G/MQ (FILATO N.E. 32/40) CON FILO DI BARIO, NON STERILE, RIBORDATA, IN SACCHETTO DI CARTA.
 NOLINT – PURE COTTON HYDROPHILIC GAUZE SWAB, 20 THREADS/CM², WEIGHT 28 G/SQM (YARN N.E. 32'S/40'S) WITH BARIUM X-RAY THREAD, HEMMED, PACKED INTO PAPER BAG, NON STERILE.

DESTINAZIONE D'USO/ INTENDED USE

- La compressa di garza è usata per:
- Assorbire, tamponare e proteggere durante gli interventi chirurgici
 - Coprire ferite di qualsiasi forma e dimensione
 - Disinfettare prima della medicazione ed in genere per la pulizia delle ferite
 - Proteggere i punti di intersezione dei tubi di drenaggio

The gauze is used to:

- Absorb, dab and protect during surgery
- Cover wounds of any shape and size
- Disinfect before dressing and generally cleaning wounds
- Protect the points of intersection of the drainage pipes

CARATTERISTICHE GENERALI / GENERAL SPECIFICATIONS

1	FILO DI BARIO RADIOPACO BARIUM X-RAY THREAD	Intessuto longitudinalmente nella garza, fabbricato in polipropilene biocompatibile, con 60% di solfato di bario. Woven longitudinally in the gauze, made of biocompatible polypropylene, with 60% barium sulphate.
2	STERILITA' STERILITY	Il prodotto fornito non sterile è sterilizzabile a ETO in apposito confezionamento e secondo cicli validati a cura del committente in accordo alle Norme: UNI EN 556, UNI EN ISO 11135 The product, supplied non-sterile, is suitable to be sterilized by EO in proper packaging and according to cycles validated by the buyer in accordance with Standards: EN 556, UNI EN ISO 11135
3	NORMATIVE DI RIFERIMENTO NORM OF REFERENCE	-Ai sensi del D.Lgs. 46/97 di attuazione della Direttiva 93/42/CEE, e del D.Lgs 37/10 di attuazione della Direttiva 2007/47/CEE, sui Dispositivi Medici. -Farmacopea Ufficiale Italiana IX edizione. -According to Law 46/97 implementing Directive 93/42/EEC and Law 37/10 implementing Directive 2007/47/EEC about the Medical Devices. -Italian Official pharmacopoeia Edition IX.
4	CLASSE DI APPARTENENZA CLASS	Dispositivo medico di "Classe IIa" ai sensi del D.Lgs. 46/97 di attuazione della Direttiva 93/42/CEE e del D.Lgs. 37/10 di attuazione della Direttiva 2007/47/CEE, sui Dispositivi Medici "Class IIa" Medical Device according to the Standard 93/42/CEE, and the Standard 2007/47/CEE reported on Medical Device
5	ASSENZA DI LATTICE LATEX FREE	Totale assenza di lattice nel prodotto finito, nel confezionamento e nel ciclo produttivo. Total absence of latex in the finished product, in the packaging and in the production cycle.
6	STERILIZZAZIONE STERILIZATION	Il prodotto fornito non sterile è sterilizzabile a ETO in apposito confezionamento e secondo cicli validati a cura del committente in accordo alle Norme: UNI EN 556, UNI EN ISO 11135 The product, supplied non-sterile, is suitable to be sterilized by EO in proper packaging and according to cycles validated by the buyer in accordance with Standards: EN 556, UNI EN ISO 11135

ST 084-M – data di emissione – 2nd Apr. 2010

Rev. 00 – data di revisione – 2nd Apr. 2010

Technical Office:
Stefano Rolfi



Quality Assurance:
Mirko Castelli




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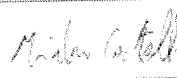
7	AMBIENTI DI PRODUZIONE PRODUCTION CLEAN-ROOMS	Fabbricati in ambienti a contaminazione controllata in classe ISO7 The goods are manufactured into environment based on controlled contamination class ISO7
8	MODALITA' DI CONSERVAZIONE INSTRUCTION FOR STORAGE	Proteggere dalla luce solare diretta e conservare in un luogo fresco e asciutto, in ambienti privi di odori e lontano da fonti di calore. Le caratteristiche del dispositivo sono garantite a confezione integra. Protect from direct sunlight and store in a cool, dry and odorless place, away from heat sources. The device specifications can be guaranteed only if the packaging is unopened.
9	VITA UTILE DEL PRODOTTO SHELF LIFE	5 anni 5 years
10	SMALTIMENTO DISPOSAL	Il prodotto è completamente smaltibile e non lascia residui tossici durante e dopo l'incenerimento. Smaltire in accordo alla vigente normativa. The product is completely disposable and does not leave toxic residue during and after the incineration. Dispose of in accordance with current legislation.
11	FABBRICANTE MANUFACTURER	Mediberg S.r.l. – Sede legale – Uffici e officina di produzione: Via Vezze 16/18 24050 Calcinato (BG) Italy – Tel. 0039/0358354911 – Fax:0039/4429074 e-mail:info@mediberg.com – http://www.mediberg.com Mediberg S.r.l. – Registered Office production workshop: Via Vezze 16/18 – 24050 – Calcinato (BG) Italy – Tel. 0039/0358354911 – Fax: 0039/4429074 e-mail:info@mediberg.com – http://www.mediberg.com

CARATTERISTICHE CHIMICO FISICHE E MICROBIOLOGICHE GARZA

CHEMICAL-PHYSICAL AND MICROBIOLOGICAL SPECIFICATIONS OF THE GAUZE

CARATTERISTICHE MICROBIOLOGICHE MICROBIOLOGICAL SPECIFICATION	Carica batterica inferiore a 100 U.F.C./g Bacteria load less than 100 C.F.U./gram. 
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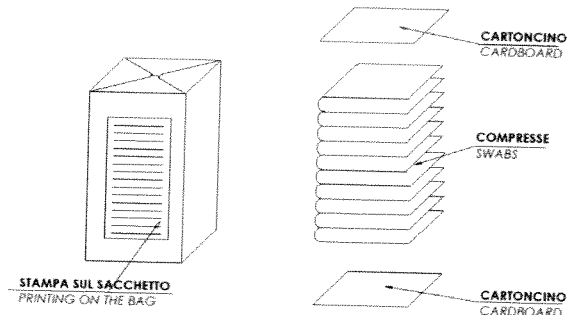
CARATTERISTICHE CHIMICO FISICHE / CHEMICAL-PHYSICAL SPECIFICATIONS		
DESCRIZIONE TEST DESCRIPTION OF THE TEST	RISULTATI RESULTS	LIMITI MASSIMI DA F.U.I. IX EDIZIONE MAXIMUM LIMIT AT F.U.I. IX EDITION
N° FILI PER 10 CM IN ORDITO THREADS NUMBER IN 10 CM OF WARP	120	120 ± 6
N° FILI PER 10 CM IN TRAMA THREADS NUMBER IN 10 CM OF WEFT	80	80 ± 5
PESO: g/mq – (FILATO N.E. 32/40) WEIGHT: g/sqm (YARN N.E. 32'S/40'S)	28	27 ≤ g/m² ≤ 30
COLORE COLOUR	Bianco	/
CARICO MINIMO DI ROTTURA FILO ORDITO MINIMUM BREAKING LOAD WARP THREAD	65 N/5cm	>60 N/cm
CARICO MINIMO DI ROTTURA FILO TRAMA MINIMUM BREAKING LOAD WEFT THREAD	40 N/5cm	> 35 N/5cm
PRESENZA DI FIBRE ESTRANEE PRESENCE OF FOREIGN FIBRES	Assenti Absent	Assenti Absent
TEMPO DI IMMERSIONE TIME OF IMMERSION	4 secondi 4 seconds	< 10 secondi < 10 seconds
PERDITA DELL'ESSICCAMENTO LOSS ON DRYING	2%	< 8%
ACIDITA' – ALCALINITA' ACIDITY - ALKALINITY	Assenti Absent	Assenti Absent
SOSTANZE SOLUBILI IN H₂O SUBSTANCES SOLUBLE IN H ₂ O	0,20%	< 0,50%
SOSTANZE SOLUBILI IN ETERE SUBSTANCES SOLUBLE IN ETHER	0,40%	< 0,50%

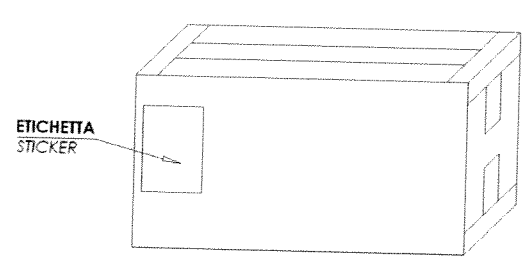
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SOSTANZE TENSIOATTIVE SURFACE-ACTIVE SUBSTANCES	Assenti Absent	< 2 mm di schiuma < 2 mm foam
FLUORESCENZA FLUORESCENCE	Nessuna fluorescenza azzurra No any light blue fluorescence	Nessuna fluorescenza azzurra No any light blue fluorescence
AMIDO E DESTRINE STARCH AND DEXTRINS	Assenti Absent	Assenti Absent
SOSTANZE COLORANTI COLOURING AGENTS	Assenti Absent	Meno intensamente colorata della soluzione primaria azzurra Less coloured than the primary light blue solution
CENERI SOLFORICHE SULPHURIC ASHES	0,3%	< 0,4%

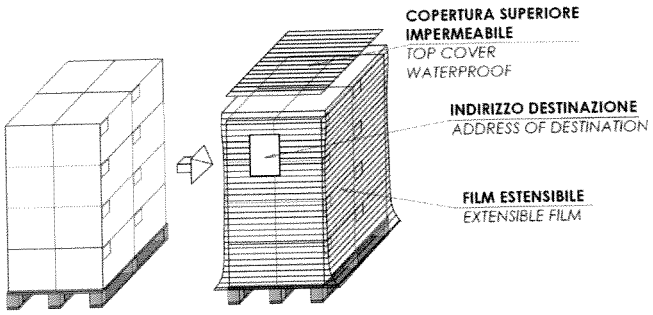
CONFEZIONAMENTO / PACKAGING

IMBALLO PRIMARIO (SACCHETTO) / PRIMARY PACKAGING (BAG)		
MATERIALE RAW MATERIAL	Sacchetto in carta Paper bag	 <p>STAMPA SUL SACCHETTO PRINTING ON THE BAG</p> <p>SACCHETTO CHIUSO CLOSED BAG</p> <p>CONTENUTO SACCHETTO BAG CONTENT</p>
COLORE COLOUR	Bianco White	
STAMPA SUL SACCHETTO PRINT ON THE POLYBAG	Stampa di colore nero, come da esempio a pagina 5 Print in black color, according to the example show at page 5	
CODICE A BARRE BAR CODE	EAN 13	

IMBALLO SECONDARIO (CARTONE TRASPORTO) / SECONDARY PACKAGING (TRANSPORT CARTON)		
TIPOLOGIA TYPE	Cartone ondulato tripla onda Triple wave cardboard carton	 <p>ETICHETTA STICKER</p>
COLORE CARTONE CARTON COLOUR	Avana Light-brown	
CHIUSURA CARTONE TO SEAL THE CARTON	NASTRO ADESIVO TRASPARENTE A "H" Transparent adhesive tape "H"-shaped	
ETICHETTA SUL CARTONE STICKER ON CARTON	Etichetta posizionata come da disegno a lato, e da layout a pag. 5 (dimensioni 7x12 cm) Sticker to be attached as shown by picture beside. Artwork as shown at page 5 (label size 7x12 cm)	

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PALLETIZZAZIONE / PALLET STRUCTURE











































TIPOLOGIA TYPE	Standard a perdere, non EPAL, dimensioni cm 120x80, altezza massima cm 220. <i>Standard one-way, not EPAL, dimension cm 120x80, maximum height cm 220.</i>	
FASCIATURA PALLET PALLET WRAPPING	Film estensibile 23 µm laterale e copertura impermeabile superiore <i>Extensible film 23 µm at side; waterproof cover on the top.</i>	
INDIRIZZO DESTINATARIO ADDRESS OF DESTINATION	Indirizzo cliente <i>Customer's address</i>	

CODICI RIORDINO / ITEM CODES

CODICI MEDIBERG MEDIBERG CODES	FORMATO SIZE	STRATI LAYERS	IMBALLO PRIMARIO (PEZZI PER SACCHETTO) PRIMARY PACKAGING (PIECES INTO BAG)	IMBALLO SECONDARIO (PEZZI NEL CARTONE TRASPORTO) SECONDARY PACKAGING (PIECES INTO CARTON)	PESO CARTONE (kg) CARTON WEIGHT (KG)
02GRZ007XD	5X5	16	100	2.000	2,70
02GRZ020XD	7,5X7,5	8	100	2.000	3,27
02GRZ023XD	7,5X7,5	12	100	1.000	2,5
02GRZ025XD	7,5X7,5	16	100	1.000	2,96
02GRZ042XD	7,5X9	8	100	2.000	3,81
02GRZ052XD	7,5X9	16	100	1.000	3,48
02GRZ060XD	10X10	8	100	1.000	2,79
02GRZ062XD	10X10	12	100	1.000	3,97
02GRZ065XD	10X10	16	100	1.000	5,10
02GRZ100XD	10X20	8	50	1.000	5,47
02GRZ105XD	10X20	12	50	600	4,69
02GRZ110XD	10X20	16	50	600	6,08
02GRZ155XD	10X15	16	100	600	4,60

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FORMATI DI PIEGATURA / FOLDING SCHEMES

Piegatura 16 strati <i>Folding at 16 layers</i> cm 10 x 10 cm 7,5 x 7,5 cm 5 x 5	 1  2  3  4  5	Piegatura 8 strati <i>Folding at 8 layers</i> cm 10 x 20	 1  2  3  4
Piegatura 8 strati <i>Folding at 8 layers</i> cm 10 x 10 cm 7,5 x 7,5	 1  2  3  4	Piegatura 12 strati <i>Folding at 12 layers</i> cm 10 x 20	 1  2  3  4  5
Piegatura 8 strati <i>Folding at 8 layers</i> cm 7,5 x 9	 1  2  3  4	Piegatura 16 strati <i>Folding at 16 layers</i> cm 10 x 20	 1  2  3  4  5
Piegatura 16 strati <i>Folding at 16 layers</i> cm 7,5 x 9	 1  2  3  4  5	Piegatura 16 strati <i>Folding at 16 layers</i> cm 10 x 15	 1  2  3  4  5
Piegatura 12 strati <i>Folding at 12 layers</i> cm 10 x 10 cm 7,5 x 7,5	 1  2  3  4  5		

Altri formati sono realizzabili su richiesta / Other size are available on request

SERVIZIO ASSISTENZA CLIENTI:

E' attivo un servizio di assistenza clienti contattabile per qualsiasi informazione ai seguenti numeri:

Tel. 035 / 83 54 911 – Fax 035 / 44 29 074 – E-mail: info@mediberg.com – <http://www.mediberg.com>

CUSTOMER SERVICE:

Our customer service can be contacted for any information at the following numbers:

Tel: 0039 035/8354911 – Fax: 0039 035/4429074 – Email: info@mediberg.com – <http://www.mediberg.com>

