



REPUBLICA MOLDOVA

LICENȚĂ

Seria A MMII

Nr. 044322

Denumirea autorității de licențiere

Camera de Licențiere

Denumirea, forma juridică de organizare, sediul
(adresa juridică) a titularului de licență

Societatea cu Răspundere Limitată
"BIOSISTEM MLD"

mun. Chișinău, str. Albișoara, 16/1, ap. 7

Data și numărul certificatului de
înregistrare de stat a titularului de licență

12.08.2010 MD 0101250

Numărul de înregistrare
a întreprinderii sau IDNO

1010600028048

Codul fiscal

Genul de activitate, integral sau parțial,
pentru a cărui desfășurare se eliberează licența

* Importul, comercializarea, asistența tehnică
și reparația dispozitivelor medicale *

Data eliberării licenței

4 octombrie 2010

Reperfectată: 1) 19.10.2012; 2) 14.05.2014

Valabilă pînă la

4 octombrie 2015

Prelungită pînă la: 03.10.2020

Semnătura conducătorului
autorității de licențiere

Director al Camerei de Licențiere

Valentin GUZNAC



Notă: Licența este valabilă numai cu anexa autenticată de autoritatea de licențiere,
în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.



BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

Republica Moldova, MD-2068
mun. Chișinău, 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. Московской, 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 MD95ML000000002251429243.

Codul băncii MOLDMD2X329.

Director

Nina Turcan

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

L. Svirepova
semnătura

MD 0101250





„CAMERA ÎNREGISTRĂRII DE STAT” Î.S.
Secția fonduri speciale și informații curente

EXTRAS
din Registrul de stat al persoanelor juridice

nr. 14419 din 11.07.2016

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 și codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

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

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

1 Activitatea farmaceutică;

2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;

3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;

4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;

5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;

6 Consultații în domeniul sistemelor de calcul.

Capitalul social: **5400 lei.**

Administrator: POIATA VITALIE, IDNP 0983103892591,

Asociați:

1. POIATA VITALIE , IDNP 0983103892591

cota 1803.60 lei, ce constituie 33,4 %

2. NASEDCHIN ALEXANDR , IDNP 2002001070747

cota 1798.20 lei, ce constituie 33,3 %

3. KOJEVNIKOV DMITRII , IDNP 0972305012362

cota 1798.20 lei, ce constituie 33,3 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 11.07.2016.

Specialist principal
tel. 022-266-252


Lazari Aliona



Lista fondatorilor Biosistem-mld SRL

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

-----:
ORDIN DE PLATA NR.: 145 TIP.DOC. 1 :
DATA EMITERII:31 martie 2020 :
=====:
PLATITI: 250-00 LEI: Doua Sute Cincizeci lei 00 ban :
i :
:
=====:
PLATITOR: (R) "BIOSISTEM CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L. MD95ML000000002251429243 :
CODUL FISCAL :1010600028048 / :
:
:
=====:
PRESTATORUL PLATITOR CODUL BANCII:
BC"Moldindconbank"S.A. suc."Invest" Chisinau :MOLDMD2X329:
=====:
BENEFICIAR (R) IMSP SPITAL CONTUL DE PLATI/CODUL IBAN :
UL CLINIC BALTI MD77ML000000002251821544 :
CODUL FISCAL :1003602150732 / :
:
:
=====:
PRESTATORUL BENEFICIAR CODUL BANCII:
BC"Moldindconbank"S.A. :MOLDMD2X :
=====:
DESTINATIA PLATII:Pentru setul documente: TIPUL TRANSFERULUI :
lor de atribuire" sau "Pentru garantia p: NORMAL/URGENT :N:
entru oferta la procedura de achizi?ie p: :
ublica nr. ocds-b3wdp1-MD-1584442018692 :
din 06.04.2020 :
: L.S. :
=====:
CODUL TRANZACTIEI:001: :
DATA PRIMIRII:31/03/2020 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
:-----:
CONDUCTOR:Web Poiata Vitalie :
MIIGQQYJKoZIhvcNAQcCoIIGMjCCBj8CAQExCzAJBgUrDgMCGGUAMAsGCSqGS Ib:
DQEHAaCCBEowggRGMII DLqADAgECAhNHAABcVycdZVmKkP29AAAAAFxXMA0GCSq:
S Ib3DQEBcWUAMC IxIDAeBgNVBAMTF0NFU lQxLUNBLU l vbGRpbmRjb25iYW5rMB4:
DTE5MDEyODEwMTYyOFoXDTIxMDEyODEwMjYyOFowfjELMAkGA1UEBhMCTUQxGjA:
gNVBAoTEUJpb3Npc3RlbSBNTEQgUlJMMRIwEAYDVQQLEwkwNjkyMDAzMTQx FzA :
:
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGUgYJKoZIhvcNAQcCoIIGQzCCBj8CAQExCzAJBgUrDgMCGGUAMAsGCSqGS Ib3:
DQEHAaCCBFswggRXMIIDP6ADAgECAhNHAABcVpWe/gMeSmneAAAAAFxWMA0GCSqG:
S Ib3DQEBcWUAMC IxIDAeBgNVBAMTF0NFU lQxLUNBLU l vbGRpbmRjb25iYW5rMB4X:
DTE5MDEyODEwMTQwNFoXDTIxMDEyODEwMjQwNFowY4xCzAJBgNVBAYTAk1EMScw:
YDVQQKEx5NZWRlY29yIFNSTCwgQmlvc2lzdGVtIE1MRCBTUkwxEjAQBgNVBAsT :
:
L.S. (semnatura electronica) :
CONDUCTOR: :
(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMNATURA PRESTATORUL L.S. :
:
MOTIVUL REFUZULUI : L.S. :
-----:

Cod Fiscal: 1010600028048; IBAN: MD95ML000000002251429243;
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;
Adresa poștală a băncii: mun. Chișinău, bd. Moscovei, 14/1;

Către Grupul de lucru pentru evaluarea

Licitație deschisă Nr. ocds-b3wdp1-MD-1584442018692

din 06.04.2020

din cadrul IMSP Spitalul Clinic Bălți

Declarație

Prin prezenta, SRL „Biosistem-MLD”, declara ca, n-are restanta fata de buget public national.

_____Poiata Vitalie

L.Ș.



www.imq.it

**CERTIFICATO N.
CERTIFICATE N. 9190.CRC3**

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

CERACARTA SPA

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

UNITA' OPERATIVE / OPERATIVE UNITS

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

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

ISO 9001:2008

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

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

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID).

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

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

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

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

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

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

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



IAF: 07, 09, 19, 29

SGQ N°005A, SGA N°006D, SCR N°005F,
SSI N°003G, FSM N°007I, SGE N°006M,
EMAS N°003P, PRD N°005B, PRS N°008C,
ISP N°003E, LAB N°012I, LAT N°002I
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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

Organismo di Certificazione Federato CISQ
www.imq.it



CISQ is a member of



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



www.cisq.com

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



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

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

CERACARTA SPA

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

for the following scope:

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

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

has implemented and maintains a

Quality Management System

which fulfills the requirements of the following standard

ISO 9001:2008

Issued on: **2017 - 10 - 13**

First issued on: **2002 - 11 - 26**

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

Registration Number: IT - 112265



Alex Stoichitoiu
President of IQNET



Ing. Claudio Provetti
President of CISQ

IQNet Partners:**

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

* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

** The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



www.imq.it

**CERTIFICATO N.
CERTIFICATE N. 9124.CRC4**

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

CERACARTA SPA

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

UNITA' OPERATIVE / OPERATIVE UNITS

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

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

EN ISO 13485:2012

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG.

Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

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

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

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

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

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

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

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

CISQ is a member of



*IQNet, the association of the world's first
class certification bodies, is the largest
provider of management System
Certification in the world.*

*IQNet is composed of more than 30
bodies and counts over 150 subsidiaries
all over the globe.*

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

*CISQ is the Italian Federation
of management system
Certification Bodies.*



SGQ N°005A, SGA N°006D, SCR N°005F,
SSI N°003G, FSM N°007I, SGE N°006M,
EMAS N°003P, PRD N°005B, PRS N°008C,
ISP N°003E, LAB N°012I, LAT N°002I

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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



www.cisq.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

A handwritten signature in black ink, appearing to read 'N. Manzoni', with a stylized flourish at the end.



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° 004I
PRS N° 089C



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° 0041
PRS N° 089C

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

Registration No.: DD 60100980 0001

Report No.: 26300270 002

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

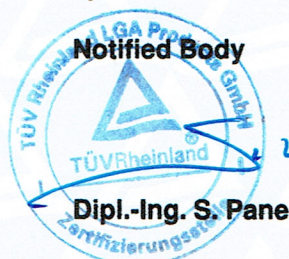
Products: (see attachments for products and site included)
Replaces approval, registration no.: DD 60040589 0001

Expiry Date: 2020-04-13

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

Effective Date: 2015-04-30

Date: 2015-04-30



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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60100980 0001
Report No.: 26300270 002

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

Products included:

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

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

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

Date: 2015-04-30



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

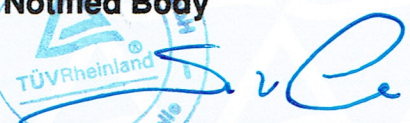
Registration No.: DD 60100980 0001
Report No.: 26300270 002

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

Site included:

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

Date: 2015-04-30


Notified Body

Dipl.-Ing. S. Pane

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

Registration No.: HD 60100981 0001

Report No.: 26300270 002

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

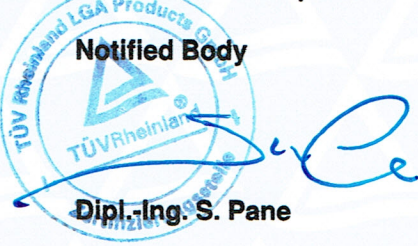
Products: (see attachments for products and site included)
Replaces approval, registration no.: HD 60040590 0001

Expiry Date: 2020-04-13

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

Effective Date: 2015-04-30

Date: 2015-04-30

Notified Body

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: HD 60100981 0001
Report No.: 26300270 002

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

Products included:

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

Date: 2015-04-30



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60100981 0001
Report No.: 26300270 002

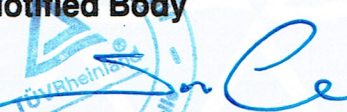
Manufacturer: Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Site included:

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

Date: 2015-04-30




Dipl.-Ing. S. Pane

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

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

Proof has been furnished that the requirements specified in

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

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

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

Certification Body



Date 2015-04-30



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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

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

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

Scope: Site included:

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

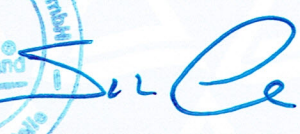
Distribution

Certification Body



Date: 2015-04-30




Dipl.-Ing. S. Pane

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

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

Proof has been furnished that the requirements specified in

EN ISO 9001:2008

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

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

Certification Body

Date 2015-04-30



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

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

Scope: Site included:

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

Distribution

Date: 2015-04-30

**Certification Body**

Dipl.-Ing. S. Pane

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



Date 2018-06-29

Maciej Sciera
Maciej Sciera



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>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**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



Date: 2018-06-29

Maciej Sciera

