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 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. #***
Vassoi e bacinelle portastrumenti *Trays and tool cases*	26584 – 26626 - 26611
Drum e scatole per sterilizzazione *Drum and sterilization boxes*	26674 – 26669 – 26654 – 26655 – 26656 – 26674 – 26680 - 26681
Laccio emostatico FAST *FAST hemostatic tourniquet*	25727
Bracciali per sfigmomanometri *Pressure cuffes for sphygmomanometers*	32834
Martelletti neurologici *Neurological hammers*	31251
Lucciole/penne luminose *Penlight*	25632
Otoscopi *Otoscopes*	31440
Schizzettoni Janet e cannule *Janet syringes and cannulas*	25802
Oftalmoscopi *Ophthalmoscopes*	31476
PINZA ANATOMIA – 16 cm *ANATOMY FORCEPS – 16 cm*	26691
MONOFILAMENTO 2 – valutatore di sensibilità *MONOFILAMENT TOOL 2 – sensory evaluator*	31282
PINZA CHIRURGICA – 16 cm – 1x2 *SURGERY FORCEPS – 16 cm – 1x2*	26693
FORBICI RETTE – punte acute – 14,5 cm *SCISSORS STRAIGHT SHARP/SHARP – 14.5 cm*	26744
PINZA PEAN - retta – 16 cm *PEAN FORCEPS - 16 cm*	26720
DIAPASON IN ALLUMINIO 128 Hz – con piedino *ALUMINIUM TUNING FORK 128 Hz – with foot*	31226
PINZA BIOPSIA 3,5 x 8 mm – punte a coppa *BIOPSY FORCEPS 3.5 x 8 mm CUP JAWS*	29421
TESTA ILLUMINAZIONE A FIBRE OTTICHE *F.O. ILLUMINATION HEAD*	25593

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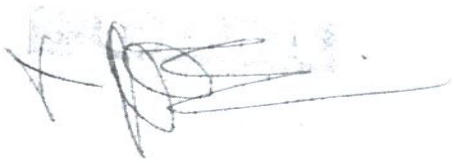
classe di rischio I (non sterile), in accordo all'Allegato IX della Direttiva 93/42/CEE e ss.mm.ii. (recepita in Italia con D.lgs. 46/97, e ss.mm.ii.), dichiara, sotto la propria esclusiva responsabilità, che tali dispositivi:
risk class I non sterile, according to the Annex IX, Directive 93/42/EEC and 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, 30/10/2017

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



CERTIFICATE

Reg. Number	10164 - M	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2018-10-01
Valid until	2021-10-14		

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Trade, packaging and service of: medical devices (MD), in vitro diagnostic products (IVD), medical accessories, furniture and aids,

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

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

GIMA S.p.A.
Registered Headquarters
- Via Grossi, 2 20121 Milano Italia

Certified Sites
- Via Marconi, 1 20060 Gessate (MI) Italia

CERMET

IAF

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 007A
SGA N° 010C
PRD N° 069B
ISM N° 004C
PRS N° 089C

EC Certificate
Full Quality Assurance System

Certificate No.:
13422-2018-CE-CZS-NA-PS Rev. 1.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

This is to certify that the quality system of:

Biosintex S.R.L.
4 Vladiceasca Str.
077168 Snagov
Romania

For design, production and final product inspection/testing of:

Sterile surgical sutures

Has been assessed with respect to:

The conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 11 September 2019

For: DNV GL Presafe AS

Tone Elise Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

NORWEGIAN ACCREDITATION

PROD 021
Notified Body No.: 2460

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.:
13422-2018-CE-CZS-NA-PS Rev 1.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Original Certificate	2018-11-01
1.0	**Change of product name**	**2019-09-11**

Products covered by this Certificate:

Product Description	Product Name	Class
Surgical suture with /without needle	**DACRIL**- Polyglycolic acid multifilament coated absorbable **DACRIL RAPID**- Polyglycolic acid multifilament coated fast absorbable **DACRIL 910** - Poly(glycolide-co-Lactide) (90/10) multifilament coated absorbable **PDO-x** - Polydioxanone monofilament absorbable **MONO-x** - Poly(glycolide-co-caprolactone) (75/25) monofilament absorbable **BIOPRO**- Polypropylene monofilament non-absorbable	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 13464-2018-CE-CZS-NA-PS

Sites covered by this certificate

Site Name	Address
BIOSINTEX S.R.L.	4 Vladicеasca Str., RO 077168, Snagov, Romania

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

Management System Certificate

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
257642-2018-AQ-CZE-NA-PS Rev. 1.0	PRJC-575485-2017-MSC-CZE	11 April 2019	11 April 2022

This is to certify that the management system of:

Biosintex S.R.L.
4 Vladiceasca Str.
077168 Snagov
Ilfov County
Romania

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Design, development, manufacturing and trade of sterile surgical sutures, with / without needles, surgical sterile prosthesis for soft tissues and surgical meshes for women urinary incontinence.

Place and Date:
Høvik, 11 April 2019

NORWEGIAN ACCREDITATION
MSYS 018

For
DNV GL PRESAFE AS

Bjørg Synnøve Nesgård

This Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info.

CSQ

MED

www.imq.it

CISQ is a member of

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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N°005A, SGA N°006D, SCR N°005F, SSI N°003G, PSH N°007I, SGE N°006M, EMAS N°003P, PRD N°005B, PAS N°006C ISP N°063E, LAB N°012L, 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 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

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

DNV BUSINESS ASSURANCE

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE

Certificate No. 65242-2009-CE-ITA-NA Rev. 2.0
This Certificate consists of 3 pages

This is to certify that the Quality Management System of

CERACARTA S.P.A.

Italy

for production and final product inspection/testing of

Electromedical Recording Paper

has been assessed with respect to

the conformity assessment procedure described in Article 11.5 and Annex V (Module D1) of Council Directive 93/42/EEC on Medical Devices for the aspects of manufacture concerned with the conformity of the products with metrological requirements, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 08 September 2014

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

Aud Løken Eiklid
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

CE

Notified Body No.:
0434

This Certificate is valid until:
09 September 2019

Angela Lanna
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
0	Original Certificate	2004-09-09
1	Re-certification	2009-09-09
2	**Re-certification**	**2014-09-09**

Products covered by this Certificate

Product Description	Product	Class
Electromedical Recording Paper	Recording paper for: • ECG • EEG • CTG • laboratory analysis	Im

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Site Name	Address
CERACARTA S.p.A.	Via Secondo Casadei, 14 - Z.I. Villa Selva – 47122 Forlì - Italy

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid.

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE

G-CERTI Certificate

G-CERTI hereby certifies that

DURICO C&T INC.

33, Oedap 6-gil, Sangju-si, Gyeongsangbuk-do, Korea

Has been audited by G-CERTI and has implemented

Medical Devices-Quality Management Systems

ISO 13485:2003

Scope of Registration

Design, Development, Manufacture and Sevice of Special Paper (Thermal Paper, Ink-Jet Paper, Photographic Paper, Mat Sheet)

Issue Date	: 30	Jun.	2017
Expiry Date	: 04	Jul.	2020
Original Date	: 05	Jul.	2014
Certification No	: GK - 0233 - MD		

Chief Executive

To verify the validity of this certificate please visit : www.gcerti.com
This is to certify that the Management Systems of this company has been found to confirm to the above G CERTI FI 12 03

ACCREDITED
Management Systems Certification Body
MSCB-113

G-CERTI SYSTEM SERVICE

G-CERTI 15F, #88, Eunpyeong-ro, Eunpyeong-gu, Seoul, Korea / www.gcerti.com

EC Declaration of Conformity

Manufacturer: Durico C&T, Inc.
Oedap-6 gil 33, Sangju-si
Gyeongbuk 742-320, Korea

Phone: 82 2 525 8405
Fax: 82 2 525 7461
E-mail: info@durico.co.kr, http://www.durico.co.kr

European Representative: Durico Imaging s.a.r.l.
158 Rue Diderot
93500 PANTIN, France

Product: Thermal Paper for Video Printer (Super ULSTAR Brand)
Model: ULSTAR-1100 HG, ULSTAR-1100 HD, Ulstar-1100 HD Matt, Ulstar-2100 HD, & ULSTAR-1100 S

Classification: Class I by the rules of Classification Criteria, Annex IX, MDD 93/42/EEC.

Conformity Assessment Route: Annex VII, MDD 93/42/EEC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Place and Date of issue: Korea, July 1, 2014

Signature:

J.W. Kim, President
on behalf of Durico C&T, Inc.

СИСТЕМА СЕРТИФИКАЦИИ ГОСТ Р

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

Добровольная сертификация

СЕРТИФИКАТ СООТВЕТСТВИЯ

№ РОСС RU.ИМ02.Н18061

Срок действия с 24.06.2019г. по 24.06.2020г.

№ 0405450

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 паровой стерилизации химические одноразовые «ИНТЕСТ-П-«ВИНАР» по ТУ 9398-041-11764404-2003
Серийный выпуск.

код ОК
034-2014 (КПЕС 2008)
32.50.50.190

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ НОРМАТИВНЫХ ДОКУМЕНТОВ

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

код ТН ВЭД
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 № 16-853 от 20.06.2016г. ИЦ МИ АНО «ВНИИИМТ» (№ RA.RU.21ИМ04).

Регистрационные удостоверения № РЗН 2013/39 от 08.02.2013г. Федеральной службы по надзору в сфере здравоохранения (РОСЗДРАВНАДЗОР)

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

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

Добровольная сертификация

СЕРТИФИКАТ СООТВЕТСТВИЯ

№ РОСС RU.ИМ02.Н18058

Срок действия с 24.06.2019г. по 24.06.2020г.

№ 0405447

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 воздушной стерилизации химические интегрирующие одноразовые (класс 5) «Стеритест-В-«ВИНАР» и «Стеритест-Вл-«ВИНАР» по ТУ 9398-019-11764404-2003

Серийный выпуск.

КОД ОК
034-2014 (КПЕС 2008) 32.50.50.190

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ НОРМАТИВНЫХ ДОКУМЕНТОВ

ГОСТ ISO 11140-1-2011 (класс 5),

ГОСТ Р 50444-92 (разделы 3,5,8)

КОД ТН ВЭД
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 № 16-855 от 20.06.2016г. ИЦ МИ АНО «ВНИИИМТ» (№ RA.RU.21ИМ04).

Регистрационное удостоверение № РЗН 2013/42 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

Орган по сертификации медицинских изделий для сертификатов и деклараций М.П. 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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Italia

CERTIFICATO

Nr. 50 100 5990/B - Rev.006

Si attesta che / This is to certify that

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

FAZZINI S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

STRADA STATALE PADANA SUPERIORE 317
IT - 20090 VIMODRONE (MI)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI CEI EN ISO 13485:2016

SISTEMI QUALITÀ – DISPOSITIVI MEDICALI
QUALITY SYSTEMS – MEDICAL DEVICES

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

VEDI ALLEGATO 1
SEE ANNEX 1

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 049A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Andrea Coscia
Direttore Divisione Business Assurance

Validità /Validity
Dal / From: 2018-10-01
Al / To: 2021-06-14

Data emissione / Printing Date
2018-10-01

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2006-07-02

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2018-06-14
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE 2018-06-14

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Italia

ALLEGATO 1 AL CERTIFICATO NR 50 100 5990/B - Rev.006
ANNEX 1 TO CERTIFICATE NO 50 100 5990/B - Rev.006

IL CERTIFICATO NR 50 100 5990/B - Rev.006 È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE:
THE CERTIFICATE N 50 100 5990/B - Rev.006 IS VALID FOR THE FOLLOWING SCOPE:

Progettazione, gestione della fabbricazione, immissione in commercio e assistenza post vendita di dispositivi attivi chirurgici (aspiratori chirurgici), dispositivi non attivi per terapia intensiva (aspiratori chirurgici manuali), dispositivi attivi per la respirazione (aerosol) e loro accessori. Gestione della progettazione e della fabbricazione, immissione in commercio e assistenza post vendita di dispositivi non attivi con funzione di misura (sfigmomanometri, bilance), dispositivi non attivi per l'anestesia e l'emergenza e la cura intensiva (palloni, accessori per respirazione, anestesia ed aerosolterapia, immobilizzatori, laringoscopi endotracheali, set di pronto soccorso, barelle), dispositivi non attivi ortopedici e per la riabilitazione (ausili per disabili e riabilitazione), strumenti chirurgici non attivi, strumenti chirurgici attivi (elettrobisturi), dispositivi non attivi (dispositivi ospedalieri ed ambulatoriali per il supporto e la movimentazione del paziente e accessori, stetoscopi), dispositivi attivi non impiantabili e relativi accessori. Gestione della progettazione e della fabbricazione, immissione in commercio e assistenza post vendita di dispositivi attivi per monitoraggio (elettrocardiografi, pulsossimetri, monitor, bilance). Commercializzazione e assistenza post vendita di dispositivi non attivi per l'anestesia e l'emergenza e la cura intensiva (accessori per respirazione ed anestesia, accessori per medicazioni e per prelievi), dispositivi attivi per il posizionamento ed il trasporto del paziente (tavoli operatori), dispositivi attivi per la respirazione (accessori per respirazione), dispositivi attivi per la disinfezione e sterilizzazione (sterilizzatrici), dispositivi attivi per monitoraggio (termometri, misuratori di pressione), dispositivi per l'elettrochirurgia, la stimolazione o l'inibizione (stimolatori), dispositivi non attivi con funzione di misura (termometri)

Design, manufacturing management, trade and after sales service of active surgical devices (suction pumps), non-active devices for intensive care (manual suction pumps), active devices for breathing therapy (aerosol) and their accessories. Management of design and manufacture, trade and after sales service of non-active devices with a measuring function (blood pressure monitors, scales), non-active devices for anesthesia, emergency and intensive care (balloons, accessories for breathing, anesthesia and aerosol therapy, immobilizers, laryngoscopes endotracheal, first aid kit, stretchers), non-active devices for orthopedic and rehabilitation (aids for the disabled and rehabilitation), non-active surgical instruments, active surgical instruments (electrocautery), non-active devices (devices for hospitals and ambulatory for the support and movement of the patient and accessories, stethoscopes), non-active implantable devices and related accessories. Management of design and manufacture, marketing and after sales service of active devices for monitoring (electrocardiographs, pulse oximeters, monitors, scales). Trade and after sales service of non-active devices for anesthesia, emergency and intensive care (accessories for breathing and anesthesia, dressings and accessories for withdrawals), active devices for positioning and patient transport (operating tables) , active devices for respiration (breathing accessories), active devices for disinfection and sterilization (sterilizers), active devices for monitoring (thermometers, blood pressure monitors), devices for electrosurgery, stimulation or inhibition (stimulators), non active devices with a measuring function (thermometers)

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