ORDIN DE PLATA NR.: 21 TIP.DOC. 1

DATA EMITERII:23 ianuarie 2020

PLATITI: 5000-00 LEI: Cinci Mii lei 00 bani

PLATITOR: (R) 'BIOSISTEM MLD" SRL

CONTUL DE PLATI/CODUL IBAN MD95ML000000002251429243

CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR: BC"Moldindconbank"S.A. fil."Invest" Chisinau

CODUL BANCII: MOLDMD2X329

BENEFICIAR (R)Institutul d e Cardiologie IMSP

CONTUL DE PLATI/CODUL IBAN MD98ML000000002251902161

CODUL FISCAL :1003600150613 /

PRESTATORUL BENEFICIAR: BC"Moldindconbank"S.A.

CODUL BANCII: MOLDMD2X

DESTINATIA PLATII:Garan?ia de buna execu?ie” sau “Pentru garantia de buna execu?ie la licitatia publica nr. ocds-b3wdp1-MD-1577965957088 din 23.01.2020

TIPUL TRANSFERULUI NORMAL/URGENT :N

L.S.

CODUL TRANZACTIEI:001

DATA PRIMIRII:23/01/2020

DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie
MIIGQQYJKoZIhvcNAQcCoIIGMjCCBi4CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb
DQEHAaCCBEowggRGMIIDLqADAgECAhNHAABcVycdZVmKkP29AAAAAFxXMA0GCSq
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(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr
MIIGUgYJKoZIhvcNAQcCoIIGQzCCBj8CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3
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DTE5MDEyODEwMTQwNFoXDTIxMDEyODEwMjQwNFowgY4xCzAJBgNVBAYTAk1EMScw
YDVQQKEx5NZWRlY29yIFNSTCwgQmlvc2lzdGVtIE1MRCBTUkwxEjAQBgNVBAsT

L.S. (semnatura electronica)

CONDUCATOR:

(semnatura manuala)

CONTABIL-SEF:

(semnatura manuala)

Digitally signed by Poiata Vitalie
Date: 2020.01.23 10:31:47 EET
Reason: MoldSign Signature
Location: Moldova

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

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

EXPORT DIVISION
tel. +39 02 953854209/221/225
fax +39 02 95380056
export@gimaitaly.com

Gessate, 7 February 2012

CONFORMITY OF GIMA PRODUCTS

According to the annex VII of the Council Directive 93/42/EEC

as amended by the European Directive 2007/47/EEC concerning medical devices

GIMA declares that all medical devices illustrated on

GIMA INTERNATIONAL CATALOGUE

meet the provisions of the following Council Directive (when applicable)

93/42/EEC AS AMENDED BY THE EUROPEAN DIRECTIVE 2007/47/EEC

as below:

A) For all products classified in **CLASS I**, we have in our company a technical file as required from annex VII, and it is available a certificate of conformity signed by the responsible inside the EU (generally GIMA).

B) For all products in CLASS IIa and IIb it is available, or it will be available in one month, a declaration of conformity signed by an official European Notified Body or the ISO 9002 certificate of the manufacturer.

GIMA S.p.A.
Q.A. Department
Nicola Manzoni

CERTIFICATE

Reg. Number	10164 - A	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2018-10-01
Valid Until	2021-10-14	IAF Sector	29

Quality Management System Certificate

ISO 9001:2015

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Trade, packaging and service of medical devices (MD), in vitro diagnostic products (IVD), personal protective equipments (PPE), biocides, veterinary items, medical accessories furniture and aids

Chief Operating Officer
Giampiero Belcredi

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

SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 0041
PRS N° 089C

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

SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 004I
PRS N° 089C

GRENA®

VAT no. GB 821 2900 64

1000 Great West Road, Brentford, Middlesex TW8 9HH,.UK Phone +44 131 208 207 6 Fax +44 131 777 80 77

DECLARATION OF CONFORMITY

Manufacturer

Grena Limited
1000 Great West Road
Brentford, Middlesex, TW8 9HH
United Kingdom

Product(s)

Disposable circular staplers with related surgical instruments (class IIb, rule 8)
Disposable linear staplers and cartridges for linear staplers (class IIb, rule 8)
Disposable bone marrow aspiration needles (class IIa, rule 6)
Disposable bone marrow biopsy needles (class IIa, rule 6)
Disposable staples cartridges for reusable linear staplers (class IIb, rule 8)
Disposable staples cartridges for reusable circular staplers (class IIb, rule 8)
Disposable endoscopic linear cutting staplers (class IIa, rule 6)
Cartridges for disposable endoscopic linear cutting staplers (class IIb, rule 8)
Surgical meshes (class IIb, rule 8)
Disposable automatic clip appliers with clips (class IIb, rule 8)
LigaV® – Titanium ligating clips (class IIb, rule 8)
VClip® – Titanium ligating clips (class IIb, rule 8)
Click'a-V® – Polymer ligating clips (class IIb, rule 8)
Disposable endoscopic instruments:
- Disposable grasper with ratchet atraumatic fenestrated (class IIb, rule 9)
- Disposable grasper with ratchet-Allis (class IIb, rule 9)
- Disposable grasper with ratchet-Maxi Grip (class IIb, rule 9)
- Disposable toothed grasper with ratchet (class IIb, rule 9)
- Disposable grasper with ratchet –Babcock (class IIb, rule 9)
- Disposable Metzenbaum scissors-curved (class IIb, rule 9)
- Disposable scissors-straight (class IIb, rule 9)
- Disposable scissors-hook (class IIb, rule 9)
- Disposable dissector-Maryland (class IIb, rule 9)
- Disposable dissector with ratchet- Maryland (class IIb, rule 9)
- Disposable endoscopic dissector 3mm – Maryland, non-ratcheted
- Disposable endoscopic dissector 3mm – Maryland, ratcheted
- Disposable endoscopic grasper 3mm – atraumatic fenestrated
- Disposable endoscopic scissors 3mm – curved

Limited use endoscopic instruments:
- Limited use dissector- Maryland (class IIb, rule 9)
- Limited use dissector with ratchet- Maryland (class IIb, rule 9)
- Limited use Metzenbaum scissors- curved (class IIb, rule 9)
- Limited use scissors-straight (class IIb, rule 9)
- Limited use scissors-hook (class IIb, rule 9)
- Limited use grasper with ratchet atraumatic fenestrated (class IIb, rule 9)
- Limited use disposable grasper with ratchet-Allis (class IIb, rule 9)
- Limited use grasper with ratchet-Maxi Grip (class IIb, rule 9)
- Limited use toothed grasper with ratchet (class IIb, rule 9)
- Limited use grasper with ratchet –Babcock (class IIb, rule 9)

Reusable endoscopic surgical instruments (class IIb, rule 9)
Disposable linear cutting staplers and cartridges for cutting staplers (class IIb, rule 8)
Disposable trocars with accessories (class IIa, rule 7)
Sterile disposable skin staplers (class IIa, rule 7)
Thoracentesis/paracentesis sets (class IIa, rule 6)
Suction cannulas and suction sets (class IIa, rule 7)
Suction-irrigation sets (class IIa, rule 6)
Disposable skin staples removers (class I sterile, rule 1)
Chest drainage systems (class I sterile, rule 1)
Connecting tubes (class I sterile, rule 1)
Retrieval bags (class IIa, rule 6)
Veress needles (class IIa, rule 6)
Silicone slings (class IIa, rule 6)
Arida® absorbing pads (class I, rule 1)
Arida® absorbing pads – sterile (class I sterile, rule 1)
Solidifying agent (class I, rule 1)
Open surgery and endoscopic clip appliers (class I, rule 6)
Vomit bags (class I, rule 1)

Grena Limited – Incorporated in England & Wales – Company No. 04793131

GRENA®

VAT no. GB 821 2900 64

1000 Great West Road, Brentford, Middlesex TW8 9HH,.UK Phone +44 131 208 207 6 Fax +44 131 777 80 77

Classification According to Annex IX of Directive 93/42/EEC

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the directive 93/42/EEC concerning medical devices which apply to them. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied

All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.

Notified Body

CE 0197

TÜV Rheinland LGA Products GmbH
Lillystrasse 2
90431 Nürnberg
Germany

EC Certificate(s)

HD 60040590 0001
DD 60040589 0001

Brentford, 09.05.2014

Wiesław Brodaczewski
Director

Grena Limited – Incorporated in England & Wales – Company No. 04793131

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60100980 0001

Report No.: 26300270 002

Manufacturer:
Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Products: (see attachments for products and site included)

Replaces approval, registration no.: DD 60040589 0001

Expiry Date: 2020-04-13

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2015-04-30

Date: 2015-04-30

Notified Body

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60100980 0001
Report No.: 26300270 002

Manufacturer:
Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Products included:

- Disposable trocars
- Infusion sets
- Retrieval bags
- Disposable skin staplers
- Suction cannulas and suction sets
- Thoracentesis/Paracentesis sets
- Transfusion sets
- Veress needles
- Thoracic catheters
- Suction-irrigation sets
- Silicone slings

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Disposable skin staples removers
- Chest drainage systems
- Connecting tubes
- Absorbing pads

Date: 2015-04-30

TÜV Rheinland LGA Products GmbH

Notified Body

Dipl.-Ing. S. Pane

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60100980 0001
Report No.: 26300270 002

Manufacturer:
Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Site included:

Grena Limited
Chelsea House, Chelsea Street,
Nottingham, NG7 7HP,
United Kingdom

TÜV Rheinland LGA Products GmbH

Notified Body

Date: 2015-04-30

Dipl.-Ing. S. Pane

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60100981 0001

Report No.: 26300270 002

Manufacturer:
Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Products: (see attachments for products and site included)

Replaces approval, registration no.: HD 60040590 0001

Expiry Date: 2020-04-13

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2015-04-30

Date: 2015-04-30

Notified Body

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60100981 0001
Report No.: 26300270 002

Manufacturer: Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Products included:

- Reusable endoscopic surgical instruments
- Disposable endoscopic surgical instruments
- Disposable linear cutting staplers with cartridges
- Disposable linear staplers with cartridges
- Disposable circular staplers with related surgical instruments
- Staples cartridges for reusable circular staplers
- Staples cartridges for reusable linear staplers
- Ligating clips
- Surgical meshes
- Cartridges for disposable endoscopic linear cutting staplers
- Disposable endoscopic linear cutting staplers

Notified Body

Date: 2015-04-30

Dipl.-Ing. S. Pane

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60100981 0001
Report No.: 26300270 002

Manufacturer: Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Site included:

Grena Limited
Chelsea House,Chelsea Street,
Nottingham, NG7 7HP,
United Kingdom

Notified Body

Date: 2015-04-30

Dipl.-Ing. S. Pane

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

has established and applies a quality management system for medical devices for the following scope:

Design and development, production and distribution of disposable and reusable medical devices for surgical and patient care procedures
(See attachment for site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2015-04-30
Certificate Registration No.:	SX 60100982 0001
An audit was performed. Report No.:	26300270 002
This Certificate is valid until:	2018-04-13

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH

Date 2015-04-30

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60100982 0001
Report No.: 26300270 002

Organization:
Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Scope:

Site included:

Grena Limited
Chelsea House, Chelsea Street,
Nottingham, NG7 7HP,
United Kingdom

Distribution

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland

Date: 2015-04-30

Dipl.-Ing. S. Pane

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

has established and applies a quality management system
for the following scope:

Design and development, production and distribution of disposable and reusable medical devices for surgical and patient care procedures (see attachment for site included)

Proof has been furnished that the requirements specified in

EN ISO 9001:2008

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2015-04-30
Certificate Registration No.:	SY 60100983 0001
An audit was performed. Report No.:	26300270 002
This Certificate is valid until:	2018-04-13

Certification Body

TÜV Rheinland LGA Products GmbH TÜVRheinland

Dipl.-Ing. S. Pane

Date 2015-04-30

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SY 60100983 0001
Report No.: 26300270 002

Organization:
Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Scope:

Site included:

Grena Limited
Chelsea House, Chelsea Street,
Nottingham, NG7 7HP,
United Kingdom

Distribution

Certification Body

Date: 2015-04-30

Dipl.-Ing. S. Pane

LivaNova

Health innovation that matters

DICHIARAZIONE DI CONFORMITÀ CE
EC DECLARATION OF CONFORMITY

La sottoscritta **Sorin Group Italia S.r.l.** (Via Crescentino sn, 13040 Saluggia, VC – Italia) dichiara sotto la propria responsabilità di Fabbricante che i prodotti sotto elencati sono conformi alle disposizioni applicabili della Direttiva del Consiglio 93/42/CEE e del Regolamento (UE) della Commissione no. 207/2012.

*We, the undersigned **Sorin Group Italia S.r.l.** (Via Crescentino sn, 13040 Saluggia, VC – Italy) declare under our sole responsibility as Manufacturer that the products identified below conform to the relevant provisions of Council Directive 93/42/EEC and Commission Regulation (EU) no. 207/2012.*

Identificazione prodotto *Product identification*				
Prodotto *Product*	**Taglia** *Size*	**Codice prodotto (REF)** *Catalogue number (REF)*	**Codice d'ordine** *Ordering code*	**Classe** *Class*
Bicarbon Fitline LFA Aortic	19	ART19LFA	ICV0917	III
	21	ART21LFA	ICV0918	
	23	ART23LFA	ICV0919	
	25	ART25LFA	ICV0920	
	27	ART27LFA	ICV0921	
	29	ART29LFA	ICV0922	
	31	ART31LFA	ICV0923	
Bicarbon Fitline LFM Mitral	19	MTR19LFM	ICV0924	III
	21	MTR21LFM	ICV0925	
	23	MTR23LFM	ICV0926	
	25	MTR25LFM	ICV0927	
	27	MTR27LFM	ICV0928	
	29	MTR29LFM	ICV0929	
	31	MTR31LFM	ICV0930	
	33	MTR33LFM	ICV0931	
Bicarbon Slimline LSA Aortic	17	ART17LSA	ICV0934	III
	19	ART19LSA	ICV0935	
	21	ART21LSA	ICV0936	
	23	ART23LSA	ICV0937	
	25	ART25LSA	ICV0938	
	27	ART27LSA	ICV0939	
Bicarbon Overline Aortic	16	ART16LOV	ICV0870	III
	18	ART18LOV	ICV0871	
	20	ART20LOV	ICV0872	
	22	ART22LOV	ICV0873	
	24	ART24LOV	ICV0874	

Sorin Group Italia S.r.l.
a wholly-owned subsidiary of LivaNova Plc

Sede Legale:
Via Benigno Crespi, 17 – 20159 Milano – Italy
Sede Amministrativa:
Via Statale 12 Nord, 86 – 41037 Mirandola (MO) Italy
Tel.+39 0535 29811 Fax +39 0535 25229
Stabilimenti:
Via Statale 12 Nord, 86 – 41037 Mirandola (MO) Italy
Tel.+39 0535 29811 Fax +39 0535 25229
Via Crescentino sn – 13040 Saluggia (VC) Italy
Tel.+39 0161 487.1 Fax +39 0161 487.681
Viale Cesare Cattaneo, 20 – 22063 Cantù (CO) Italy
Tel.+39 031 7370411 Fax +39 031 7370410

Sedi Commerciali:
Via Statale 12 Nord, 86 – 41037 Mirandola (MO) Italy
Tel.+39 0535 29811 Fax +39 0535 25229
Via Benigno Crespi, 17 – 20159 Milano – Italy
Tel.+39 02 69465.211 – Fax +39 02 69465.300

Servizio Clienti Italia: +39 02 37014960
International Customer Service: +39 02 37027030

Capitale Sociale: € 8.550.034,00
Registro Imprese di Milano N. 10556980158
R.E.A. MILANO 1767776 – N.Mecc. Imp./Exp. MI 352423
Cod. Fisc. 10556980158 – Part. IVA 02109510368
ISO CODE IT02109510368
Registro Nazionale Produttori AEE N. IT08020000000823

www.livanova.com

Società soggetta all'attività di direzione e coordinamento da parte della capogruppo LivaNova Plc

LivaNova

Health innovation that matters

Informazioni relative alla valutazione della conformità *Conformity assessment information*		
Organismo Notificato *Notified Body*	**Procedura di valutazione conformità** *Conformity assessment procedure*	**Numero certificati CE** *CE Certificates number*
TÜV SÜD Product Service GmbH (0123) Ridlerstr. 65, D-80339 München, GERMANY	Certificazione CE di conformità del tipo di cui all' Allegato III, Direttiva 93/42/CEE, unitamente alla Dichiarazione di Conformità CE di cui all' Allegato V (garanzia di qualità della produzione) *EC type-examination set out in Annex III, Directive 93/42/EEC coupled with the EC Declaration of Conformity set out in Annex V (production quality assurance)*	- Annex III: G5 17 09 01664 011 Valid until: 2021-12-19 - Annex V: G2 18 02 01664 023 Valid until: 2023-03-31

La presente Dichiarazione di Conformità è valida per i dispositivi prodotti presso l'officina Cardiac Surgery sita in Via Crescentino sn, 13040 Saluggia, VC – Italia e descritti nel Technical File TF-08.

This Declaration of Conformity is valid for the medical devices manufactured in the Cardiac Surgery facility of Via Crescentino sn, 13040 Saluggia, VC – Italy and described in the Technical File TF-08.

La presente Dichiarazione di Conformità è valida a partire dal 1° Aprile 2018 e fino alla prima data di scadenza dei certificati sopra indicati.

This Declaration of Conformity is valid from April the 1st, 2018 until the earliest expiry date of the certificates identified above.

Saluggia, March 13, 2018

Mauro Ercolani
Director, Regulatory Affairs
Sorin Group Italia S.r.l.

Sorin Group Italia S.r.l.
a wholly-owned subsidiary of LivaNova Plc
Sede Legale:
Via Benigno Crespi, 17 – 20159 Milano – Italy
Sede Amministrativa:
Via Statale 12 Nord, 86 – 41037 Mirandola (MO) Italy
Tel.+39 0535 29811 Fax +39 0535 25229
Stabilimenti:
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Viale Cesare Cattaneo, 20 – 22063 Cantù (CO) Italy
Tel.+39 031 7370411 Fax +39 031 7370410

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Servizio Clienti Italia: +39 02 37014960
International Customer Service: +39 02 37027030

Capitale Sociale: € 8.550.034,00
Registro Imprese di Milano N. 10556980158
R.E.A. MILANO 1767776 – N.Mecc. Imp./Exp. MI 352423
Cod. Fisc. 10556980158 – Part. IVA 02109510368
ISO CODE IT02109510368
Registro Nazionale Produttori AEE N. IT08020000000823

www.livanova.com

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 18 02 01664 023

Manufacturer:

SORIN GROUP ITALIA S.r.l.
Via Crescentino sn
13040 Saluggia (VC)
ITALY

Facility(ies):

SORIN GROUP ITALIA S.r.l.
Via Crescentino sn, 13040 Saluggia (VC), ITALY

Product Category(ies):

Mechanical heart valves and associated accessories (sizers, rotators, handles)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: ITA1077973

Valid from: 2018-04-01
Valid until: 2023-03-31

Date, 2018-02-23

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

EC Type-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex III
(Devices in class IIb or III)

No. G5 17 09 01664 011

Manufacturer:

SORIN GROUP ITALIA S.r.l.
Via Crescentino sn
13040 Saluggia (VC)
ITALY

Product:

Heart Valves
Sorin Mechanical Heart Valves

The Certification Body of TÜV SÜD Product Service GmbH declares that a type examination has been carried out on the respective device type in accordance with MDD Annex III (4). This representative sample for the envisaged production conforms to the requirements of this Directive. For marketing of class III devices an additional Annex IV or V certificate is mandatory. For marketing of class IIb devices an additional Annex IV, V or VI certificate is mandatory. See also notes overleaf.

Report no.: 713114103

Valid from: 2017-10-17
Valid until: 2021-12-19

Date, 2017-10-16

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
EC Type-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex III
(Devices in class IIb or III)

No. G5 17 09 01664 011

Model(s):

Bicarbon Fitline
Bicarbon Slimline
Bicarbon Overline

Parameters:

Model Name	Product codes
Bicarbon Fitline LFA Aortic	ICV0917/ART19LFA
	ICV0918/ART21LFA
	ICV0919/ART23LFA
	ICV0920/ART25LFA
	ICV0921/ART27LFA
	ICV0922/ART29LFA
	ICV0923/ART31LFA
Bicarbon Fitline LFM Mitral	ICV0924/MTR19LFM
	ICV0925/MTR21LFM
	ICV0926/MTR23LFM
	ICV0927/MTR25LFM
	ICV0928/MTR27LFM
	ICV0929/MTR29LFM
	ICV0930/MTR31LFM
	ICV0931/MTR33LFM
Bicarbon Slimline LSA Aortic	ICV0934/ART17LSA
	ICV0935/ART19LSA
	ICV0936/ART21LSA
	ICV0937/ART23LSA
	ICV0938ART25LSA
	ICV0939/ART27LSA
Bicarbon Overline Aortic	ICV0870/ART16LOV
	ICV0871/ART18LOV
	ICV0872/ART20LOV
	ICV0873/ART22LOV
	ICV0874/ART24LOV

Facility(ies):

SORIN GROUP ITALIA S.r.l.
Via Crescentino sn, 13040 Saluggia (VC), ITALY

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Istituto Superiore di Sanità

Organismo Notificato 0373
Sezione Presso O.N.DI.CO.
Notified Body 0373
Unit relating to O.N.DI.CO.

Certificato n° *Certificate no.* **QPZ-1746-14**

Addendum n° *addendum no.* **01-14**

Data di emissione *Issue date* **30.09.2014**

Data di scadenza *Expiry date* **29.09.2019**

APPROVAZIONE DEL SISTEMA DI GARANZIA DELLA QUALITA' DELLA PRODUZIONE E/O DELLA STERILIZZAZIONE

secondo l'Allegato V della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.
(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)

APPROVAL OF QUALITY ASSURANCE SYSTEM FOR PRODUCTION AND/OR STERILIZATION

according to Annex V of EC Directive 93/42/EEC and subsequent modifications and integrations.
(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)

L'Istituto Superiore di Sanità, Organismo Notificato 0373, certifica che il sistema di garanzia della qualità della produzione e/o della sterilizzazione attuato da

The Istituto Superiore di Sanità, Notified Body 0373, certifies that the quality assurance system for the production and/or sterilization enforced by

INDUSTRIA FARMACEUTICA GALENICA SENESE S.r.l.

***Sede Legale/** Registered Office:*
Via Cassia Nord, 351 – 53014 Monteroni D'Arbia (SI) ITALIA

Altre sedi del Fabbricante /Other sites of the Manufacturer:
Sede Produttiva/** Production Site: **Via Cassia Nord, 351 – 53014 Monteroni D'Arbia (SI) Italia

per il dispositivo/i *for the device(s)*

MD 0113 Dispositivi non attivi per perfusione e conservazione degli organi, sterile/Non –active perfusion and organs preservation device, sterile ***(vedi allegato tecnico/ see technical sheet)**

è conforme ai requisiti applicabili della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.

is in compliance with the applicable requirements of Council Directive 93/42/EEC and subsequent modifications and integrations.

Il Direttore dell'O.N.DI.CO.
The Director of O.N.DI.CO.
(Dr. Carmine Guarino)

ORGANISMO NOTIFICATO 0373 - SEZIONE PRESSO ONDICO

*** L'allegato tecnico è parte integrante del presente Certificato**
The technical sheet is an integral part of this Certificate.

Istituto Superiore di Sanità

Organismo Notificato 0373
Sezione Presso O.N.DI.CO.
Notified Body 0373
Unit relating to O.N.DI.CO.

ALLEGATO TECNICO

TECHNICAL SHEET

Il Certificato n°
The Certificate no. **QPZ-1746-14**

Addendum n°
addendum no. **01-14**

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

MD 0113 Dispositivi non attivi per perfusione e conservazione degli organi, sterile/Non –active perfusion and organs preservation device, sterile **Classe** *(Class)*: **IIa**
Nome prodotto *(Product name)*
SOLUZIONE DI BRETSCHNEIDER MODIFICATA, STERILE *Soluzione per la conservazione degli organi da trapianto*

Il Direttore dell'O.N.DI.CO.
The Director of O.N.DI.CO.
(Dr. Carmine Guarino)

ORGANISMO NOTIFICATO 0373 - SEZIONE PRESSO ONDICO

Certificate of Registration

This certificate has been awarded to

Industria Farmaceutica Galenica Senese srl

Via Cassia Nord 351, 53014 Monteroni d'Arbia (SI), Italy

in recognition of the organization's Quality Management System which complies with

ISO 13485:2016

The scope of activities covered by this certificate is defined below

Production and Trading of Medical Devices in Aqueous Solution (for example Solutions for Irrigation, for Inhalation, for Washing of Extracorporeal Circuit, for Organs Preservation and Haemodyalisis).

Certificate Number:	Date of Issue: (Original)	Date of Issue:
61225/D/0001/UK/En	07 April 2017	22 January 2019
Issue No:	**Expiry Date:**	
3	23 May 2020	

Issued by: *On behalf of the Schemes Manager*

0043

Certificate of Registration

This certificate has been awarded to

Industria Farmaceutica Galenica Senese srl

Via Cassia Nord 351, 53014 Monteroni d'Arbia (SI), Italy

in recognition of the organization's Quality Management System which complies with

ISO 9001:2015

The scope of activities covered by this certificate is defined below

Production and Trading of Pharmaceutical Products infusion terminally sterilized, small and large volume, for human and veterinary use; non-sterile products: liquids for internal use (solutions for hemodialysis), production and trading of medical devices in aqueous solution (solutions for Irrigation, for inhalation and hemodialysis).

Certificate Number:	Date of Issue: (Original)	Date of Issue:
61225/A/0001/UK/En	18 December 2013	13 December 2018
Issue No:	**Expiry Date:**	
4	24 December 2019	

Issued by: *On behalf of the Schemes Manager*

UKAS MANAGEMENT SYSTEMS 0043