GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) – Italy
www.gimaitaly.com

ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

DICHIARAZIONE DI CONFORMITA'/*DECLARATION OF CONFORMITY*

La Società GIMA S.p.A., con sede a Gessate (MI), Via Marconi 1, in qualità di fabbricante dei dispositivi medici:
We undersigned GIMA S.p.A., with head office addressed in Gessate (MI), Via Marconi 1, as the manufacturer of medical devices:

Dispositivi medici / *Medical Devices*	**Codici/Ref. #**
FORBICI RETTE – punte acute – 18 cm *SCISSORS STRAIGHT SHARP/SHARP – 18 cm*	26894

classe di rischio I non sterile, in accordo all'Allegato IX della Direttiva 93/42/CEE e ss.mm.ii., (recepita in Italia con D.lgs 46/97, e ss.mm.ii.), dichiara, sotto la propria esclusiva responsabilità, che tali dispositivi:
risk class I non sterile, according to the Annex IX, Directive 93/42/EEC and further amendments (enforced in Italy by Leg. Decree No. 46/97 and further amendments), declare under its own full liability that those devices:

- sono conformi ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii., come da fascicolo tecnico conservato in Azienda;
  comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as per the Technical Documentation filed in the Company;
- sono fabbricati in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato VII della sopra citata direttiva.
  are manufactured according to the Quality System which satisfies requirements of the Annex VII of the above mentioned directive.

GIMA S.p.A.
Direttore Generale
Dr. Giulio Manzoni

GIMA S.p.A.
Responsabile Direzione
Nicola Manzoni

Gessate, 25/06/2015

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DICHIARAZIONE DI CONFORMITA'/*DECLARATION OF CONFORMITY*

La Società GIMA S.p.A., con sede a Gessate (MI), Via Marconi 1, in qualità di fabbricante dei dispositivi medici:
We undersigned GIMA S.p.A., with head office addressed in Gessate (MI), Via Marconi 1, as the manufacturer of medical devices:

Dispositivi medici / *Medical Devices*	**Codici/Ref. #**
FORBICI RETTE – punte smusse – 18 cm *SCISSORS STRAIGHT BLUNT/BLUNT – 18 cm*	26857

classe di rischio I non sterile, in accordo all'Allegato IX della Direttiva 93/42/CEE e ss.mm.ii., (recepita in Italia con D.lgs 46/97, e ss.mm.ii.), dichiara, sotto la propria esclusiva responsabilità, che tali dispositivi:
risk class I non sterile, according to the Annex IX, Directive 93/42/EEC and further amendments (enforced in Italy by Leg. Decree No. 46/97 and further amendments), declare under its own full liability that those devices:

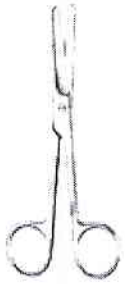
- sono conformi ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii., come da fascicolo tecnico conservato in Azienda;
  comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as per the Technical Documentation filed in the Company;
- sono fabbricati in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato VII della sopra citata direttiva.
  are manufactured according to the Quality System which satisfies requirements of the Annex VII of the above mentioned directive.

GIMA S.p.A.
Direttore Generale
Dr. Giulio Manzoni

GIMA S.p.A.
Responsabile Direzione
Nicola Manzoni

Gessate, 25/06/2015

FORBICI RETTE - punte smusse - 18 cm



Codice:	**26857**
Categoria:	**Forbici**
Unità di vendita:	**1 pz.**
Quantitativi minimi:	**1**
Dispositivo:	**Dispositivo medico**
Classe:	**I**
NSIS:	**142041**
CND:	**L010499**
EAN13:	**8023279268577**

Descrizione: **FORBICI CHIRURGICHE IN ACCIAIO INOX.**

Istruzioni: GB, FR, IT, ES, PT, DE, GR, Arabo.

FORBICI RETTE - punte acute - 18 cm

Codice:	26894
Categoria:	Forbici
Unità di vendita:	1 pz.
Quantitativi minimi:	1
Dispositivo:	Dispositivo medico
Classe:	I
NSIS:	142041
CND:	L010499
EAN13:	8023279268942
Descrizione:	FORBICI CHIRURGICHE IN ACCIAIO INOX.
	Istruzioni: GB, FR, IT, ES, PT, DE, GR, Arabo.

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EXPORT DIVISION
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DICHIARAZIONE DI CONFORMITÀ

DECLARATION OF CONFORMITY

La Società GIMA S.p.A., con sede a GESSATE (MI), Via Marconi 1, in qualità di fabbricante dei dispositivi medici:
We undersigned GIMA S.p.A., with head office addressed in Gessate (MI), Via Marconi 1, as the manufacturer of medical devices:

Dispositivi medici / *Medical Devices*	**Codici/Ref. #**
Pinza Dissezione English Toe retta *English Toe plain dissecting forceps*	26977
Pinza Mixter *Mixter forceps*	26978
Pinza Museux Vulsellum 8 mm - retta - 24 cm *Museux Vulsellum forceps 8 mm - straight - 24 cm*	26979
Pinza Luer - 15 cm - bordo affi lato *Luer forceps - 15 cm - sharp edge*	26983
Pinza Ruskin Liston – 18 cm *Ruskin Liston forceps - 18 cm*	26984
Pinza Cheron - 25 cm *Pinza Cheron - 25 cm*	26986
Pinza Rampley *Rampley forceps*	26987 – 26988

classe di rischio I (non sterile), in accordo all'Allegato IX della Direttiva 93/42/CEE e ss.mm.ii. (recepita in Italia con D.lgs. 46/97, e ss.mm.ii.), dichiara, sotto la propria esclusiva responsabilità, che tali dispositivi:
risk class I non sterile, according to the Annex IX, Directive 93/42/EEC and further amendments (enforced in Italy by Leg. Decree No. 46/97 and further amendments), declare under its own full liability that those devices:

- sono conformi ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii. come da Fascicolo Tecnico archiviato presso l'azienda;
  comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as per the Technical Documentation filed in the Company;
- sono fabbricati in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato VII del sopra citato decreto legislativo.
  are manufactured according to the Quality System which satisfies requirements of the Annex VII of the above mentioned directive.

Gessate, 29/11/2017

GIMA S.p.A.
Il legale Rappresentante
(Nicola Manzoni)

PINZA OSSIVORA LUER GOUGE - 15 cm

Codice:	**26983**
Categoria:	**Pinze**
Unità di vendita:	**1 pz.**
Quantitativi minimi:	**1**
Dispositivo:	**Dispositivo medico**
Classe:	**I**
NSIS:	**1767786**
CND:	**L9099**

Descrizione: **Pinza Luer - 15 cm - bordo affilato**

- **ACCIAIO INOX**

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DICHIARAZIONE DI CONFORMITA'/*DECLARATION OF CONFORMITY*

La Società GIMA S.p.A., con sede a Gessate (MI), Via Marconi 1, in qualità di fabbricante dei dispositivi medici:
We undersigned GIMA S.p.A., with head office addressed in Gessate (MI), Via Marconi 1, as the manufacturer of medical devices:

Dispositivi medici / *Medical Devices*	**Codici/Ref. #**
PINZA ANATOMIA – 18 cm *ANATOMY FORCEPS – 18 cm*	26706

classe di rischio I non sterile, in accordo all'Allegato IX della Direttiva 93/42/CEE e ss.mm.ii., (recepita in Italia con D.lgs 46/97, e ss.mm.ii.), dichiara, sotto la propria esclusiva responsabilità, che tali dispositivi:
risk class I non sterile, according to the Annex IX, Directive 93/42/EEC and further amendments (enforced in Italy by Leg. Decree No. 46/97 and further amendments), declare under its own full liability that those devices:

- sono conformi ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii., come da fascicolo tecnico conservato in Azienda;
  comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as per the Technical Documentation filed in the Company;
- sono fabbricati in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato VII della sopra citata direttiva.
  are manufactured according to the Quality System which satisfies requirements of the Annex VII of the above mentioned directive.

GIMA S.p.A.
Direttore Generale
Dr. Giulio Manzoni

GIMA S.p.A.
Responsabile Direzione
Nicola Manzoni

Gessate, 25/06/2015

PINZA ANATOMIA - 18 cm

Codice:	**26706**
Categoria:	**Pinze**
Unità di vendita:	**1 pz.**
Quantitativi minimi:	**1**
Dispositivo:	**Dispositivo medico**
Classe:	**I**
NSIS:	**141832**
CND:	**L031310**
EAN13:	**8023279267068**
Descrizione:	**Pinza anatomia in acciaio inox - 18 cm**

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20060 Gessate (MI) –Italy
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EXPORT DIVISION
export@gimaitaly.com

DICHIARAZIONE DI CONFORMITÀ

DECLARATION OF CONFORMITY

La Società GIMA S.P.A., con sede a GESSATE (MI), Via Marconi 1, in qualità di fabbricante dei dispositivi medici:

We undersigned GIMA S.p.A., with head office addressed in Gessate (MI), Via Marconi 1, as the manufacturer of medical devices:

Dispositivi medici / *Medical Devices*	**Codici/Ref. #**
Porta aghi/tronchesini per filo/forbici per bende *Needle holder / Wire trunks / Band scissors*	26544-26546-26530-26531-26532-26540-26541-26536-26537-26852-26818-26732-26819-26733-26741-26730-26731-26550-26551-26552-26554 / 26570-26571-26572-26575 / 34125-34129-34130
Drum e scatole per sterilizzazione *Drum and sterilization boxes*	26673-26676-26678-26682-26683-26684-26685-26686 / 26668-26670-26671
Vassoi e bacinelle portastrumenti *Trays and tool cases*	26600-26601-26599-26602-26603-26604-26597-26598-26605-26606-26607-26608-26609-26592-26593-26590-26591-26586-26587-26588-26616-26617-26618-26619-26621-26622-26623-26624-26625-26628-26627-26610-26612-26580-26581-26582-26583-26585-26589

classe di rischio I (non sterile), in accordo alla regola 1 dell'Allegato IX della Direttiva 93/42/CEE e ss.mm.ii. (recepita in Italia con D.lgs. 46/97, e ss.mm.ii.), dichiara, sotto la propria esclusiva responsabilità, che tali dispositivi:
risk class I non sterile, according to rule 1 of the Annex IX, Directive 93/42/EEC and further amendments (enforced in Italy by Leg. Decree No. 46/97 and further amendments), declare under its own full liability that those devices:

- sono conformi ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii. come da Fascicolo Tecnico archiviato presso l'azienda;
  comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as per the Technical Documentation filed in the Company
- sono fabbricati in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato VII del sopra citato decreto legislativo.
  are manufactured according to the Quality System which satisfies requirements of the Annex VII of the above mentioned directive.

Gessate, 09/01/17

GIMA S.p.A.
Il legale Rappresentante
(Nicola Manzoni)

PORTA AGHI MAYO HEGAR - 16 cm

Codice:	26732
Categoria:	Porta aghi
Unità di vendita:	1 pz.
Quantitativi minimi:	1
Dispositivo:	Dispositivo medico
Classe:	I
NSIS:	142068
CND:	L0205
EAN13:	8023279267327
Descrizione:	PORTA AGHI MAYO HEGAR IN ACCIAIO INOX.
	Istruzioni: GB, FR, IT, ES, PT, DE, GR, Arabo.

Certificate

kiwa
Partner for progress

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	20
Primo rilascio / First issue *date*	2006-10-25	Valido da / *Valid from*	2016-10-24
Scadenza / *Valid until*	2021-10-24	Ultima modifica / *Last change date*	2016-11-07

Certificato CE del Sistema di Garanzia della Qualità/ *EC Quality Assurance System Certificate*

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

GIMA S.p.A.

sede operativa / Operational Headquarter:
Via Marconi, 1
20060 Gessate, MI - Italia
sede legale
Via Tommaso Grossi, 2
Milano - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Aspiratori chirurgici e accessori / *Surgical aspirators and accessories*
Bilancia ad uso medicale / *Scales for medical use*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*
Dispositivi per aerosolterapia / *Nebulizer therapy devices*
Dispositivi per la misurazione della saturazione di O2 / *Oxygen saturation measuring devices*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*
Dispositivi per misurazione / *Measuring devices*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*
Dispositivi per terapia termica / *Thermic therapy devices*
Elettrocardiografi / *Electrocardiographs*
Sfigmomanometri / *Sphygmomanometers*

Rif. rapporto di audit/ *Ref. audit report:* 19-20-21/09/2016

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* ==

Rif. analisi dossier progettazione/ *Ref. design dossier analysis:* ==

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

PAPETTE GIMA

Codice:	**29737**
Categoria:	**Spazzolini e dispositivi prelievo**
Unità di vendita:	**conf. 100 pz.**
Quantitativi minimi:	**1**
Dispositivo:	**Dispositivo medico**
Classe:	**I S**
NSIS:	**414964**
CND:	**U089002**
EAN13:	**8023279297379**

Descrizione:

GIMA collector sterile

- **Materiale: plastica**
- **Lunghezza bastoncino: 19,5 cm**
- **Imbustate singolarmente in confezione sterile in conf. da 100 pezzi**

Un unico movimento rotatorio di questo strumento permette di prelevare sia cellule endocervicali che esocervicali, compresa la zona di trasformazione, con un minor trauma rispetto alle tecniche tradizionali.

CISQ is a member of

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CSQ
www.imq.it

CERTIFICATO N.
CERTIFICATE N. 9190.CRC3

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2008

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Ulteriori informazioni riguardanti l'applicabilità del requisiti ISO 9001:2008 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2017-10-13	2020-10-07

L'Organizzazione dovrà ottenere la certificazione secondo la norma ISO 9001:2015 entro il 2018/09/14;
in caso contrario, il presente certificato cesserà la propria validità in tale data
The Organization shall obtain the certification according to ISO 9001:2015 within 2018/09/14;
otherwise the validity of this certificate will expire

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Omago

Data di scadenza del precedente ciclo di certificazione: 2017-10-07
Data di conclusione dell'audit di rinnovo: 2017-10-11
Data della decisione di rinnovo: 2017-10-13

IMQ

FEDERAZIONE CISQ
www.cisq.com

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

IAF: 07, 09, 19, 29

SGQ N°005A, SGA N°006D, SCR N°005F,
SSI N°003G, FSM N°007I, SGE N°006M,
EMAS N°003P, PRD N°003B, PRS N°088C
ISP N°063F, LAB N°012I, LAT N°021
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

I processi riconducibili a settori IAF sottolineati risultano non ancora coperti da accreditamento
Processes related to underlined IAF sectors are not yet covered by accreditation
La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

Organismo di Certificazione Federato CISQ
www.imq.it

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *as an IQNet Partner hereby states that the organization*

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

for the following scope:

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Further clarifications regarding the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization

has implemented and maintains a

Quality Management System

which fulfills the requirements of the following standard

ISO 9001:2008

Issued on: **2017 – 10 – 13**

First issued on: **2002 – 11 – 26**

for the validity date, please refer to the original certificate issued by IMQ*

Registration Number: IT – 112265

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners**:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Certification *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland* PCBC *Poland*
Quality Austria *Austria* RR *Russia* SIGE *México* SII *Israel* SIQ *Slovenia* SIRIM QAS International *Malaysia*
SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* Vinçotte *Belgium* YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document
** The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

CSQ

MED

www.imq.it

CISQ is a member of

IQNet

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. 9124.CRC4

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

EN ISO 13485:2012

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use

Ulteriori informazioni riguardanti l'applicabilità dei requisiti EN ISO 13485:2012 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of EN ISO 13485:2012 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1999-07-20	2017-10-13	2020-10-07

L'Organizzazione dovrà ottenere la certificazione secondo la norma ISO 13485:2016 entro il 2019/02/28;
in caso contrario, il presente certificato cesserà la propria validità in tale data
The Organization shall obtain the certification according to ISO 13485:2016 within 2019/02/28;
otherwise the validity of this certificate will expire

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

Data di scadenza del precedente ciclo di certificazione: 2017-10-07
Data di conclusione dell'audit di rinnovo: 2017-10-11
Data della decisione di rinnovo: 2017-10-13

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.

CISQ is the Italian Federation of management system Certification Bodies.

FEDERAZIONE CISQ

www.cisq.com

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N°005A, SGA N°005D, SCR N°005F, SSI N°003G, PSM N°007I, SGE N°005M, EMAS N°003P, PRD N°050D, PRS N°080C ISP N°036E, LAB N°0121, LAT N°021
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianze annuali e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

СИСТЕМА СЕРТИФИКАЦИИ ГОСТ Р

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

СЕРТИФИКАТ СООТВЕТСТВИЯ

№ РОСС RU.ИМ02.Н17793

Срок действия с 21.06.2016г. **по** 21.06.2019г.

№ 1758739

ОРГАН ПО СЕРТИФИКАЦИИ № RA. RU.11ИМ02
МЕДИЦИНСКИХ ИЗДЕЛИЙ АНО «ВНИИИМТ»
129301, г. Москва, ул. Касаткина, д.3 тел. (495) 683-97-92, факс (499)187-89-54,
e-mail: im02@bk.ru

ПРОДУКЦИЯ Индикаторы бумажные паровой стерилизации многопараметрические химические одноразовые «МедИС-«ВИНАР»
ТУ 9398-027-11764404-2003
Серийный выпуск.

код ОК 005 (ОКП): 93 9854

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ НОРМАТИВНЫХ ДОКУМЕНТОВ
ГОСТ ISO 11140-1-2011 (класс 4),
ГОСТ Р 50444-92 (разделы 3,5,8)

код ТН ВЭД России: 3822 00 000 0

ИЗГОТОВИТЕЛЬ Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»), Россия, 105094, г. Москва, Госпитальный вал, д.5, стр.7А, пом.VIII ИНН 5023001024
Место производства-141009, Московская обл., г.Мытищи, ул.Колонцова,д.17/2

СЕРТИФИКАТ ВЫДАН Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»)
Россия, 105094, г. Москва, Госпитальный вал, д.5, стр.7А, пом.VIII
тел./факс (495) 988-76-67

НА ОСНОВАНИИ протокола испытаний № 16-852 от 20.06.2016г. ИЦ МИ АНО «ВНИИИМТ» (№ RA.RU.21ИМ04).

Регистрационное удостоверение № РЗН 2013/38 от 08 февраля 2013г. Федеральной службы по надзору в сфере здравоохранения (РОСЗДРАВНАДЗОР)

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ Маркирование продукции производится знаком соответствия Системы сертификации ГОСТ Р при добровольной сертификации продукции

М.П. Для сертификатов и деклараций RA.RU.11ИМ02 АНО "ВНИИИМТ"

Руководитель органа _____ (подпись) Е. И. Полянская (инициалы, фамилия)

Эксперт _____ (подпись) В.В. Русова (инициалы, фамилия)

Сертификат не применяется при обязательной сертификации

СИСТЕМА СЕРТИФИКАЦИИ ГОСТ Р

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

СЕРТИФИКАТ СООТВЕТСТВИЯ

№ РОСС RU.ИМ02.Н17797

Срок действия с 21.06.2016г. **по** 21.06.2019г.

№ 1758743

ОРГАН ПО СЕРТИФИКАЦИИ № RA.RU.11ИМ02
МЕДИЦИНСКИХ ИЗДЕЛИЙ АНО «ВНИИИМТ»
129301, г. Москва, ул. Касаткина, д. 3 тел. (495) 683-97-92, факс (499)187-89-54
e-mail: im02@bk.ru

ПРОДУКЦИЯ Индикатор бумажный воздушной стерилизации химический многопараметрический одноразовый «МедИС-В-Винар» (модификации МедИС-В-160/150-1, МедИС-В-180/60-1) по ТУ 9398-032-11764404-2004
Серийный выпуск.

код ОК 005 (ОКП): 93 9854

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ НОРМАТИВНЫХ ДОКУМЕНТОВ

код ТН ВЭД России: 3822 00 000 0

ГОСТ ISO 11140-1-2011 (класс 4),

ГОСТ Р 50444-92 (р.р. 3, 5, 8)

ИЗГОТОВИТЕЛЬ Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»), Россия, 105094, г. Москва, Госпитальный вал, д. 5, стр. 7А, пом. VIII ИНН 5023001024
Место производства - 141009, Московская обл., г. Мытищи, ул. Колонцова, д. 17/2

СЕРТИФИКАТ ВЫДАН Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»)
Россия, 105094, г. Москва, Госпитальный вал, д. 5, стр. 7А, пом. VIII
тел./факс (495) 988-76-67

НА ОСНОВАНИИ протокола испытаний № 16-854 от 20.06.2016г. ИЦ МИ АНО «ВНИИИМТ» (№ RA.RU.21ИМ04).

Регистрационные удостоверения: № ФСР 2009/04944 от 06.03.2013г., № ФСР 2009/05017 от 06.03.2013г. Федеральной службы по надзору в сфере здравоохранения (РОСЗДРАВНАДЗОР)

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ Маркирование продукции производится знаком соответствия Системы сертификации ГОСТ Р при добровольной сертификации продукции

М.П.

Руководитель органа _____ Е.И. Полянская
подпись инициалы, фамилия

Эксперт _____ В.В. Русова
подпись инициалы, фамилия

Сертификат не применяется при обязательной сертификации

Индикаторы серии "МедИС-В"

ТУ 9398 – 032 – 11764404 –2004

Индикаторы МедИС-В предназначены для оперативного визуального контроля соблюдения критических переменных воздушной стерилизации – температуры и времени стерилизационной выдержки – в камере воздушных стерилизаторов с предельным отклонением температуры ±3°С.

Характеристики продукта:

• относятся к классу 4 (многопеременные индикаторы) по классификации ГОСТ ISO 11140-1-2011;
• помещаются в камере стерилизатора снаружи стерилизуемых изделий;
• чёткий цветовой переход от начального голубого к конечному коричневому;
• липкий слой на обратной стороне индикатора облегчает его закрепление на упаковках и изделиях и облегчает вклеивание в журнал при документировании;
• нетоксичны, не содержат соединений свинца, в процессе применения и хранения не выделяют вредных и токсичных компонентов;

• гарантийный срок годности - 36 месяцев.

Регистрационные удостоверения ФСР 2009/04944, ФСР 2009/05017 от 06.03.2013. Срок действия: не ограничен.

Сертификат соответствия РОСС RU.ИМ28.Н01345. Срок действия до 27.09.2014 г.

Применяются в следующих режимах:

Наименование индикатора	Режим воздушной стерилизации (температура, °С /время, мин)	Контрольные значения (температура, °С/время, мин)
МедИС-В-160/150	$160 \pm 3/150^{+5}$	160/150
МедИС-В-180/60	$180 \pm 3/60^{+5}$	180/60

Индикаторы серии "МедИС"

ТУ 9398-027-11764404-2003

Индикаторы МедИС предназначены для оперативного визуального контроля соблюдения критических переменных паровой стерилизации – температуры стерилизации, времени стерилизационной выдержки и наличия насыщенного водяного пара – в камере паровых стерилизаторов с удалением воздуха методом продувки паром.

Характеристики продукта:

- относятся к классу 4 (многопеременные индикаторы) по классификации ГОСТ ISO 11140-1-2011;
- помещаются в камере стерилизатора снаружи стерилизуемых изделий;
- чёткий цветовой переход от начального зелёного к конечному коричневому;
- липкий слой на обратной стороне индикатора облегчает его закрепление на стерилизуемых упаковках и вклеивание в документы архива;
- нетоксичны, не содержат соединений свинца, в процессе применения и хранения не выделяют вредных и токсичных компонентов;
- гарантийный срок годности – 36 месяцев.

Применяются в следующих циклах стерилизации:

Наименование индикатора	Режим паровой стерилизации (температура, °С /время, мин / давление пара, Мпа)	Контрольные значения (температура,°С/время, мин)
МедИС-120/45	$120^{+2}/45^{+3}/0.11^{+0.02}$	120/45
МедИС-126/30	$126 \pm 2/30^{+2}/0.14 \pm 0.02$	124/30
МедИС-132/20	$132 \pm 2/20^{+2}/0.20 \pm 0.02$	130/20

Общество с ограниченной ответственностью
«Научно-производственная фирма «ВИНАР»
Юр.адрес: 105094, г. Москва, ул. Госпитальный вал, д 5, стр.7А, пом.VIII
Для писем: 105094, г. Москва, а/я 26
тел/факс: (495) 988-76-67, 360-61-46, 360-72-19
http:\\www.vinar.ru e-mail: main@vinar.ru

Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР»

ПАСПОРТ КАЧЕСТВА

Индикаторы контроля параметров паровой стерилизации химические одноразовые ТУ 9398-027-11764404-2003

Регистрационное удостоверение
№ РЗН 2013/38
от 08.02.2013 г.

Сертификат соответствия
№ РОСС RU. ИМ02.Н17793
от 21.06.2016 г.

Наименование продукта **«МедИС-132/20-1»**

Партия ***7173028*** ***Дата изготовления*** ***Февраль 2018 г.***

Гарантийный срок ***3 года***
Условия эксплуатации и хранения ***в соответствии с инструкцией производителя***
Код ОКП 93 9854

Наименование показателя	Норма	Значение
Технические характеристики	ТУ 9398-027-11764404-2003	Соответствует
Соответствие ГОСТ	класс 4 по ГОСТ ISO 11140-1-2011	Соответствует

Ответственный
за контроль качества

ОТДЕЛ КОНТРОЛЯ КАЧЕСТВА

О.С.Громаковская

Общество с ограниченной ответственностью
«Научно-производственная фирма «ВИНАР»
Юр.адрес: 105094, г. Москва, ул. Госпитальный вал, д.5, стр.7А, пом.VIII
Для писем: 105094, г. Москва, а/я 26
тел/факс: (495) 988-76-67, 360-61-46, 360-72-19
http:\\www.vinar.ru e-mail: main@vinar.ru

Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР»

ПАСПОРТ КАЧЕСТВА

Индикаторы бумажные воздушной стерилизации химические многопараметрические одноразовые ТУ 9398-032-11764404-2004

Регистрационное удостоверение
№ ФСР 2009/05017
от 06.03.2013 г.

Сертификат соответствия
№ РОСС RU. ИМ02.Н17797
от 21.06.2016 г.

Наименование продукта **«МедИС-В-180/60-1»**

Партия 7178028 *Дата изготовления* Февраль 2018 г.

Гарантийный срок *3 года*
Условия эксплуатации и хранения *в соответствии с инструкцией производителя*
Код ОКП 93 9854

Наименование показателя	Норма	Значение
Технические характеристики	ТУ 9398-032-11764404-2004	Соответствует
Соответствие ГОСТ	класс 4 по ГОСТ ISO 11140-1-2011	Соответствует

Ответственный за контроль качества О.С.Громаковская

М.П. ОТДЕЛ КОНТРОЛЯ КАЧЕСТВА

Общество с ограниченной ответственностью
«Научно-производственная фирма «ВИНАР»
Юр.адрес: 105094, Москва, ул.Госпитальный вал, д.5,стр.7А, пом.VIII
Для писем: 105094, г.Москва, а/я 26
тел/факс: (495) 963-7310, 988-76-67
http://www.vinar.ru e-mail: koltrade@vinar.ru

Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР»

Исх № 1
от 16.04.13г

Индикаторы бумажные воздушной и паровой стерилизации химические одноразовые серии «МедИС» представляют собой прямоугольные полоски бумажного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:
1. Полимерной связки на основе полиэфира – 60%.
2. Пигмент – 40%, состоящий:
- оксалат железа 60-90%;
- натриевая соль уксусной кислоты 5-12,5%;
- краситель на основе бромфенолового синего 5-12,5%.

Индикаторы бумажные воздушной и пленочные паровой стерилизации химические одноразовые серии «Стеритест» представляют собой прямоугольные полоски с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:
1. Полимерной связки на основе полистирола – 60%.
2. Пигмент – 40%, состоящий:
- нитрат аммония 10-20%;
- сульфаминовой кислоты 5-10%;
- диоксида титана – 30-40%;
- краситель на основе бромфенолового синего 20-30%.

Индикаторы паровой стерилизации химические одноразовые серии «Интест» представляют собой прямоугольные полоски бумажно-пленочного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:
1. Полимерной связки на основе полистирола – 50%.
2. Пигмент – 50%, состоящий:
- нитрат аммония 15-25%;
- сульфаминовой кислоты 5-10%;
- диоксида титана – 20-30%;
- краситель на основе бромфенолового синего 20-30%.

Индикаторы паровой стерилизации химические одноразовые серии «Фарматест» представляют собой прямоугольные полоски бумажно-пленочного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:
1. Полимерной связки на основе полистирола – 60%.
2. Пигмент – 40%, состоящий:
- щавелевой кислоты 20-40%;
- аммониевой соли щавелевой кислоты 10-20%;
- диоксида титана – 20-40%;
- краситель на основе бромфенолового синего 10-20%.

Индикаторы паровой стерилизации химические одноразовые «Винар-5класс» представляют собой прямоугольные полоски бумажно-пленочного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:
1. Полиэфирной связки – 72%.
2. Пигмент – 28%, состоящий:
- янтарной кислоты 20-40%;
- натриевой соли янтарной кислоты 10-20%;
- диоксида титана – 20-40%;
- краситель на основе бромкрезоловый зеленый 10-20%.

Индикаторы паровой стерилизации химические одноразовые серии «Винар-6 класс» представляют собой прямоугольные полоски бумажно-пленочного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:
1. Полиэфирной связки – 65%.
2. Пигмент – 35%, состоящий:
- карбоновой (щавелевой) кислоты 20-50%;
- калиевой соли щавелевой кислоты 10-40%;
- диоксида титана – 5-20%;
- краситель на основе бромкрезоловый зеленый 10-20%.

Индикаторы парового обеззараживания химические одноразовые серии «СанИС» представляют собой прямоугольные полоски пленочного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения, с тыльной стороны индикаторы имеют липкий слой, закрытый бумагой.
Индикаторная композиция состоит из:
1. Полимерной связки на основе полистирола – 55%.
2. Пигмент – 45%, состоящий:
- нитрат аммония 13-20%;
- сульфаминовой кислоты 25-35%;
- диоксида титана – 20-30%;
- краситель на основе бромфенолового синего 15-25%.

Генеральный директор
ООО «НПФ «ВИНАР» Андреев В.С.

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CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
30.03.2018

MADE IN ITALY

ARTICOLO: **CONTENITORI FORMA ROTONDA**
ITEM: **ROUND SHAPE CONTAINERS**

DESCRIZIONE / *DESCRIPTION*

CONTENITORE PER RIFIUTI SPECIALI FORMA ROTONDA
Questa serie si compone di sette misure di contenitori monouso e resistenti alla perforazione a forma rotonda per lo smaltimento di rifiuti acuminati, taglienti, pungenti e affilati. La forma conica e le tacche sul coperchio agevolano lo smaltimento e la rimozione degli aghi, mentre le alette antideflusso sul coperchio impediscono la fuoriuscita dei rifiuti. Tutti i modelli sono provvisti di chiusura provvisoria e definitiva e dotati di manico solido; i tre modelli più capienti sono dotati di manico ergonomico per un utilizzo più agevole.

SAFETY CONTAINERS ROUND SHAPE
This line includes round shape disposable and puncture resistant containers for the disposal of sharp and cutting waste and it comes in sever sizes.
The conical shape and the indent on the lid ease the disposal and the remove of needles, whilst the anti-defluxion flow wings on the lid prevent the outflow of the waste. All the models have temporary and definite closure and are fitted with solid handle; the three most volumious models are fitted with an ergonomic handle that eases use.

MATERIALE / *RAW MATERIAL*

Materiale plastico ecologico (Polipropilene copolimero colorato conforme alla normativa REACH con colorante senza cadmio). Il corpo del contenitore è di colore giallo e il coperchio di colore rosso per consentirne l'immediata individuazione ed avvertire della pericolosità del contenuto.

Ecological plastic material (colored copolymer polypropylene compliant to REACH regulations and with masterbatch heavy metal free and cadmium free). The container body is yellow and the lid is red to allow the immediate detection and warning of the dangers of the content.

CERTIFICAZIONI / *CERTIFICATIONS*

Conformi alla Norma AFNOR NF X-30-500
Conformi alla Norma ISO 23907
Conformi all'accordo ADR - Certificato UN
FDA (Food and Drug Administration) Approval K071517
Conformi alla Norma tedesca TRBA 250
Autoclavabile a +134°C per 18 minuti

Compliant to AFNOR NF X-30-500
Compliant to ISO 23907
Compliant to ADR - UN Certificate
FDA (Food and Drug Administration) Approval K071517
Compliant to German standard TRBA 250
Autoclavable at +134°C for 18 minutes

ISO 23907: 2012
KM 99113

FDA K071517

TRBA 250

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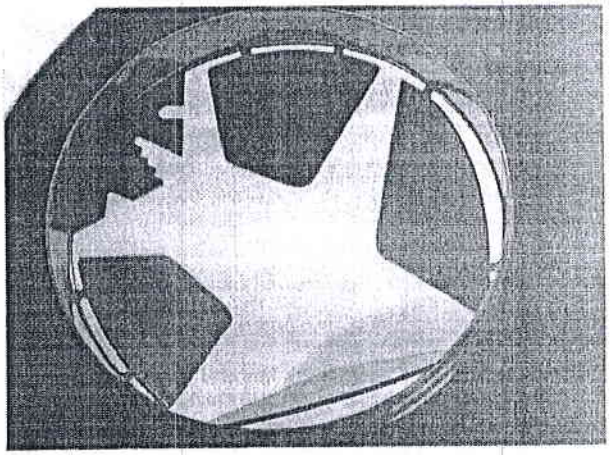
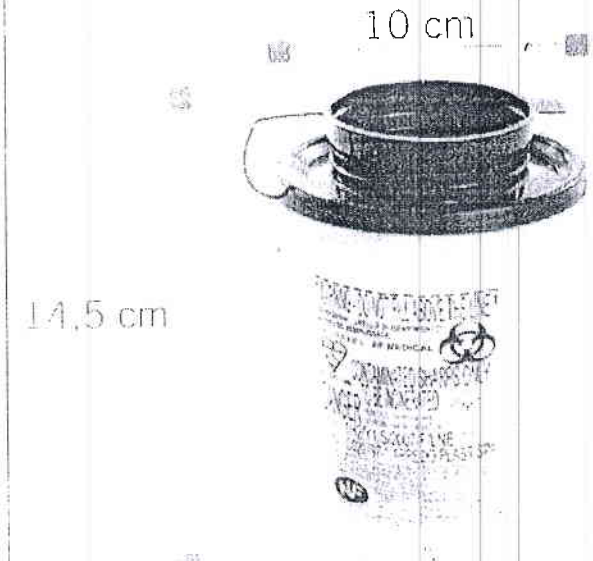
- Manico ergonomico per i modelli più capienti
- Alette antideflusso per impedire la fuoriuscita dei rifiuti
- Meccanismo di sgancio aghi da insulina
- Chiusura permanente irreversibile
- Indicazione del livello di riempimento massimo
- Disponibilità di supporti vari
- Nessuna emissione di gas nocivi in fase di incenerimento. Alla fine del ciclo vitale, i contenitori vengono smaltiti per incenerimento, senza emanazioni nocive e senza deposito di materiali pesanti
- Il contenitore può essere autoclavato a 134' per 18 minuti



- *Ergonomic handle for the more spacious models*
- *Anti-defluxion wings that prevent the outflow of the waste*
- *Machanism for unhooking insulin needles*
- *Irreversible permanent closure*
- *Maximum filling level indicator*
- *Various supports available*
- *No emission of any harmful gasses during the inceneration process. Once filled, the containers have to be disposed through incineration, releasing no toxic emissions*
- *Suitable to autoclave at 134° for 18 min*



DIMENSIONI ESTERNE	*EXTERNAL DIMENSIONS*
Ø100 x 145 mm H	
SPESSORE	*THICNESS*
1,9 mm	
FORMA	*SHAPE*
Tronco di cono / *Truncated cone*	
PESO	WEIGHT
81 gr.	
CARICO MASSIMO	MAXIMUM LOAD
0,4 Kg.	
CAPACITÀ NOMINALE	NOMINAL VOLUME
0,60 Lt.	
CAPACITÀ EFFETTIVA	EFFECTIVE VOLUME
0,67 Lt.	
CAPACITÀ UTILE	USEFUL VOLUME
0,536 Lt.	

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COD. 7008

Modello concepito per le postazioni a debole produzione di rifiuti (vassoio di cura, trolley, domicilio del paziente, ecc.)
Item designed for low volumes of waste (care tray, trolley, domestic care, doctor's office)

DIMENSIONI ESTERNE	*EXTERNAL DIMENSIONS*
Ø100 x 184 mm H	
SPESSORE	*THICNESS*
1,9 mm	
FORMA	*SHAPE*
Tronco di cono / *Truncated cone*	
PESO	WEIGHT
104,20 gr.	
CARICO MASSIMO	MAXIMUM LOAD
0,460 Kg.	
CAPACITÀ NOMINALE	NOMINAL VOLUME
0,80 Lt.	
CAPACITÀ EFFETTIVA	EFFECTIVE VOLUME
0,81 Lt.	
CAPACITÀ UTILE	USEFUL VOLUME
0,652 Lt.	

COD. 7015

Modello di utilizzo corrente (Ospedale, Centro di cure, Clinica, ecc.)
Item designed for frequent use (Hospitals, Helthcare Centres, Clinics, etc.)

DIMENSIONI ESTERNE	*EXTERNAL DIMENSIONS*
Ø140 x 165 mm H	
SPESSORE	*THICNESS*
1,9 mm	
FORMA	*SHAPE*
Tronco di cono / *Truncated cone*	
PESO	WEIGHT
139 gr.	
CARICO MASSIMO	MAXIMUM LOAD
0,850 Kg.	
CAPACITÀ NOMINALE	NOMINAL VOLUME
1,50 Lt.	
CAPACITÀ EFFETTIVA	EFFECTIVE VOLUME
1,60 Lt.	
CAPACITÀ UTILE	USEFUL VOLUME
1,20 Lt.	

APTACA
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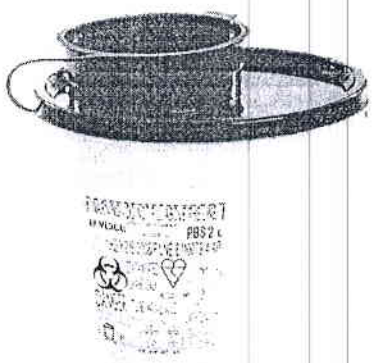
COD. 7020

14 cm



DIMENSIONI ESTERNE	*EXTERNAL DIMENSIONS*
Ø140 x 210 mm H	
SPESSORE	*THICNESS*
1,9 mm	
FORMA	*SHAPE*
Tronco di cono / *Truncated cone*	
PESO	WEIGHT
175 gr.	
CARICO MASSIMO	MAXIMUM LOAD
1,2 Kg.	
CAPACITÀ NOMINALE	NOMINAL VOLUME
2,00 Lt.	
CAPACITÀ EFFETTIVA	EFFECTIVE VOLUME
2,25 Lt.	
CAPACITÀ UTILE	USEFUL VOLUME
1,60 Lt.	

COD. 7050

21,3 cm

DIMENSIONI ESTERNE	*EXTERNAL DIMENSIONS*
Ø213 x 195 mm H	
SPESSORE	*THICNESS*
1,9 mm	
FORMA	*SHAPE*
Tronco di cono / *Truncated cone*	
PESO	WEIGHT
376 gr.	
CARICO MASSIMO	MAXIMUM LOAD
2 Kg.	
CAPACITÀ NOMINALE	NOMINAL VOLUME
5,00 Lt.	
CAPACITÀ EFFETTIVA	EFFECTIVE VOLUME
4,70 Lt.	
CAPACITÀ UTILE	USEFUL VOLUME
3,632 Lt.	

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COD. 7070

Modello di utilizzo corrente (Ospedale, Centro di cure, Clinica, ecc.)
Item designed for frequent use (Hospitals, Helthcare Centres, Clinics, etc.)

DIMENSIONI ESTERNE / *EXTERNAL DIMENSIONS*
Ø248 x 195 mm H
SPESSORE / *THICNESS*
1,9 mm
FORMA / *SHAPE*
Tronco di cono / *Truncated cone*
PESO / WEIGHT
447 gr.
CARICO MASSIMO / MAXIMUM LOAD
2,8 Kg.
CAPACITÀ NOMINALE / NOMINAL VOLUME
7,00 Lt.
CAPACITÀ EFFETTIVA / EFFECTIVE VOLUME
6,20 Lt.
CAPACITÀ UTILE / USEFUL VOLUME
4,96 Lt.

COD. 7120

Modello di utilizzo corrente (Ospedale, Centro di cure, Clinica, ecc.)
Item designed for frequent use (Hospitals, Helthcare Centres, Clinics, etc.)

DIMENSIONI ESTERNE / *EXTERNAL DIMENSIONS*
Ø248 x 310 mm H
SPESSORE / *THICNESS*
1,7 mm contenitore / *containers* 1,8 mm tappo / *lid*
FORMA / *SHAPE*
Tronco di cono / *Truncated cone*
PESO / WEIGHT
565 gr.
CARICO MASSIMO / MAXIMUM LOAD
2,2 Kg.
CAPACITÀ NOMINALE / NOMINAL VOLUME
12,00 Lt.
CAPACITÀ EFFETTIVA / EFFECTIVE VOLUME
11,00 Lt.
CAPACITÀ UTILE / USEFUL VOLUME
8,8 Lt.

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USO / *USE*

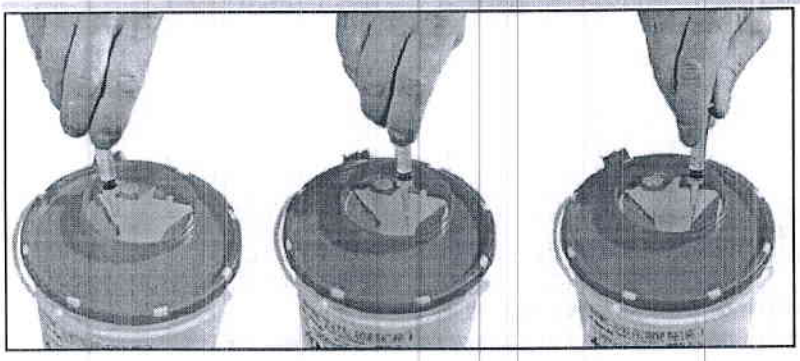
Durante l'uso, aprire e chiudere il contenitore utilizzando il tappo dal lato della chiusura provvisoria.

During use, open and close the cap in temporary mode.

Chiudere il contenitore definitivamente ed irreversibilmente utilizzando il tappo dal lato della chiusura definitiva.

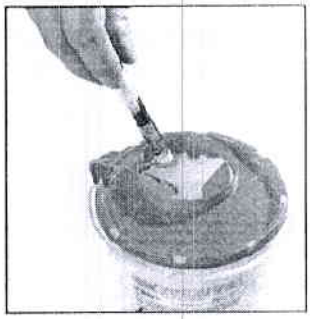
Close the container permanently and irreversibly once full, positioning the lid on the permanent closure side.

SGANCIO AGHI / *NEEDLES REMOVAL*



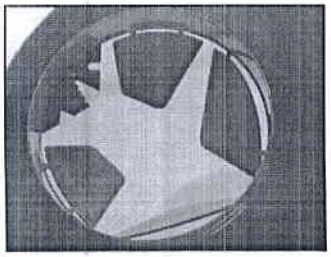
Utilizzare la tacca a "V" per sganciare l'ago dalla siringa.

Use the "V" removal device to separate needle and syringe



Penne da insulina: Introdurre nella tacca a "margherita" e applicare sulla penna un movimento dal basso verso l'alto (effetto del braccio sulla leva) prima di iniziare a svitare.

Insulin pens removal: *Use the "marguerite" device and pull the pen bottom-up (leverage effect) before unscrewing*



Orifizio per introduzione rifiuti: orifizio di grandi dimensioni per permettere l'introduzione tra gli altri, di provette, bisturi, ecc.

Hole for introduction of waste: *large orifice to allow the introduction among others, of tubes, scalpels, etc..*

SAFETY CONTAINERS

A complete line of containers for needles, sharp and cutting waste, hospital waste made of first choise ecologic plastic (coloured copolymer polypropylene compliant to REACH regulations and heavy metal free and Cadmium free). Resistant to fluids and solvents and completely disposable into incinerator without releasing harmful gases. All the products line is designed to withstand puncture by needles and cannulas, main cause of injuries among Hospital staff. Containers are conform to European and International rules (conform to EN ISO 23907). According to the typology of container, they have Quality certification NF302 according to standard NF X 30-500, compliant to ADR norms with specific UN certificate and they are certificated Kitemark® according to ISO 23907, FDA approved.
Autoclavable up to 134 °C for 18 min. Seven sizes round shape containers. Lid with temporary and definitive closure, provided with mechanism for

unhooking insulin needles and anti-defluxion wings that prevent the outflow of the waste. The more spacious models (5-7-12 Lt.) are provived with ergonomic handle. Maximum filling level indicator.

Cod.	Dim. mm	Vol. lt
7006	Ø 100 x 145	0.6
7008	Ø 100 x 184	0.8
7015	Ø 140 x 165	1.5
7020	Ø 140 x 210	2
7050	Ø 213 x 195	5
7070	Ø 248 x 195	7
7120	Ø 248 x 310	12

Certificado ES10/81672

The management system of

DELTALAB, S.L.

Pol. Ind. La Llana, Plaza De La Verneda, 1
08191 Rubí (Barcelona)

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis. Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.

Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis de microbiología, biología molecular, hematología, bioquímica, histología, microscopia y coloración. Comercialización de equipos para el almacenamiento de muestras preparadas, almacenamiento de muestras para criogenización, material general de laboratorio y envases industriales.

in/ from the following sites

Pol. Ind. La Llana, Plaza De La Verneda 1 - 08191 Rubí (Barcelona)

This certificate is valid from
29 November 2017 until 11 October 2019.
Issue 7. Certified since October 2010.

Este certificado es válido desde
29 de noviembre de 2017 hasta 11 de octubre de 2019.
Edición 7. Certificado desde octubre de 2010..

Authorized by

Dirección de Certificación

SGS ICS Ibérica, S.A. (Unipersonal)
C/Trespaderne, 29. 28042 Madrid. España.
t 34 91 313 8115 f 34 91 313 8102 www.sgs.com

Cardboard waste containers

Cardboard containers with lid, designed for storage and disposal of group II solid and semi-solid waste. With an integrated low density polyethylene bag (stuck in their interior). They can be incinerated without release of toxic fumes. The lid features two seals. One temporary that will avoid unpleasant smells and eliminate the risk of contamination while using the container. The second one is a definitive, positive seal: closing the bag with a belt already included, sealing the lids, and reinforcing them with an adhesive tape.
These containers embody lateral handles.
Model 3, code **250050**, 50 l capacity, is made of cardboard 2.7 mm minimal thick. PEBD 60 µ bag, adhered to the base and the walls. **Its height allows users not to need to lean forward as they throw away waste**. Easy to assemble thanks to its auto-mountable bottom. A maximum filling line is printed on its body.
Model 4, code **270045**, 50 l capacity, is manufactured in **reinforced cardboard, double thickness** (4 mm minimum). PEBD bag 54 µ adhered to the base. Safe closure with the help of raised edges. Both are printed with the biohazard anagram and text; assembling and closing instructions and drawings; identification formulary, and standards. In accordance with UN ADR (road transport), and manufactured pursuant to ISO 9001 standards. Containers are supplied folded up for space-saving. Those containers are not suitable for needle disposal. For this purpose see the special containers on previous pages.

mod.	code	capacity l	container dimensions mm	maximum load kg	weight ut. g	pallet dimensions	pallet weight
3	**250050**	50	263 x 263 x 756	12.5	642	100 x 120 x 180	40 x 10
4	**270045**	50	290 x 377 x 490	18.0	930	120 x 100 x 220	300

Minimum order quantity: 20 units (**it is recommended to order the whole pallet to avoid to dirty the boxes**).

Rectangular waste containers

Made of yellow, perforation resistant, virgin polypropylene. Suitable for solid or semi-solid waste, II and III Groups. Lids feature a central handle for a better handling in the daily use and also while carrying containers.
Secure closure thanks to their fourteen closing points. Lateral handles for further help carrying. Can be incinerated with no release of toxic fumes. Stackable when empty, or full and closed. Minimum wall thickness: 2.5 mm.
In accordance with UN ADR and AFNOR NF X30 500. Manufactured following ISO 9002 and ISO 14001.

mod	code	capacity l	container dimensions mm	maximum load (ADR) kg	weight ut. g	pallet dimensions	pallet weight
1	**240035**	30	415 x 314 x 373	14	1,400	80 x 120 x 200	130
2	**240065**	60	415 x 314 x 575	25	2,000	80 x 120 x 200	115

Minimum order quantity: code **240035** : 10 units, code **240065**: 5 units.

bsi.

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 577120**

Issued To: **Joint Stock Company "Ryazan State Instrument-Making Enterprise"**
32, Seminarskaya Str.
390000, Ryazan
Russian Federation

In respect of:

Manufacture, final inspection and test of intraocular pressure tonometers and magnetic field therapy devices.

Производство, выходной контроль и тестирование тонометров внутриглазного давления и аппаратов для магнитной терапии.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2016-06-27** Date: **2019-02-07** Expiry Date: **2021-11-07**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 577120**

Date: **2019-02-07**

Issued To: **Joint Stock Company "Ryazan State Instrument-Making Enterprise"**
32, Seminarskaya Str.
390000, Ryazan
Russian Federation

Subcontractor:	**Service(s) supplied**
"Kasimov Instrument-Making Enterprise"--Branch "Ryazan State Instrument-Making Enterprise" 3, Industrialnaya Str. 391300 Kasimov Russian Federation	**Manufacture**
Tonom GmbH Mergelberg 115 A 48161 Münster Germany	**EU Representative**

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EC Certificate - Production Quality Assurance
Certificate History

Certificate No: **CE 577120**
Date: **2019-02-07**
Issued To: **Joint Stock Company "Ryazan State Instrument-Making Enterprise"**
~~32, Seminarskaya Str.~~
390000, Ryazan
Russian Federation

Date	Reference Number	Action
27 June 2016	8536503	First issue. Transfer from another Notified Body.
04 November 2016	8633374	Certificate Renewal
Current	8862697	Traceable to NB 0086.