ORDIN DE PLATA NR.: 942 TIP.DOC. 1

DATA EMITERII:11 octombrie 2021

PLATITI: 8000-00 LEI: Opt 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 de Cardiologie IMSP

CONTUL DE PLATI/CODUL IBAN
MD98ML000000002251902161
CODUL FISCAL :1003600150613 /

PRESTATORUL BENEFICIAR
BC"Moldindconbank"S.A.

CODUL BANCII:
:MOLDMD2X :

DESTINATIA PLATII:Pentru garantia pentru: oferta la procedura de achizi?ie public: a nr. ocds-b3wdp1-MD-1630655182514 din 11.10.2021

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:11/10/2021
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSqSIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4XDTIxMDEyODExMzgwNVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRAwDgYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqGSIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4XDTIxMDEyODExMzkxOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAwDgYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

L.S.

CONDUCATOR: _____

(semnatura manuala)

CONTABIL-SEF: _____

(semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

Digitally signed by Poiata Vitalie
Date: 2021.10.08 17:57:11 EEST
Reason: MoldSign Signature
Location: Moldova

BC "MOLDINDCONBANK" S.A.
Filiala "Invest"

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 – 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московей, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000022514292 43**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării **12.08.2010**

Data eliberării **12.08.2010**

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

MD 0101250

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. **8506** din **28.04.2021**

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**

Denumirea prescurtată: **«BIOSISTEM MLD» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat şi codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

Sediul: **MD-2001, str. Albişoara, 16/1, ap.(of.) 7, mun. Chişinău, Republica Moldova.**

Obiectul principal de activitate:

1 Activitatea farmaceutică;

2 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;

3 Acordarea asistenţei medicale de către instituţiile medico-sanitare private;

4 Comerţul cu ridicata al calculatoarelor, echipamentelor periferice şi software-ului;

5 Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul;

6 Consultaţii în domeniul sistemelor de calcul.

Capitalul social: **5400** lei.

Administrator: POIATA VITALIE,

Asociaţi:

1. POIATA VITALIE 33,40 %

2. NASEDCHIN ALEXANDR 33,30 %

3. KOJEVNIKOV DMITRII 33,30 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 28.04.2021.

Specialist coordonator
tel. 022-207-840

Lazari Aliona

"AGENŢIA SERVICII PUBLICE" IDNO 1002600024700 REPUBLICA MOLDOVA CHIŞINĂU 003

EB 0358735

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandr Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

Anexa nr.7.2 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № A2117023 **din** / от 07.10.2021

1. Destinația / Назначение

Pentru participarea la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea / Наименование	**Codul fiscal / Numărul de identificare** / Фискальный код / Идентификационный номер
BIOSISTEM MLD S.R.L.	1010600028048
Adresa sediului de bază (strada, numărul) / Адрес основного месторасположения (улица, номер)	**Codul - Denumirea localității** / Код - Наименование населенного пункта
Albisoara nr.16 bl.1 of.7	0150-SEC.RISCANI

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat / Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет: **0,00** lei/лей.

4. Valabil pînă la / Действителен до 22.10.2021

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Șef DDF Rîșcani a DGAF mun. Chișinău
Funcția/Должность

Semnătura/Подпись

Viorica CĂUȘ
Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

Executor: **Claudia GOJAN**
Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 07.10.2021 ora 13:24:20 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (3,52)

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: str. Albișoara 16/1 of.7, or. Chișinău
tel.+373-22-808517, +373-22-808719, fax +373-22-808519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Către Grupul de lucru pentru evaluarea
Procedurii de achiziție nr. ocds-b3wdp1-MD-1630655182514
Din 20 sept 2021, 16:00 - 11 oct 2021, 12:00
din cadrul IMSP Institutul de Cardiologie

Declarație

Prin prezenta, SRL „Biosistem-mld", declara ca :

- Va înregistra în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale bunurile contractate pînă la momentul livrării acestora.
- Va prezenta monstre, în termen de 3 zile de la solicitarea autorității contractante.

_____Vitalie Poiata

L.Ş.

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

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, manufacture 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 13485:2016

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

Effective Date:	2020-02-25
Certificate Registration No.:	SX 60147335 0001
An audit was performed. Report No.:	26300270 015
This Certificate is valid until:	2021-04-13

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2020-02-25

Sebastian Mniszek

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 Certificate
Registration No.: SX 60147335 0001
Report No.: 26300270 015

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

Scope:

Site included:

Grena Ltd.
Chelsea House
Chelsea Street
Nottingham NG7 7HP
United Kingdom

Activity: Design and development, manufacture and distribution of disposable and reusable medical devices for surgical and patient care procedures. Especially: production, purchasing, logistics and distribution of disposable and reusable medical devices.

Certification Body

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-02-25

Sebastian Mniszek

TÜVRheinland®

EC Certificate

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

Registration No.: DD 60147049 0001

Report No.: 26300270 017

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

Products: (see attachments for products and site included)

Replaces EC Certificate, registration no.: DD 60100980 0001

Expiry Date: 2024-05-26

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: 2020-02-25

Date: 2020-02-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Sebastian Mniszek

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 60147049 0001
Report No.: 26300270 017

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

Products included:

- Disposable trocars
- Retrieval bags
- Veress needles
- Disposable wound protectors /retractors

Notified Body

Date: 2020-02-25

Sebastian Mniszek

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60147049 0001
Report No.: 26300270 017

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: 2020-02-25

Sebastian Mniszek

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜVRheinland®

EC Certificate

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

Registration No.: HD 60147050 0001

Report No.: 26300270 016

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 60100981 0001

Expiry Date: 2024-05-26

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: 2020-02-25

Date: 2020-02-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Sebastian Mniszek

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 60147050 0001
Report No.: 26300270 016

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
- Staples cartridge for reusable linear cutting staplers
- Ligating clip cartridge to be used with reusable automatic clip appliers

Notified Body

Date: 2020-02-25

Sebastian Mniszek

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60147050 0001
Report No.: 26300270 016

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

Activity: Desing, development and manufacture

Notified Body

Date: 2020-02-25

Sebastian Mniszek

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

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. Servicing of suction devices. (see attachment for site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date:	2018-06-29
Certificate Registration No.:	SX 60130220 0001
An audit was performed. Report No.:	26300270 007
This Certificate is valid until:	2021-04-13

Certification Body

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

Date 2018-06-29

Sciera Maciej

Maciej Sciera

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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 Certificate
Registration No.: SX 60130220 0001
Report No.: 26300270 007

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

Scope:

Site included:

Grena Ltd.
Chelsea House
Chelsea Street
Nottingham NG7 7HP
United Kingdom

Activity: Design and development, production and distribution of disposable and reusable medical devices for surgical and patient care procedures. Especially: production, purchasing, logistics and distribution of disposable and reusable medical devices.

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2018-06-29

Sciera

Maciej Sciera

CERTIFICATE

Number: 2090418

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

including the implementation meets the requirements of the standard:

ISO 9001:2015
EN ISO 13485:2016

Scope:
Sales, order management, warehousing and distribution of medical devices.
Including regulatory affairs, post market surveillance, technical service, customer education and spine loaner operations

Certificate expiry date: 1 July 2024
Certificate effective date: 1 July 2021
Certified since: 1 July 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

MGMT. SYS. RvA C 589

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Certified organization(s) and/or locations:

	Different scope
Medtronic Trading NL B.V. Larixplein 4 5616 VB Eindhoven The Netherlands	Sales, order management and distribution of medical devices. Including customer education
Medtronic Italia S.p.A. Via Varesina 162 20156 Milano Italy	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Danmark A/S. Arne Jacobsens Alle 17 2300 Kopenhagen Denmark	Sales, order management and distribution of medical devices. Including customer education
Medtronic Finland Oy Lentajantie 3 01530 Vantaa Finland	Sales, order management and distribution of medical devices. Including customer education.
Medtronic AB P.O. Box 1034 164 21 Kista Sweden	Sales, order management and distribution of medical devices. Including customer education
Medtronic Norge AS Martin Linges vei 25 1364 Fornebu Norway	Sales, order management and distribution of medical devices. Including customer education.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Africa (Pty) Ltd. Waterfall Distribution Campus CNR K101 and Bridal Veil Road Waterfall Midrand 1685 Gauteng South Africa	Sales, order management, warehousing and distribution of medical devices. Including customer education and spine loaner operations.
Medtronic Medikal Teknoloji Ticaret Ltd Sti Saray Mah. Esnaf Sk. Akkom Ofis Park Laodik Plaza Sitesi B Blok Apt: 2/8 34764 Umraniye - Istanbul Turkey	Sales, order management and distribution of medical devices. Including customer education
Medtronic Ibérica S.A. Calle de Maria de Portugal, 11 28050 Madrid Spain	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Ibérica S.A. WTC Almeda Park Placa de la Pau, s/n. Edificio 7, 3 piso Cornella de Llobregat 08940 Barcelona Spain	Sales, order management and distribution of medical devices.
Medtronic Portugal LDA- Rua Tomas da Fonseca Torre E, 11 piso 1600 Lisboa Portugal	Sales, Order Management and distribution of medical devices including customer education. Warehousing and distribution of medical devices, including spine loaner operations

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Portugal, LDA- Avenida Gomes Pereira 61B Benfica 1600 Lisboa Portugal	Sales, Order Management and distribution of medical devices. Including customer education. Warehousing and distribution of medical devices, including spine loaner operations.
Medtronic GmbH Earl-Bakken-Platz 1 40670 Meerbusch Germany	Scope for EN ISO 13485:2016: Sales, order management and distribution of medical devices. Including customer education. ISO 9001:2015 excluded
Medtronic GmbH Mollsfeld 12 40670 Meerbusch Germany	Scope for EN ISO 13485:2016: Sales, order management and distribution of medical devices. Including customer education. ISO 9001:2015 excluded
Medtronic Osterreich GmbH Milennium Tower, 20th floor Handelskai 94-96 1200 Wien Austria	Sales, order management, warehousing and distribution of medical devices. Including customer education
Medtronic (Schweiz) AG Talstrasse 9 3053 Munchenbuchsee Switzerland	Sales, order management, warehousing and distribution of medical devices. Including customer education
Medtronic France SAS 9, boulevard Romain Rolland 75014 Paris France	Sales, order management and distribution of medical devices. Including customer education

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Hellas S.A. Avenue Kifisias 24 Building B 151 25 Marousi Pref. Attica Greece	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Hellas S.A. Diabetes Shop Mesogeion Avenue 2-4 115 27 Athens Greece	Sales, order management and distribution of diabetes medical devices. Including customer education.
Medtronic Romania SRL Ploiesti 42-44, Building B, B2 Wing, 2nd floor, district 1 Baneasa Business & Technology Park 013696 Bucharest Romania	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Hungária Kft. Bocskai ut 134-146 Cepulet 3. emelet 1113 Budapest Hungary	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Serbia Ltd. Bulevar Zorana Djindjica, 64a 11070 Belgrade Serbia	Sales, order management and distribution of medical devices. Including customer education.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Poland Sp.z o.o Medtronic Customer Care Center of Experience Warsaw Polna 11 00-633 Warszawa Poland	Order management of medical devices.
Medtronic Trading Ltd. 10 Hamada Street 4673344 Herzlya Israel	Import, sales, order management and distribution of medical devices. Including customer education
Medtronic Czechia s.r.o. Prosek Point, Budova B, Prosecka 852/66 852 66 Praha Czech Republic	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Bulgaria EOOD 48 Sitnyakovo blvd., R-N OBORISHTE DISTR., floor 7 1505 Sofia Bulgaria	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Limited Building 9, Croxley ParkHatters Ln WD18 8WW Watford United Kingdom	Sales, order management and distribution of medical devices. Including customer education.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Ireland Limited Block 3090-3094Lake Drive, Citywest Business Campus D24 NW2F Dublin Ireland	Sales, order management and distribution of medical devices. Including customer education.
Medtronic B.V. Medtronic Service & Repair EMEA Jan Campertstraat 21-A 6416 SG Heerlen	Order management, warehousing and technical service of medical devices including field service EMEA.
Medtronic Slovakia s.r.o. CBC III, Karadzicova 12 821 08 Bratislava Slovak Republic	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Belgium Burgemeester E. Demunterlaan 5 1090 Brussel Belgium	Sales, Order Management and distribution of medical devices. Including customer education
Medtronic Croatia Folnegoviceva 1c 10000 Zagreb Croatia	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Slovenia Ameriska Ulica 8 1000 Ljubljana Slovenia	Sales, order management and distribution of medical devices

Addendum expiry date: 1 July 2024
Addendum effective date: 1 July 2021

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 077608 0079 Rev. 00

Manufacturer:

Covidien llc
15 Hampshire Street
Mansfield, MA 02048
USA

Product Category(ies):

Medical Instruments, Surgical Products and Hemostatic Materials:
- **Surgical Suture Products, Pledgets and Retention Tapes**
- **Endoscopy Instruments and Accessories including Lubricant**
- **Surgical Staple, Clip Products and Accessories**
- **Manual Surgical Instruments**
- **Implantable Wound Dressing Materials**
- **Ultrasonic Surgical Devices and Accessories**
- **Suction / Irrigation Devices and Accessories**
- **Arthroscopy Implants, Instruments and Accessories**
- **Bone Wax**
- **Temporary Cardiac Pacing Lead**
- **Powered Stapling Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713164286

Valid from: 2019-09-13
Valid until: 2024-05-26

Date, 2019-09-13

Stefan Preiß
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 077608 0079 Rev. 00

Facility(ies):

Covidien llc
15 Hampshire Street,
Mansfield, MA 02048, USA

./.

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

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www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 057574 0070 Rev. 00

Manufacturer:

Sorin Group Italia S.r.l.
Via Statale 12 Nord, 86
41037 Mirandola MO
ITALY

Product Category(ies): **Disposable products for cardiopulmonary extracorporeal circulation (ECC), extracorporeal membrane oxygenation (ECMO) and extracorporeal life support (ECLS); disposable products for blood processing, autotransfusion and blood monitoring systems. (as listed in the attachment)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: ITA1292686

Valid from: 2019-06-24
Valid until: 2024-05-26

Date, 2019-06-24

Stefan Preiß
Head of Certification/Notified Body

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

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A4 / 07.17

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

Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:
- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract
Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.
On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:
- Validity of the quoted test standard(s)

In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约
认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
- 生产场地通过定期的监督

認証契約
認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項
- 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
- 定期的な工場監査を実施している

Contrato de certificação
A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD.
Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
- Auditoria de monitoração realizada regularmente.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 057574 0070 Rev. 00

Facility(ies): Sorin Group Italia S.r.l.
Via Statale 12 Nord, 86, 41037 Mirandola MO, ITALY

Attachment:

Product Families	Classification
DIDECO KIDS ARTERIAL FILTERS: Newborn- infant Arterial filters	IIa
DIDECO MICRO: Newborn- infant, Paediatric and Adult Arterial filters / bubble traps	IIa
VENOUS / CARDIOTOMY RESERVOIRS : Venous Cardiotomy reservoirs	IIa
DIDECO CARDIOPLEGIA SETS: Cardioplegia perfusion sets including also VANGUARD, DIDECO HELIOS and CSC14 Cardioplegia heat exchangers	IIa
CARDIOACCESSORIES/DIDECO CARDIOACCESSORIES: Auxiliary devices for cardiac surgery	IIa
HEMOCONCENTRATORS: Infant, paediatric and Adult Haemoconcentrators (DHF & SH models) and sets (KH & D models)	IIa
INSPIRE: adult and small adult oxygenators	IIa
DIDECO D905 EOS Paediatric and small adult oxygenators	IIa
SYNTHESIS: adult oxygenators including also VBT 8 venous bubble trap	IIa
DIDECO KIDS: new born- infant oxygenators	IIa
DIDECO LILLI PUT 1/LILLI PUT 2: newborn infant oxygenators	IIa
REVOLUTION: centrifugal pumps for extracorporeal circulation	IIa
PERFUSION TUBING SYSTEMS: Perfusion tubing systems for cardiac surgery, ECMO and ECLS, including one or more main components (oxygenator, arterial filter, bubble trap, arterial line, venous line, pump boot tubing, centrifugal pump, hard or soft shell reservoir) feasibly connectable to auxiliary lines (secondary, cardioplegia or haemoconcentration sets, connectors or ancillary disposables).	IIa
DIDECO PERFUSION TUBING SYSTEMS: Perfusion tubing systems for cardiac surgery, ECMO and ECLS, including one or more main components (oxygenator, arterial filter, bubble trap, arterial line, venous line, pump boot tubing, centrifugal pump, hard or soft shell reservoir) feasibly connectable to auxiliary lines (secondary, cardioplegia or haemoconcentration sets, connectors or ancillary disposables,	IIa
DIDECO COLLECTION SYSTEMS: Autotransfusion collection systems, filters and accessories	IIa
BRAT 2: - Blood bags, collection systems / disposable sets for autotransfusion, PPP, PRP, PLT gel including blood bags	IIb

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Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:
- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract
Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.
On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:
- Validity of the quoted test standard(s)

In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约
认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
- 生产场地通过定期的监督

認証契約
認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。
その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項
- 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
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- 定期的な工場監査を実施している

Contrato de certificação
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Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
- Auditoria de monitoração realizada regularmente.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 057574 0070 Rev. 00

- Collection systems / disposable sets without blood bags and accessories for autotransfusion, PPP, PRP, PLT gel	IIa
BOWL: -Blood Bags and wash sets / autotransfusion sets including blood bags - Wash sets / autotransfusion sets without blood bags and accessories for autotransfusion	IIb IIa
ELECTA: - Collection systems / disposable sets for autotransfusion, PPP, PRP, PLT gel including blood bags -Collection systems / disposable sets without blood bags and accessories for autotransfusion, PPP, PRP, PLT gel	IIb IIa
XTRA: -Collection systems / disposable sets for autotransfusion, PPP, PRP, PLT gel including blood bags -Collection systems / disposable sets without blood bags and accessories for autotransfusion, PPP, PRP, PLT gel	IIb IIa
DIDECO DATA MASTER: Blood monitoring disposables connectors	IIa

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Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:
- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract
Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.
On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:
- Validity of the quoted test standard(s)

In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约
认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
- 生产场地通过定期的监督

認証契約
認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。
その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項
- 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
- 定期的な工場監査を実施している

Contrato de certificação
A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD.
Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
- Auditoria de monitoração realizada regularmente.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 002436 0006 Rev. 00

Manufacturer: **LivaNova USA, Inc.**
14401 West 65th Way
Arvada CO 80004
USA

Product Category(ies): **Autotransfusion Sterile Disposables (Reservoirs, Suction, Drainage and Infusion Sets), Perfusion Sterile Disposables (Tubing, Connectors, Check Valves) and Endoscopic Vessel Harvesting Systems (Vessel Retractors, Vessel Dissectors, Electrosurgical Bipolar Wands)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72146306

Valid from: 2019-11-22
Valid until: 2024-05-26

Date, 2019-11-20

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 002436 0006 Rev. 00

Facility(ies):

LivaNova USA, Inc.
14401 West 65th Way, Arvada CO 80004, USA

./.

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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 Health and Safety Management System which complies with

OHSAS 18001:2007

The scope of activities covered by this certificate is defined below

Production and Trading of terminally Sterilized, Small and Large Volume Infusion Drugs for Human and Veterinary Use; Non-sterile Products: Liquids for Internal Use (Hemodialysis Solutions); Production and Trading of Medical Devices in Aqueous Solution (Solutions for Irrigation, Inhalation and Hemodialysis)

Certificate Number:	Date of Issue: (Original)	Date of Issue:
61225/E/0001/UK/En	18 January 2019	18 January 2019
Issue No:	**Expiry Date:**	
1	11 March 2021	

Issued by: *On behalf of the Schemes Manager*

UKAS MANAGEMENT SYSTEMS
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 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*

UKAS MANAGEMENT SYSTEMS 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 Environmental Management System which complies with

ISO 14001:2015

The scope of activities covered by this certificate is defined below

Production and Trading of terminally Sterilized, Small and Large Volume Infusion Drugs for Human and Veterinary Use; Non-sterile Products: Liquids for Internal Use (Hemodialysis Solutions); Production and Trading of Medical Devices in Aqueous Solution (Solutions for Irrigation, Inhalation and Hemodialysis)

Certificate Number:	Date of Issue: (Original)	Date of Issue:
61225/F/0001/UK/En	21 January 2019	21 January 2019
Issue No:	**Expiry Date:**	
1	20 January 2022	

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

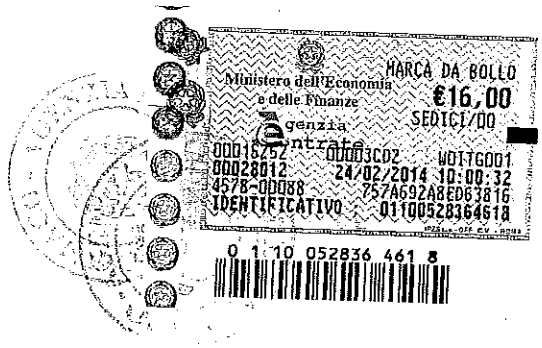
The scope of activities covered by this certificate is defined below

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	18 December 2019
Issue No:	**Expiry Date:**	
5	17 December 2022	

Issued by: *On behalf of the Schemes Manager*

UKAS MANAGEMENT SYSTEMS 0043



Agenzia Italiana del Farmaco

Certificate No: IT/77-1/H/2014

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of Italy confirms the following:
The manufacturer INDUSTRIA FARMACEUTICA GALENICA SENESE S.R.L.
Site address VIA CASSIA NORD, 351 - 53014 MONTERONI D'ARBIA (SI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 28/2014 dated 02/12/2014 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D.Lvo 219/2006 art. 50.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 09/25/2013 it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.
The authenticity of this certificate may be verified with the issuing authority.

AIFA Italian Medicines Agency
Manufacturing Authorization Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 4945

VI
GMP

Agenzia Italiana del Farmaco

Part 2

Name and address of the site: INDUSTRIA FARMACEUTICA GALENICA SENESE S.R.L. - VIA CASSIA NORD, 351 , 53014 MONTERONI D'ARBIA(SI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.1	**SterileProducts**	
	1.1.2	*Terminally sterilised*
	1.1.2.1	Large volume liquids
	1.1.2.3	Small volume liquids
1.2	**Non-sterile products**	
	1.2.1	*Non-sterile products*
	1.2.1.6	Liquids for internal use

Rome, 03/31/2014

Name and signature of the authorised person of the Competent Authority of Republic of Italy

Dott. Renato Massimi
AIFA – Manufacturing Authorization Unit

AIFA Italian Medicines Agency
Manufacturing Authorization Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 4945

VI
GMP

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

Reg. Numero / *Reg. Number*	MED 23010A	Revisione / *Revision*	29
Primo rilascio / *First issue date*	2003-03-17	Valido da / *Valid from*	2018-03-16
Scadenza / *Valid until*	2023-03-17	Ultima modifica / *Last change date*	2021-05-20

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 completo di garanzia di Qualità dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:*

MEDICA S.p.A.

Sede Legale e Operativa / *Registered and Operational Headquarter:*
Via degli Artigiani, 7
41036 Medolla, MO - Italia

Sede Operativa / *Operational Headquarter*
Medica Méditerranée Z.I. Menzel Jemil, lot n. 53 bis - Bizerte - Tunisia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II escluso il pto 4, 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 II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Apparecchiatura per diagnosi di gastroenterologia
Cateteri e accessori *Catheters and accessories*
Dispositivi medici attivi di misura per urologia *Measure active medical devices for urology*
Dispositivi medici attivi diagnostico/riabilitativi per urodinamica *Diagnostic/rehabilitation active medical devices for urodynamic*
Dispositivi medici attivi diagnostico/riabilitativi per urologia e gastroenterologia ed accessori *Active Diagnostic/rehabilitation medical devices and accessories for urology and gastroenterology*
Dispositivi medici attivi per emoperfusione, plasmaferesi e reoferesi *Active medical devices for hemoperfusion, plasmapheresis, reopheresis*
Dispositivi medici attivi per trattamento sangue, termoregolazione e controllo fluidi *Active medical devices for blood management, thermoregulation and fluids control*
Dispositivi medici per il trattamento del sangue *Medical devices for blood treatment*
Dispositivi medici per la gestione del sangue *Medical devices for blood management*
Dispositivi medici per ultrafiltrazione *Medical devices for ultrafiltration*
Dispositivo medico attivo per perfusione d'organo *Active medical device for organ perfusion*
Dispositivo medico attivo per perfusione intraperitoneale ipertermica e perfusione di arto isolata *Active medical device for hyperthermic intraperitoneal perfusion and isolated limb perfusion*
Dispositivo per CRRT, plasmaferesi, emoperfusione, rimozione CO2 *Device for CRRT, plasmapheresis, hemoperfusion, CO2 removal*
Filtri per lavaggio/disinfezione dispositivi medici *Filters for medical devices washing/disinfection*
Linee ed accessori monouso per trattamento sangue *Disposable tubing sets and accessories for blood treatment*
Linee ed accessori monouso per drenaggio (toracentesi e paracentesi)
Linee ed accessori per infusione / ultrafiltrazione /recupero liquidi *Infusion / ultrafiltration / liquids recovery tubing sets and accessories*
Linee ed accessori per infusione / ultrafiltrazione /recupero liquidi / urologia per dispositivi medici attivi *Infusion / ultrafiltration / liquids recovery / urology tubing sets and accessories for active medical devices*
Linee per perfusione con ossigenatore *Perfusion lines with oxygenator*
Set nutrizione *Nutrition set*

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* del/dated 30/03/2021

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:21/05/2021 09:45:31

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 S.r.l.
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

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Apparecchiatura per diagnosi di gastroenterologia

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1301

Modello / Model:

BLU RUNNER

Tipologia / *Medical Devices:*
Cateteri e accessori / *Catheters and accessories*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Cateteri per manometria / Catheters for manometry

Modello / Model:

Cateteri per urodinamica / Catheters for urodynamics

Tipologia / *Medical Devices:*
Dispositivi medici attivi di misura per urologia / *Measure active medical devices for urology*

Classe di rischio / *Risk class:*
I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / *NANDO codes:*
MD 1301

Marca / *Brandname:*
MENFIS DIVISION

Modello / Model:

FLOWZIG

Modello / Model:

PICOFLOW2

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:21/05/2021 09:45:53

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
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

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 23010A	Revisione / *Revision*	29
Primo rilascio / *First issue date*	2003-03-17	Valido da / *Valid from*	2018-03-16
Scadenza / *Valid until*	2023-03-17	Ultima modifica / *Last change date*	2021-05-20

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi medici attivi diagnostico/riabilitativi per urodinamica / *Diagnostic/rehabilitation active medical devices for urodynamic*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1301

Marca / *Brandname:*
MENFIS DIVISION

Modello / Model:
PICO SMART

Tipologia / *Medical Devices:*
Dispositivi medici attivi diagnostico/riabilitativi per urologia e gastroenterologia ed accessori / *Active Diagnostic/rehabilitation medical devices and accessories for urology and gastroenterology*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1301

Marca / *Brandname:*
MENFIS DIVISION

Modello / Model:
CLIPPER

Modello / Model:
DYNO SMART

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:21/05/2021 09:46:16

Organismo Notificato n. 0476
Notified Body nr. 0476

Reg. Numero / *Reg. Number*	MED 23010A	Revisione / *Revision*	29
Primo rilascio / *First issue date*	2003-03-17	Valido da / *Valid from*	2018-03-16
Scadenza / *Valid until*	2023-03-17	Ultima modifica / *Last change date*	2021-05-20

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi medici attivi per emoperfusione, plasmaferesi e reoferesi / *Active medical devices for hemoperfusion, plasmapheresis, reopheresis*

Classe di rischio / *Risk class:*
II b

Codice NANDO / *NANDO codes:*
MD 1101

Modello / Model:

AFERSMART "F"; AFERSMART "M"; AFERSMART "T" Pentracor

Tipologia / *Medical Devices:*
Dispositivi medici attivi per trattamento sangue, termoregolazione e controllo fluidi / *Active medical devices for blood management, thermoregulation and fluids control*

Classe di rischio / *Risk class:*
II b

Codice NANDO / *NANDO codes:*
MD 1101

Modello / Model:

AcuSmart, Equasmart - Sistema per CRRT/ CRRT systems

Modello / Model:

KALOS - Dispositivo medico attivo per riscaldare o mantenere la temperatura di liquidi corporei, soluzioni per dialisi e liquidi di sostituzione / KALOS - System for heating or temperature management of body fluids, dialisys solutions and replacement fluids

Codice NANDO / *NANDO codes:*
MD 1101, MDS 7010

Modello / Model:

AFERsmart™, PLASMAPHER, LIPIDsmart - Sistemi per emoperfusione, plasmaferesi e reoferesi / System for hemoperfusion, plasmapheresis, reopheresis

Modello / Model:

CARDIOsmart Sistemi per trattamento dello scompenso cardiaco congestizio / System for congestive heart failure treatments

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
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

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:21/05/2021 09:46:49

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 23010A	Revisione / *Revision*	29
Primo rilascio / *First issue date*	2003-03-17	Valido da / *Valid from*	2018-03-16
Scadenza / *Valid until*	2023-03-17	Ultima modifica / *Last change date*	2021-05-20

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi medici attivi per trattamento sangue, termoregolazione e controllo fluidi / *Active medical devices for blood management, thermoregulation and fluids control*

Modello / Model:

DECAPsmart Plus®, APHERCAP, FLOWSMART, ESTORFLOW - Sistema per emoperfusione, decapneizzazione e rimozione endotossine / System for hemoperfusion, carbon dioxide and endotoxins removal

Modello / Model:

LEUKOsmart™, LEUCAPHER - Sistema per leucocitoaferesi / Leukocytapheresis System

Tipologia / *Medical Devices:*
Dispositivi medici per il trattamento del sangue / *Medical devices for blood treatment*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Concentratori per proteine plasmatiche ed emocomponenti / Concentrators for plasma proteins and hemocomponents

Modello / Model:

Scambiatori di calore / Heat exchangers

Tipologia / *Medical Devices:*
Dispositivi medici per la gestione del sangue / *Medical devices for blood management*

Classe di rischio / *Risk class:*
II b

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Radiation

Modello / Model:

Adsorbitore di leucociti / Leukocyte adsorber

Modello / Model:

Emoconcentratori / Hemoconcentrators

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
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www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:21/05/2021 09:47:19

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi medici per la gestione del sangue / *Medical devices for blood management*

Modello / Model:

Filtri per dialisi / Hemodialyzers

Modello / Model:

Linee con emoconcentratori / Tubing sets with hemoconcentrators

Modello / Model:

Plasmafrazionatori / Plasma fractionators

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Radiation, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Emofiltri / Hemofilters

Modello / Model:

Linee con emofiltri / Tubing sets with hemofilters

Modello / Model:

Linee con plasmafiltri / Tubing sets with plasmafilters

Modello / Model:

Plasmafiltri / Plasmafilters

Tipologia / *Medical Devices:*
Dispositivi medici per ultrafiltrazione / *Medical devices for ultrafiltration*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Linee con ultrafiltri / Tubing sets with ultrafilters

Modello / Model:

Ultrafiltri / Ultrafilters

Modello / Model:

Ultrafiltri per riuniti odontoiatrici / Dental chair unit ultrafilters

Chief Operating Officer
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Kiwa Cermet Italia S.p.A.
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CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivo medico attivo per perfusione d'organo / *Active medical device for organ perfusion*

Classe di rischio / *Risk class:*
II b

Codice NANDO / *NANDO codes:*
MD 1101, MDS 7010

Modello / Model:

Vitasmart

Tipologia / *Medical Devices:*
Dispositivo medico attivo per perfusione intraperitoneale ipertermica e perfusione di arto isolata / *Active medical device for hyperthermic intraperitoneal perfusion and isolated limb perfusion*

Classe di rischio / *Risk class:*
II b

Codice NANDO / *NANDO codes:*
MD 1101, MDS 7010

Modello / Model:

FLEXIPER

Tipologia / *Medical Devices:*
Dispositivo per CRRT, plasmaferesi, emoperfusione, rimozione CO2 / *Device for CRRT, plasmapheresis, hemoperfusion, CO2 removal*

Classe di rischio / *Risk class:*
II b

Codice NANDO / *NANDO codes:*
MD 1101

Modello / Model:

Intensa

Kiwa Cermet Italia S.p.A.
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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Filtri per lavaggio/disinfezione dispositivi medici / *Filters for medical devices washing/disinfection*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0108, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

CULLIGAN PURE SSU

Modello / Model:

MEDIAPURE SSU

Tipologia / *Medical Devices:*
Linee ed accessori monouso per trattamento sangue / *Disposable tubing sets and accessories for blood treatment*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG), MDS 7006 Radiation

Modello / Model:

Linee sangue / Blood tubing sets

Tipologia / *Medical Devices:*
Linee ed accessori monouso per drenaggio (toracentesi e paracentesi)

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Aghi cannula / I.V. cannula needles

Modello / Model:

Set per aspirazione / Suction sets

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CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Linee ed accessori monouso per drenaggio (toracentesi e paracentesi)

Modello / Model:

Set per drenaggio / Drainage sets

Modello / Model:

Set per infusione / Infusion sets

Modello / Model:

Set per raccolta ultrafiltrato / Ultrafiltrate collection sets

Tipologia / *Medical Devices:*
Linee ed accessori per infusione / ultrafiltrazione /recupero liquidi / *Infusion / ultrafiltration / liquids recovery tubing sets and accessories*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Codici / Codes:

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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Chief Operating Officer
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Date:21/05/2021 09:49:06

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 23010A	Revisione / *Revision*	29
Primo rilascio / *First issue date*	2003-03-17	Valido da / *Valid from*	2018-03-16
Scadenza / *Valid until*	2023-03-17	Ultima modifica / *Last change date*	2021-05-20

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Linee ed accessori per infusione / ultrafiltrazione /recupero liquidi / urologia per dispositivi medici attivi / *Infusion / ultrafiltration / liquids recovery / urology tubing sets and accessories for active medical devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Drenaggi ureterali post-operatori / Uretheral post operative drainages

Modello / Model:

Linee ed accessori per urologia / Lines and accessories for urology

Modello / Model:

Linee per esami di cavernosometria / Lines for cavernosometry

Tipologia / *Medical Devices:*
Linee per perfusione con ossigenatore / *Perfusion lines with oxygenator*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Linea unica perfusione arteria epatica – con ossigenatore O2-SMART 50AL/150AL

Modello / Model:

Linea unica perfusione rene - con ossigenatore O2-SMART 50K/150K

Modello / Model:

Linea unica perfusione vena porta – con ossigenatore O2-SMART 50PL/150PL

Kiwa Cermet Italia S.p.A.
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Date:21/05/2021 09:49:35

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 23010A	Revisione / *Revision*	29
Primo rilascio / *First issue date*	2003-03-17	Valido da / *Valid from*	2018-03-16
Scadenza / *Valid until*	2023-03-17	Ultima modifica / *Last change date*	2021-05-20

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Set nutrizione / *Nutrition set*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Codici / Codes:

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.
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Chief Operating Officer
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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATO

Reg. Numero	3686 - A	Valido da	2021-03-22
Primo rilascio	2003-03-24	Ultima modifica	2021-03-22
Scadenza	2024-03-23	Settore IAF	19, 14, 29

Certificato del Sistema di Gestione per la Qualità

ISO 9001:2015

Si dichiara che il sistema di gestione per la Qualità dell'Organizzazione:

GRUPPO MEDICA

è conforme alla norma UNI EN ISO 9001:2015 per i seguenti prodotti/servizi:

Progettazione e produzione di Dispositivi medici attivi di monitoraggio, trattamento sangue e perfusione di organi. Progettazione e produzione di Dispositivi medici non attivi per urologia, gastroenterologia, trattamento sangue ed ultrafiltrazione. Stampaggio componenti plastici per dispositivi medici. Sterilizzazione mediante ossido di etilene di dispositivi medici non attivi. Commercializzazione di Dispositivi medici generali non attivi, non impiantabili e Dispositivi medici generali attivi. Produzione di filtri e componenti per sistemi di filtrazione e depurazione. Progettazione e produzione di apparecchiature per l'assemblaggio ed il collaudo di dispositivi medici.

Chief Operating Officer
Giampiero Belcredi

Il mantenimento della certificazione è soggetto a sorveglianza annuale e subordinato al rispetto dei requisiti contrattuali di Kiwa Cermet Italia.
Questo certificato è costituito da 2 pagine. La scheda tecnica che segue fornisce i dettagli del campo di applicazione.

GRUPPO MEDICA
Sede Legale
MEDICA S.p.A. - Via degli Artigiani 7 41036 Medolla (MO) Italia

Sedi Oggetto di Certificazione
MEDICA S.p.A. - Via degli Artigiani, 7 41036 Medolla (MO) Italia
MEDICA S.p.A. - Via della Beverara 46/D 40100 Bologna Italia
MEDICA S.p.A. - Via Posta Vecchia, 23 41037 Mirandola (MO) Italia
MEDICA MÉDITERRANÉE s.a.r.l. – Z.I. Menzel Jemil, lot n. 53 bis 7080 Bizerte Tunisia
SAR-MED S.r.l. - Via Centauro, 16 09016 Iglesias (SU) Italia
SAR-MED S.r.l. - Via Centauro, 6 09016 Iglesias (SU) Italia
TECNOIDEAL S.r.l. - Via L. Cazzuoli 43 41037 Mirandola (MO) Italia

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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CERTIFICATO

Reg. Numero	3686 - A	Valido da	2021-03-22
Primo rilascio	2003-03-24	Ultima modifica	2021-03-22
Scadenza	2024-03-23	Settore IAF	19, 14, 29

Scheda tecnica allegata al Certificato

ISO 9001:2015

Unità operativa	Campo di applicazione
Medica S.p.A.	Gestione della progettazione e della produzione di Dispositivi medici attivi di monitoraggio, trattamento sangue e perfusione di organi. Progettazione e produzione di Dispositivi medici non attivi per urologia, gastroenterologia, trattamento sangue ed ultrafiltrazione. Commercializzazione di Dispositivi medici generali non attivi, non impiantabili e Dispositivi medici generali attivi.
Sar-Med S.r.l.	Produzione di Dispositivi medici non attivi per emodialisi, cateteri ed accessori. Produzione di Dispositivi medici non attivi per emodialisi, cateteri ed accessori. Produzione di Dispositivi medici non attivi per trattamento sangue ed ultrafiltrazione su specifica del committente. Produzione di filtri e componenti per sistemi di filtrazione e depurazione su specifica del committente.
Medica Mediterranée S.a.r.l.	Stampaggio componenti plastici per dispositivi medici su specifica del committente. Assemblaggio di dispositivi medici non attivi su specifica del committente. Sterilizzazione mediante ossido di etilene di dispositivi medici non attivi.
Tecnoideal S.r.l.	Progettazione e produzione di dispositivi medici attivi di monitoraggio, trattamento sangue e perfusione di organi su specifica del committente. Progettazione e produzione di apparecchiature per l'assemblaggio ed il collaudo di dispositivi medici.

Chief Operating Officer
Giampiero Belcredi

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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CERTIFICATO

Reg. Numero	3686 - M	Valido da	2021-03-21
Primo rilascio	2003-03-24	Ultima modifica	2021-03-21
Scadenza	2024-03-23		

Certificato del Sistema di Gestione per la Qualità

ISO 13485:2016

Si dichiara che il Sistema di Gestione per la Qualità dell'Organizzazione:

GRUPPO MEDICA

è conforme alla norma UNI CEI EN ISO 13485:2016 per i seguenti prodotti/servizi:

Progettazione e produzione di Dispositivi medici attivi di monitoraggio, trattamento sangue e perfusione di organi. Progettazione e produzione di Dispositivi medici non attivi per urologia, gastroenterologia, trattamento sangue ed ultrafiltrazione. Stampaggio componenti plastici per dispositivi medici. Sterilizzazione mediante ossido di etilene di dispositivi medici non attivi. Progettazione e produzione di dispositivi medici attivi di monitoraggio, trattamento sangue e perfusione di organi. Commercializzazione di Dispositivi medici generali non attivi, non impiantabili e Dispositivi medici generali attivi.

Chief Operating Officer
Giampiero Belcredi

Il mantenimento della certificazione è soggetto a sorveglianza annuale e subordinato al rispetto dei requisiti contrattuali di Kiwa Cermet Italia.

Riferirsi al manuale qualità per i dettagli delle esclusioni ai requisiti della norma UNI CEI EN ISO 13485:2016.

Questo certificato è costituito da 2 pagine. La scheda tecnica che segue fornisce i dettagli del campo di applicazione.

GRUPPO MEDICA
Sede Legale
MEDICA S.p.A. - Via degli Artigiani 7 41036 Medolla (MO) Italia

Sedi Oggetto di Certificazione
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CERTIFICATO

Reg. Numero	3686 - M	Valido da	2021-03-21
Primo rilascio	2003-03-24	Ultima modifica	2021-03-21
Scadenza	2024-03-23		

Scheda tecnica allegata al Certificato

ISO 13485:2016

Unità operativa	*Campo di applicazione*
Medica S.p.A.	Gestione della progettazione e della produzione di Dispositivi medici attivi di monitoraggio, trattamento sangue e perfusione di organi. Progettazione e produzione di Dispositivi medici non attivi per urologia, gastroenterologia, trattamento sangue ed ultrafiltrazione. Commercializzazione di Dispositivi medici generali non attivi, non impiantabili e Dispositivi medici generali attivi.
Sar-med S.r.l.	Produzione di Dispositivi medici non attivi per emodialisi, cateteri ed accessori. Produzione di Dispositivi medici non attivi per trattamento sangue ed ultrafiltrazione su specifica del committente.
Medica Mediterranée S.a.r.l.	Stampaggio componenti plastici per dispositivi medici su specifica del committente. Assemblaggio di dispositivi medici non attivi su specifica del committente. Sterilizzazione mediante ossido di etilene di dispositivi medici non attivi.
Tecnoideal S.r.l.	Progettazione e produzione di dispositivi medici attivi di monitoraggio, trattamento sangue e perfusione di organi su specifica del committente.

Chief Operating Officer
Giampiero Belcredi

Kiwa Cermet Italia S.p.A.
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www.kiwa.it

CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

Company Name : Kordon Tıp Sağlık Araç Gereçleri Müh. Prj. İth. San. Tic. Ltd. Şti.

Company Address : 10006/1 Sokak No:43 A.O.S.B. Çiğli IZMIR / TURKEY

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)

Product : Ethylene Oxide Sterilizer – Class IIb
Ethylene Oxide Sterilization Cartridges – Class IIb
Ethylene Oxide Sterilization Cartridge Packs – Class IIb

Product Types are attached.

Certificate Number : M.2017.106.7586
Report Number : MD.3232.IB
Initial Assessment Date : 14.10.2016
Registration Date : 17.01.2017
Revision Date /No : -
Expiry Date : 16.01.2022

UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd.

UDEM 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 audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The currency of the certificate can be checked through www.udemltd.com. tr.

CE 2292

Addrres: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udemltd.com.tr

This document containing 1 (one) pages is the Annex of the Certificate with the number M.2017.106.7586 and with the registration date of 17.01.2017 issued for "Kordon Tıp Sağlık Araç Gereçleri Müh. Prj. İth. San. Tic. Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. Ltd. Şti. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive

Ethylene Oxide Sterilizer	Ethylene Oxide Sterilization Cartridges	Ethylene Oxide Sterilization Cartridge Packs
Model	**Model**	**Model**
AX 60	AX 5	AR 5
AX 135	AX 6	AR 6
AX 160	AX 7	AR 7
AX 200	AX 8	AR 8
AX 225	AX 9	AR 9
AX 400	AX 10	AR 10
AX 450	AX 11	AR 11
AX 1000	AX 12	AR 12
AX 2000	AX 13	AR 13
AX 4000	AX 14	AR 14
AX 6000	AX 15	AR 15
AX 9000	AX 16	AR 16
	AX 17	AR 17
	AX 18	AR 18
	AX 19	AR 19
	AX 20	AR 20
	AX 21	AR 21
	AX 22	AR 22
	AX 23	AR 23
	AX 24	AR 24
	AX 25	AR 25
	AX 26	AR 26
	AX 27	AR 27
	AX 28	AR 28
	AX 29	AR 29
	AX 30	AR 30
	AQ 5	ARQ 5
	AQ 6	ARQ 6
	AQ 7	ARQ 7
	AQ 8	ARQ 8
	AQ 9	ARQ 9
	AQ 10	ARQ 10
	AQ 11	ARQ 11
	AQ 12	ARQ 12
	AQ 13	ARQ 13
	AQ 14	ARQ 14
	AQ 15	ARQ 15
	AQ 16	ARQ 16
	AQ 17	ARQ 17
	AQ 18	ARQ 18
	AQ 19	ARQ 19
	AQ 20	ARQ 20
	AQ 21	ARQ 21
	AQ 22	ARQ 22
	AQ 23	ARQ 23
	AQ 24	ARQ 24
	AQ 25	ARQ 25
	AQ 26	ARQ 26
	AQ 27	ARQ 27
	AQ 28	ARQ 28
	AQ 29	ARQ 29
	AQ 30	ARQ 30
	AL 7	
	AL 25	
	AL 67	
	AL 100	
	AX 67	
	AX 100	
	AX 127	
	AX 134	
	AQ 70	
	AQ 120	
	AQ 130	
	AQ 170	
	AQ 200	
	AQ 230	

UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd.

ACCREDITED BY NAC
MANAGEMENT SYSTEMS
ISO/IEC 17021-1:2015
NAC-002-MS

Certificate of Registration

This is to certify that

KORDON TIP SAĞLIK ARAÇ GEREÇLERİ MÜHENDİSLİK PROJE İTHALAT LTD. ŞTİ.

10006/1 NO:43 A.O.S.B. ÇİĞLİ - İZMİR / TÜRKİYE

Branch: 354. SOK NO:4 2. SANAYİ SİTESİ BORNOVA - İZMİR / TURKEY

complies with requirements of

ISO 9001:2015

This certificate is valid concerning all activities related to;

MANUFACTURING, DESIGN AND SALES OF ETHYLENE OXIDE STERILIZERS AND ETHYLENE OXIDE CARTIDGES. PRODUCT REALIZATION AND SALES OF BIOLOGICAL INDICATORS, STERILIZATION REELS, CHEMICAL INDICATORS, AUTOCLAVE TAPES, STERILIZATION DOCUMENTATION LABEL CHEMICAL INDICATORS, ETHYLENE OXIDE CARTRIDGE STORAGE CONTAINERS, WASHER INDICATORS, AUTOMATIC CARTRIDGE ACTIVATORS AND CONTAINERS, ETHYLENE OXIDE DETECTORS, AUTOCLAVEABLE BIOHAZARD BAGS, PATIENT TRANSFER SYSTEM, BOWIE & DICK TEST PACKS, WRAP PAPERS, BIOLOGICAL INDICATOR INCUBATORS, CHEMICAL VAPOR INDICATOR CLASS V FEED,EO INDICATOR CHEMICAL CLASS V FEED, RESIDUAL PROTEIN TEST, ULTRASONIC WASHING INDICATOR, STERILIZATION ENVELOPES,SELF ADHESIVE CHEMICAL THEY INDICATOR, HELIX CARGO CONTROL INDICATOR,LABEL GUN , WASH INDICATOR APPARATUS,PCD APPARATUS ,STERILIZATION VALIDATION AND CALIBRATION SERVICE, STERILIZATION REEL SEALING, CUTTING AND PRINTING MACHINE, NEUTRALIZATORS, HEADER BAGS, WORK STATIONS, HANGER – CUTTER APPARATUS

ETİLEN OKSİT STERİLİZATÖRLERİ VE ETİLEN OKSİT KARTUŞLARI, ÜRETİMİ , TASARIMI VE SATIŞI. BİYOLOJİK İNDİKATÖRLER, STERİLİZASYON RULOLARI, KİMYASAL İNDİKATÖRLER, OTOKLAV BANTLARI, STERİLİZASYON DÖKÜMANTASYON ETİKET KİMYASAL İNDİKATÖRLERİ, ETİLEN OKSİT KARTUŞ SAKLAMA KONTEYNIRI, YIKAMA İNDİKATÖRLERİ, OTOMATİK KARTUŞ AKTİVATÖRLERİ VE KONTEYNIRLARI, ETİLEN OKSİT DEDEKTÖRÜ, OTOKLAVLANABİLİR TIBBİ ATIK TORBASI, HASTA TRANSFER SİSTEMİ, BOWIE & DICK TEST PAKETLERİ, WRAP KAĞITLARI, BİYOLOJİK İNDİKATÖR İNKÜBATÖRÜ, BUHAR KIMYASAL İNDİKATÖR CLASS V İLERLEMELI, EO KİMYASAL İNDİKATÖR CLASS V İLERLEMELI, PROTEİN KALINTI TESTİ, ULTRASONIC YIKAMA İNDİKATÖRÜ, STERİLİZASYON ZARFLARI, KENDİNDEN YAPIŞKANLI KİMYASAL İNDİKATÖRLER, HELIX YÜK KONTROL İNDİKATÖRÜ, ETİKET TABANCASI, YIKAMA İNDİKATÖRÜ APARATLARI , PCD APARATLARI, STERİLİZASYON VALİDASYON VE KALİBRASYON HİZMETİ, STERİLİZASYON RULOSU KAPATMA / KESME VE YAZICI CİHAZLAR, NÖTRALİZATÖRLER, HEADER BAG, ÇALIŞMA İSTASYONLARI, ASKI – KESME APARATI, FASON ÜRETİMİNİN GERÇEKLEŞTİRİLMESİ VE SATIŞI

ISO 01 794 488	Jan. 3, 2020	Jan. 2, 2021
Certificate No.	***Date of this Certificate***	***Certification Expiry Date***
Dec. 26, 2019	Jan. 3, 2020	
Date of Audit	***Date of Registration***	***Managing Director / Director***

MDC MEDICERT CERTIFICATE

Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
Tersane Mah. Cemal Gürsel Cad. No:11/3 Halide Hnm. Apt. Karşıyaka / İzmir
Tel: 0232 327 33 44 www.medicert.com.tr info@medicert.com.tr

Technical Universal Verification

CERTIFICATE

This Certificate has been awarded to:

KORDON TIP SAĞLIK ARAÇ GEREÇLERİ MÜHENDİSLİK PROJE İTHALAT LTD. ŞTİ.

Head Office: 10006/1 NO:43 A.O.S.B. ÇİĞLİ - İZMİR / TURKEY

Branch Office: 354. SOK NO:4 2. SANAYİ SİTESİ BORNOVA - İZMİR / TURKEY

In Recognition of the Organisation's Management System which complies with:

ISO 9001 : 2015

For the Scope of Activities described below:

MANUFACTURING, DESIGN AND SALES OF ETHYLENE OXIDE STERILIZERS AND ETHYLENE OXIDE CARTIDGES. PRODUCT REALIZATION AND SALES OF BIOLOGICAL INDICATORS, STERILIZATION REELS, CHEMICAL INDICATORS, AUTOCLAVE TAPES, STERILIZATION DOCUMENTATION LABEL CHEMICAL INDICATORS, ETHYLENE OXIDE CARTRIDGE STORAGE CONTAINERS, WASHER INDICATORS, AUTOMATIC CARTRIDGE ACTIVATORS AND CONTAINERS, ETHYLENE OXIDE DETECTORS, AUTOCLAVEABLE BIOHAZARD BAGS, PATIENT TRANSFER SYSTEM, BOWIE & DICK TEST PACKS, WRAP PAPERS, BIOLOGICAL INDICATOR INCUBATORS, CHEMICAL VAPOR INDICATOR CLASS V FEED,EO INDICATOR CHEMICAL CLASS V FEED, RESIDUAL PROTEIN TEST, ULTRASONIC WASHING INDICATOR, STERILIZATION ENVELOPES, SELF ADHESIVE CHEMICAL THEY INDICATOR, HELIX CARGO CONTROL INDICATOR,LABEL GUN , WASH INDICATOR APPARATUS, PCD APPARATUS , STERILIZATION VALIDATION AND CALIBRATION SERVICE, STERILIZATION REEL SEALING, CUTTING AND PRINTING MACHINE, NEUTRALIZATORS, HEADER BAGS, WORK STATIONS, HANGER – CUTTER APPARATUS

Certificate No : 1015

Date of Audit : 05.12.2017

Date of Registration : 05.01.2018

Reissue Date : -

Expiry Date : 04.01.2019

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Tel.: 00 90 212 438 20 04
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• e-mail: info@techcert.com.tr

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Head Office: 10006/1 NO:43 A.O.S.B. ÇİĞLİ - İZMİR / TURKEY

Branch Office: 354. SOK NO:4 2. SANAYİ SİTESİ BORNOVA - İZMİR / TURKEY

In Recognition of the Organisation's Management System which complies with:

ISO 13485 : 2016

For the Scope of Activities described below:

MANUFACTURING, DESIGN AND SALES OF ETHYLENE OXIDE STERILIZERS AND ETHYLENE OXIDE CARTIDGES. PRODUCT REALIZATION AND SALES OF BIOLOGICAL INDICATORS, STERILIZATION REELS, CHEMICAL INDICATORS, AUTOCLAVE TAPES, STERILIZATION DOCUMENTATION LABEL CHEMICAL INDICATORS, ETHYLENE OXIDE CARTRIDGE STORAGE CONTAINERS, WASHER INDICATORS, AUTOMATIC CARTRIDGE ACTIVATORS AND CONTAINERS, ETHYLENE OXIDE DETECTORS, AUTOCLAVEABLE BIOHAZARD BAGS, PATIENT TRANSFER SYSTEM, BOWIE & DICK TEST PACKS, WRAP PAPERS, BIOLOGICAL INDICATOR INCUBATORS, CHEMICAL VAPOR INDICATOR CLASS V FEED,EO INDICATOR CHEMICAL CLASS V FEED, RESIDUAL PROTEIN TEST, ULTRASONIC WASHING INDICATOR, STERILIZATION ENVELOPES, SELF ADHESIVE CHEMICAL THEY INDICATOR, HELIX CARGO CONTROL INDICATOR,LABEL GUN , WASH INDICATOR APPARATUS, PCD APPARATUS , STERILIZATION VALIDATION AND CALIBRATION SERVICE, STERILIZATION REEL SEALING, CUTTING AND PRINTING MACHINE, NEUTRALIZATORS, HEADER BAGS, WORK STATIONS, HANGER - CUTTER APPARATUS

Certificate No : 4010

Date of Audit : 05.12.2017

Date of Registration : 05.01.2018

Reissue Date : -

Expiry Date : 04.01.2019

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Tel.: 00 90 212 438 20 04
• web: www.techcert.com.tr
• e-mail: info@techcert.com.tr

UNITED ACCREDITATION FOUNDATION UAF

Certificate of Registration

This is to certify that

Quality Management System
for Medical Devices

of

KORDON TIP SAĞLIK ARAÇ GEREÇLERİ
MÜHENDİSLİK PROJE İTHALAT LTD. ŞTİ.

10006/1 NO:43 A.O.S.B. ÇİĞLİ - İZMİR / TÜRKİYE

Branch: 354. SOK NO:4 2. SANAYİ SİTESİ BORNOVA - İZMİR / TURKEY

complies with requirements of

ISO 13485:2016

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ISO 02 795 488	Jan. 3, 2020	Jan. 2, 2021
Certificate No.	*Date of this Certificate*	*Certification Expiry Date*
Dec. 27, 2019	Jan. 3, 2020	
Date of Audit	*Date of Registration*	*Managing Director / Director*

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