VITALITEC
INTERNATIONAL
Z.A. Vague de la Noé • 35680 Domalain • FRANCE
Tel. +33 (0)2 99 96 76 76 • Fax +33 (0)2 99 96 59 68
e-mail : vitalitec@vitalitec.eu

DECLARATION DE CONFORMITE CE
EC-DECLARATION OF CONFORMITY

DOC-CLIP V15

Nous, VITALITEC INTERNATIONAL,
We, VITALITEC INTERNATIONAL,

Déclarons, sous notre seule responsabilité, que les produits suivants :
Hereby certify, *under our sole responsibility, that the following products*:

Clips Hémostatiques en Titane / *Titanium Hemostatic Clips*

Class III – GMDN code 35649

Clip Size	*SLS cat. numbers*	*NINE cat. numbers*
Micro Clips	W6060-1	W9060
Small Clips	J1120-1, J1180-1, R1120-1, R1180-1	J9180, J9135, J9324 R9180, R9135, R9324
Small-Medium Clips	L5180-1	L9180
Medium Clips	B2120-1, B2180-1	B9180, B9135, B9324
Medium-Large Clips	V3120-1	V9120
Large Clips	O4120-1	O9120

Sont conformes aux exigences essentielles de la Directive Européenne 93/42/CEE (DDM), et de ses transpositions en droit national,
Et satisfont aux exigences essentielles de l'Annexe I de la DDM, comme démontré dans le dossier technique TF98-01.
Comply with the essential requirements of the European Council Directive 93/42/EEC (MDD), and with its transpositions into national law,
And comply with the essential requirements of Annex I of the MDD, as demonstrated in technical file TF98-01.

La procédure d'évaluation de la conformité a été établie selon :
The conformity assessment procedure was established according to:

LIETUVOS RESPUBLIKA
Uždaroji akcinė bendrovė
PRINCIPALMED 1L
KAUNO MIESTAS

* L'Annexe III de la Directive 93/42/CEE / *Annex III of Directive 93/42/EEC*
  - Certificat n° / *Certificate n°* : 12468 revision 8
  - Du / from : LNE/G-MED
  - Organisme Notifié / Notified Body : 0459
  - Date d'expiration / *Expiration Date* : 2018-01-30

* L'Annexe V.3 de la Directive 93/42/CEE / *Annex V of Directive 93/42/EEC*
  - Certificat n° / *Certificate n°* : DD 60074593 0001
  - Du / from : TÜV Rheinland LGA Products GmbH
  - Organisme Notifié / Notified Body : 0197
  - Date d'expiration / *Expiration Date* : 2017-02-03

Vadybininkas
Edvinas Lekas
2013-01-07

Date d'expiration de la présente déclaration / *Expiration Date of this declaration*: 2017-02-03

Cette déclaration de conformité n'est valable qu'en relation avec le document de libération pour le lot correspondant de produits fabriqués.
This declaration of conformity is valid only in relation to the release document for the corresponding lot of manufactured products.

Domalain 2013-07-12

Jacques LE BOZEC
Président / CEO

KOPIJA TIK

LNE
Le progrès, une passion à partager

Certification
Médical-Santé
Notified Body N° 0459

ATTESTATION / *CERTIFICATE* N° 12468 rev. 8
Délivrée à Paris le 02 Juillet 2013
Issued in Paris on July 2nd, 2013

ATTESTATION CE / *EC CERTIFICATE*

Examen de type / *Type Examination*
ANNEXE III de la Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX III Directive 93/42/EEC concerning medical devices

Fabricant / *Manufacturer*

VITALITEC INTERNATIONAL
ZA Vague de la Noé
35680 DOMALAIN FRANCE

LIETUVOS RESPUBLIKA
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KAUNO MIESTAS

Catégorie du(des) dispositif(s) / *Device(s) category*

Clips hémostatiques en titane

Titanium hemostatic clips

KOPIJA TIKRA

Identification du(des) dispositif(s) / *Identification of device(s)*

Vadybininkas
Edvinas Lekas
2015-08-08

Clips SLS et clips NINE (Code GMDN : 35649)
Voir addendum

SLS and NINE clips (GMDN code : 35649)
See addendum

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) référencé(s) P101195, un échantillon représentatif de la production est conforme aux exigences de l'annexe I de la Directive 93/42/CEE

LNE/G-MED certifies that, on the basis of the results contained in the file(s) referenced P101195, a representative sample of the production complies with the requirements of the Directive 93/42/EEC, annex I

Début de validité / *Effective date :* **February 20th, 2013 (included)**
Valable jusqu'au / *Expiry date :* **January 30th, 2018 (included)**

Laboratoire national de métrologie et d'essais
LNE

For the General Director
Laurence DAGALLIER
Deputy Director

GMED_03-V2.01-2013

LNE - 12468 rev. 8
Annule et remplace le certificat 12468-7

LNE
Le progrès, une passion à partager

Certification
Médical-Santé

Addendum au certificat n° 12468 rev. 8 page 1/1
Addendum of the certificate n° 12468 rev. 8
Dossier / *File* N° P101195

Identification des dispositifs / *Identification of devices*

Reference of the finished product	Size of the clip / Clip reference	Color code	Quantities of cartridges per box	Quantities of clips per box	Packaging version	Range of product
GEM1521	Mini-Micro	Pale Blue	30	180	Blister	SYNOVIS / GEM
W9060	Micro	White	20	180	Blister	NINE
W6060-1			30	180	Blister	SLS
GEM2431		Orange	30	180	Blister	SYNOVIS / GEM
J9180	Small	Yellow	20	180	Blister	NINE
J9135			15	135	Blister	NINE
J9324			36	324	Blister	NINE
J1180-1			30	180	Blister	SLS
J1120-1			20	120	Pouch	SLS
R9180	Small	Red	20	180	Blister	NINE
R9135			15	135	Blister	NINE
R9324			36	324	Blister	NINE
R1180-1			30	180	Blister	SLS
R1120-1			20	120	Pouch	SLS
L9180	Small/Medium	Lilac	20	180	Blister	NINE
L5180-1			30	180	Blister	SLS
B9180	Medium	Blue	20	180	Blister	NINE
B9135			15	135	Blister	NINE
B9324			36	324	Blister	NINE
B2180-1			30	180	Blister	SLS
B2120-1			20	120	Pouch	SLS
V9120	Medium/Large	Green	20	120	Blister	NINE
V3120-1			20	120	Blister	SLS
O9120	Large	Orange	20	120	Blister	NINE
O4120-1			20	120	Blister	SLS

25 alinéas / *25 indented lines*

Vadybininkas
Edvinas Lekas
2015-06-03

LIETUVOS RESPUBLIKA
Uždaroji akcinė bendrovė
PRINCIPALMED TL
KAUNO MIESTAS

Laboratoire national de métrologie et d'essais
LNE

KOPIJA TIKRA

LNE/G-MED **0459**

For the General Director
Laurence DAGALLIER
Deputy Director

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

DE PINNA
NOTARIES

KOPIJA TIKRA

LIETUVOS RESPUBLIKA
Uždaroji akcinė bendrovė
PRINCIPALMED 1L

I, **David Noel Lloyd FAWCETT**, Notary Public of the City of London, England, by Royal Authority duly admitted and sworn, practising in the said City,

Vadybininkas
Edvinas Lekas
2015-11-11

DO HEREBY CERTIFY AND ATTEST:

THAT the hereunto annexed Certification has been signed on behalf of the English company styled **"GRENA LIMITED"** by **Wieslaw Mieczyslaw BRODACZEWSKI**, whose personal identity I, the Notary, attest, the Sole Director of the said company;

THAT the said **"GRENA LIMITED"** is a private limited company, duly incorporated on 10th June 2003 and existing in accordance with English Law, registered at the Companies Registration Office for England and Wales under number **4793131**, with Registered Office at 1000 Great West Road, Brentford, Middlesex TW8 9HH, England;

THAT the said **Wieslaw Mieczyslaw BRODACZEWSKI** is, under English law, a proper and competent Officer of the said company to sign such Certification on its behalf;

AND THAT, having been signed in the presence of the attesting witness, **Konrad BRODACZEWSKI**, whose personal identity I likewise attest, the said Certification is validly executed on behalf of the said company in accordance with the provisions of English law.

IN TESTIMONY WHEREOF I have hereunto set my hand and affixed my Seal of Office in the City of London aforesaid, this twenty-seventh day of October in the year Two thousand and fifteen.

David Noel Lloyd FAWCETT
Notary Public of London, England

DE PINNA
35 PICCADILLY
LONDON
W1J 0LJ

SCRIVENER NOTARIES

DE PINNA
35 Piccadilly London W1J 0LJ
Telephone: +44 (0)20 7208 2000 Facsimile: +44 (0)20 7208 0066

GRENA DG™
1000 GREAT WEST ROAD, BRENTFORD, MIDDLESEX, TW8 9HH, UK
VAT no GB 821 2900 64
Tel +44 131 208 207 6, Fax +44 131 777 80 77

Brentford, 12.10.2015

I, Wiesław Brodaczewski, the director of Grena Limited whose registered office is located at 1000 Great West Road, Brentford, Middlesex, TW8 9HH, United Kingdom

DO HEREBY CERTIFY AND ATTEST:

That the annexures hereto are true and faithful copies of their respective originals being:

1. EC Certificate – Directive 93/42/EEC Annex V – Production Quality Assurance – Medical Devices (Registration No.: DD 60100980 0001) – 3 pages.

2. EC Certificate – Directive 93/42/EEC Annex II, excluding Section 4 – Full Quality Assurance System – Medical Devices (Registration No.: HD 60100981 0001) – 3 pages.

(total of 6 pages of annexures)

In testimony whereof I have hereunto set my hand and affixed the Company stamp this twelfth day of October in the year two thousand and fifteen.

Wiesław Mieczysław Brodaczewski

Director of Grena Limited

KOPIJA TIKRA

I, Konrad Brodaczewski, do hereby confirm with my own signature that Mr Wiesław Brodaczewski personally issued the above document and signed it in his capacity of the director of Grena Limited.

Konrad Brodaczewski
witness

LIETUVOS RESPUBLIKA
Uždaroji akcinė bendrovė
PRINCIPALMED 1L
KAUNO MIESTAS

Vadybininkas
Edvinas Lekas
2015-11-11

TÜVRheinland®

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

Vadybininkas
Edvinas Lekas
2015-11-11

LIETUVOS RESPUBLIKA
Uždaroji akcinė bendrovė
PRINCIPALMED 1L
KAUNO MIESTAS

Products: (see attachments for products and site included)

KOPIJA TIKRA

Replaces approval, registration no.: DD 60040589 0001

Expiry Date: 2020-04-13

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

Effective Date: 2015-04-30

Date: 2015-04-30

Notified Body

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜVRheinland

Doc. 1/2, Rev. 1

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

LIETUVOS RESPUBLIKA
Uždaroji akcinė bendrovė
PRINCIPALMED 1L
KAUNO MIESTAS

Vadybininkas
Edvinas Lekas
2015-11-11

KOPIJA TIKRA

Products included:
- Disposable trocars
- Infusion sets
- Retrieval bags
- Disposable skin staplers
- Suction cannulas and suction sets
- Thoracenttesis/Paracentesis sets
- Transfusion sets
- Veress needles
- Thoracic catheters
- Suction-irrigation sets
- Silicone slings
- Disposable wound protectors / retractors

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
- Tubing for arthroscopy sets

Notified Body

Date: 2015-09-17

Dipl.-Ing. S. Pane

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

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

LIETUVOS RESPUBLIKA
Uždaroji
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PRINCIPALMED 1L
KAUNO MIESTAS

Vadybininkas
Edvinas Lekas
2015-11-11

KOPIJA TIKRA

Site included:

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

Notified Body

Date: 2015-04-30

Dipl.-Ing. S. Pane

TÜVRheinland®

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

LIETUVOS RESPUBLIKA
Uždaroji akcinė bendrovė
PRINCIPALMED 1L
KAUNO MIESTAS

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

Vadybininkas
Edvinas Lekas

KOPIJA TIKRA

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.

Notified Body

Effective Date: 2015-04-30

Date: 2015-04-30

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜVRheinland

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

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

LIETUVOS RESPUBLIKA
Uždaroji akcinė bendrovė
PRINCIPALMED 1L
KAUNO MIESTAS

Vadybininkas
Edvinas Lekas
2015-11-11

KOPIJA TIKRA

Products included:

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

Notified Body

Date: 2015-04-30

Dipl.-Ing. S. Pane

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

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

LIETUVOS RESPUBLIKA
Uždaroji akcinė bendrovė
PRINCIPALMED 11
KAUNO MIESTAS

Vadybininkas
Edvinas Lekas
2015-11-4

KOPIJA TIKRA

Site included:

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

Notified Body

Date: 2015-04-30

Dipl.-Ing. S. Pane

mdc medical device certification GmbH · Kriegerstraße 6 · 70191 Stuttgart

Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11

78532 Tuttlingen

Ihr Zeichen, Ihre Nachricht vom	Unser Zeichen, unsere Nachricht vom	Telefon	Datum
	RM	0711 253597-14	2011-07-08

Certification of your company

Dear Ladies and Gentlemen,

Herewith, we confirm as a nominated authorization (Notified Body No. 0483), that the Class I products have been reviewed to be adequate during the certification procedure at your company. The Class I products were found to meet all requirements of the EC Directive 93/42/EEC. Therefore, we issued the certificate according to EN ISO 13485. With this certificate, you are authorized to label your products with the CE-mark. On class I product labels the number of the Notified Body may not be next to the CE-mark.

If you have any further questions please do not hesitate to contact us.

Yours sincerely

mdc medical device certification GmbH

Dr. Regina Maurer
(Head of certification body)

Vadybininkas
Edvinas Lekas
2015-11-11

KOPIJA TIKRA
LIETUVOS RES...
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akcinė bendrov...
PRINCIPALMED
KAUNO MIEST...

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart

Telefon 0711-253597-0
Telefax 0711-253597-10
E-Mail mdc@mdc-ce.de

Geschäftsführer
Harald Rentschler
http://www.mdc-ce.de

Benannte Stelle 0483
Amtsgericht Stuttgart HRB 21357
USt-IdNr. DE812169576

Certificate

mdc medical device certification GmbH
certifies that

Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11
78532 Tuttlingen
Germany

for the scope

development, manufacturing and distribution of surgical instruments and accessories, endoscopic instruments and devices with accessories, dental instruments, instruments and implants for osteosynthesis, OR-lamps, OR-tables and accessories and repair service for rigid endoscopes

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Vadybininkas
Edvinas Lekas
2015-9-11

Valid from	2013-07-05
Valid until	2018-07-04
Registration no.	0287.58.01/0
Report no.	E 0287.58 / 2013-07-03
Stuttgart	2013-07-03

KOPIJA TINKA
LIETUVOS RESPUBLIKA Uždaroji akcinė bendrovė PRINCIPALMED 1L KAUNO

D. Bark

Head of Certification Body

medical device certification mdc

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-976.00.03-46

mdc medical device certification GmbH
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Fax: +49-(0)711-253597-10
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