

ORDIN DE PLATA NR.: 30 TIP.DOC. 1 :
DATA EMITERII:joi, 23 ianuarie 2:

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PLATITI: 3000-00 LEI: Trei Mii lei 00 bani :

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PLATITOR: (R) "BIOSISTEM CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L. MD95ML000000002251429243 :
CODUL FISCAL :1010600028048 / :

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PRESTATORUL PLATITOR CODUL BANCII:
BC"Moldindconbank"S.A. suc."Invest" Chisinau :MOLDMD2X329:

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BENEFICIAR (R) I.M.S.P. "S CONTUL DE PLATI/CODUL IBAN :
pitalul Clinic Republican Tim MD57MO2251ASV96476607100 :
ofei Mosneaga" CODUL FISCAL :1003600150783 / :

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PRESTATORUL BENEFICIAR CODUL BANCII:
OTP Bank S.A. :MOBBMD22 :

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DESTINATIA PLATII:Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la procedura de achizi?ie public: NORMAL/URGENT :N:
a nr. ocds-b3wdp1-MD-1735287369911 din :
27.01.2025 :
: L.S.
=====

CODUL TRANZACTIEI:001: _____ :
DATA PRIMIRII:23/01/2025 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :

CONDUCATOR:Web Poiata Vitalie :
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DQEHAACCBGwwggRoMIIDUKADAgECAhNHAAEIdi65avx+fxSlAAAAAQOLMA0GCSq: :
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_____ :
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
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_____ :
L.S. (semnatura electronica) :
CONDUCATOR: _____ :
(semnatura manuala) :
CONTABIL-SEF: _____ :
(semnatura manuala) :
SEMNATURA PRESTATORUL L.S. :

MOTIVUL REFUZULUI : L.S.

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





AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. 531522 data 15.09.2023

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 (IDNO): **1010600028048**

Data înregistrării de stat: **12.08.2010**

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

Obiectul principal de activitate:

- 1. Activitatea farmaceutică; importul și (sau) producerea articolelor de parfumerie și cosmetică**
- 2. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 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,**

Asociații:

1. **POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%**

Beneficiar efectiv:

- 1.1. **POIATA VITALIE, IDNP 0983103892591,**

2. **NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

- 2.1. **NASEDCHIN ALEXANDR, IDNP 2002001070747,**

3. **KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

- 3.1. **KOJEVNIKOV DMITRII, IDNP 0972305012362**

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: **15.09.2023.**

**Registrator în domeniul
înregistrării de stat**

Digitally signed by Rusu Diana
Date: 2023.09.15 16:44:17 EEST
Reason: MoldSign Signature
Location: Moldova



Rusu Diana



EB 0461494



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 în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243.**

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuș

Ex. Diana Brinza
Tel. 43-45-96

Lista fondatorilor Biosistem-mld SRL

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

EC Certificate



Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

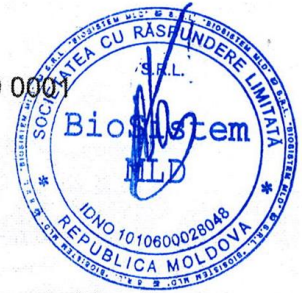
Registration No.: HD 1554225-1

Manufacturer: GRENA Ltd.
1000 Great West Road
Brentford, MIDDLESEX
TW8 9HH
United Kingdom

Products:

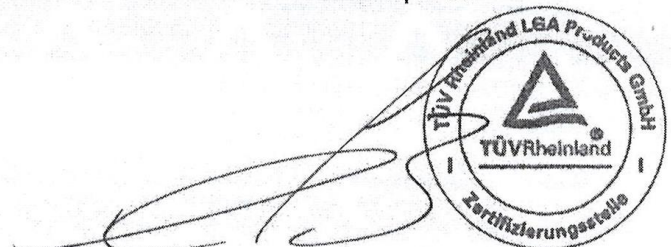
- Ligating clips
- Ligating clip cartridge to be used with reusable automatic clip appliers
- Disposable endoscopic instruments
- Reusable endoscopic instruments
- Disposable Jumbo Pack
- Disposable circular staplers with related surgical instruments
- Disposable linear staplers with cartridges
- Disposable linear cutting staplers with cartridges
- Staples cartridges for reusable linear cutting staplers

Replaces EC Certificate, Registration No.: HD 60147050 0001



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.

Report No.: 84953323-70
Effective date: 2021-05-25
Expiry date: 2024-05-26
Issue date: 2021-05-25



Rafal Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Certificate



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

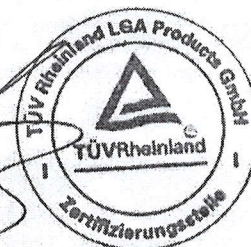
Registration No.: HD 1554225-1

Manufacturer: GRENA Ltd.
1000 Great West Road
Brentford, MIDDLESEX
TW8 9HH
United Kingdom

The scope of certification includes the following additional sites:

No.	Location	Product groups manufactured
/01	GRENA Ltd. 1000 Great West Road Brentford, MIDDLESEX TW8 9HH United Kingdom	Activity: Administration.
/02	GRENA Ltd. Chelsea Street, Chelsea House Nottingham NG7 7HP United Kingdom	Activity: Design, development and manufacture.

Report No.: 84953323-70
Effective date: 2021-05-25
Expiry date: 2024-05-26
Issue date: 2021-05-25



Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Grena Ltd. 1000 GREAT WEST ROAD, BRENTFORD, MIDDLESEX, TW8 9HH, UK

Tel./ Fax +44 115 9704 800

DECLARATION OF CONFORMITY

Manufacturer

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

Authorised representative

MDML INTL LTD.
10 McCurtain Hill Clonakilty,
Co. Cork, P85 K230
Republic of Ireland

Product

Limited use Reusable Endoscopic Instruments

REF numbers

0207-LD01RF, 0207-LD01RFB, 0207-LD01XF, 0207-LG01RF,
0207-LG02RF, 0207-LG03RF, 0207-LG04RF, 0207-LG04RFB,
0207-LG05RF, 0207-LG05RFB, 0207-LS01XF, 0207-LS02XF,
0207-LS03XF, 0207-LS03XFB

Classification

Class IIb, Rule 9.1 according to Annex IX of
the EC 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. The conformity assessment procedure was performed according to the Annex II, excluding section 4 of the Directive. All supporting documentation is retained under the premises of the manufacturer, including Product Release Reports.

Standards Applied

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

CE 0197

Notified Body

TÜV Rheinland LGA Products GmbH
Tillystrasse 2. D-90431 Nürnberg
Germany

EC Approval number

HD 1554225-1

Brentford, 01.02.2023

Rev 08

Wiesław Brodaczewski
Director



Grena Ltd. 1000 GREAT WEST ROAD, BRENTFORD, MIDDLESEX, TW8 9HH, UK

Tel./ Fax +44 115 9704 800

DECLARATION OF CONFORMITY

Manufacturer

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

Authorised representative

MDML INTL LTD.
10 McCurtain Hill Clonakilty,
Co. Cork, P85 K230
Republic of Ireland

Product

Disposable Endoscopic Instruments

REF numbers

0208-DD01RX, 0208-DD01XX, 0208-DG01RX,
0208-DG02RX, 0208-DG02RXB, 0208-DG03RX,
0208-DG04RX, 0208-DG04RXB, 0208-DG05RX,
0208-DG05RXB, 0208-DS01XX, 0208-DS02XX,
0208-DS03XX

Classification

Class IIb, Rule 9.1 according to Annex IX of
the EC 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. The conformity assessment procedure was performed according to the Annex II, excluding section 4 of the Directive. All supporting documentation is retained under the premises of the manufacturer, including Product Release Reports.

Standards Applied

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

CE 0197

Notified Body

TÜV Rheinland LGA Products GmbH
Tillystrasse 2, D-90431 Nürnberg
Germany

EC Approval number

HD 1554225-1

Brentford, 01.02.2023

Rev 07

Wiesław Brodaczewski
Director



Grena Ltd, 1000 GREAT WEST ROAD, BRENTFORD, MIDDLESEX, TW8 9HH, UK

Tel./ Fax +44 115 9704 800

DECLARATION OF CONFORMITY

Manufacturer

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

Authorised representative

MDML INTL LTD.
10 McCurtain Hill Clonakilty,
Co. Cork, P85 K230
Republic of Ireland

Product

Click'aV[®] Ligating Clips

REF numbers

0301-03M, 0301-03ML, 0301-03L, 0301-03XL,
0301-03M04, 0301-03ML04, 0301-03L04,
0301-03XL04, 0301-03ML02, 0301-03L02,
0301-03XL02

Classification

Class IIb, Rule 8-main according to Annex IX
of the EC 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. The conformity assessment procedure was performed according to the Annex II, excluding section 4 of the Directive. All supporting documentation is retained under the premises of the manufacturer, including Product Release Reports.

Standards Applied

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

**Notified Body**

TÜV Rheinland LGA Products GmbH
Tillystrasse 2. D-90431 Nürnberg
Germany

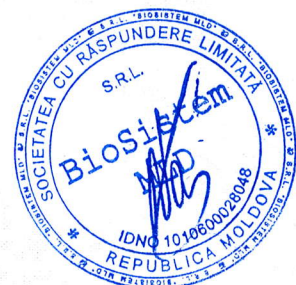
EC Approval number

HD 1554225-1

Brentford, 31.05.2021

Rev 06

Wiesław Brodaczewski
Director



DECLARATION OF CONFORMITY

Manufacturer

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

Authorised representative

MDML INTL LTD.
10 McCurtain Hill Clonakilty,
Co. Cork, P85 K230
Republic of Ireland

Product

Click'aV Plus™ Ligating Clips

REF numbers

0301-10ML, 0301-10L, 0301-10XL, 0301-10ML04,
0301-10L04, 0301-10XL04, 0301-10ML02, 0301-10L02,
0301-10XL02, 0301-10XXL02, 0301-10XXL03,
0301-10XXL04

Classification

Class IIb, Rule 8-main according to Annex IX
of the EC 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. The conformity assessment procedure was performed according to the Annex II, excluding section 4 of the Directive. All supporting documentation is retained under the premises of the manufacturer, including Product Release Reports.

Standards Applied

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

CE 0197

Notified Body

TÜV Rheinland LGA Products GmbH
Tillystrasse 2. D-90431 Nürnberg
Germany

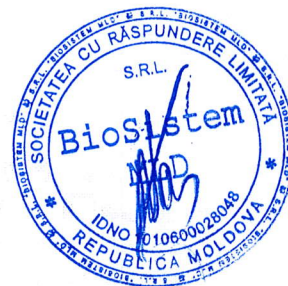
EC Approval number

HD 1554225-1

Brentford, 31.05.2021

Rev 08

Wiesław Brodaczewski
Director



Grena Ltd. 1000 GREAT WEST ROAD, BRENTFORD, MIDDLESEX, TW8 9HH, UK

Tel./ Fax +44 115 9704 800

DECLARATION OF CONFORMITY

Manufacturer

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

Authorised representative

MDML INTL LTD.
10 McCurtain Hill Clonakilty,
Co. Cork, P85 K230
Republic of Ireland

Product

LigaV[®] Ligating Clips,
VClip[®] Ligating Clips

REF numbers

0301-01S, 0301-01M, 0301-01ML, 0301-01L,
0301-01S20, 0301-01M20, 0301-01ML04

0301-06XS, 0301-06S, 0301-06S10, 0301-06SM, 0301-
06M, 0301-06M10, 0301-06ML, 0301-06ML04, 0301-
06ML10, 0301-06L

Classification

Class IIb, Rule 8-main according to Annex IX
of the EC 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. The conformity assessment procedure was performed according to the Annex II, excluding section 4 of the Directive. All supporting documentation is retained under the premises of the manufacturer, including Product Release Reports.

Standards Applied

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

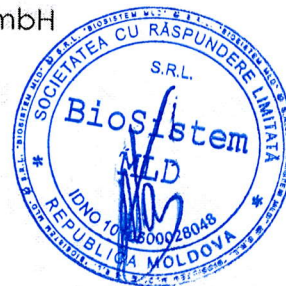
CE 0197

Notified Body

TÜV Rheinland LGA Products GmbH
Tillystrasse 2. D-90431 Nürnberg
Germany

EC Approval number

HD 1554225-1



Brentford, 08.06.2021

Rev 08

Wiesław Brodaczewski
Director

Grena Ltd. 1000 GREAT WEST ROAD, BRENTFORD, MIDDLESEX, TW8 9HH, UK

Tel./ Fax +44 115 9704 800

DECLARATION OF CONFORMITY

Manufacturer	Grena Limited 1000 Great West Road Brentford, Middlesex, TW8 9HH United Kingdom
Authorised representative	MDML INTL LTD. 10 McCurtain Hill Clonakilty, Co. Cork, P85 K230
Republic of Ireland	
Product	Reusable OMNIFinger™ Articulating Endoscopic Instruments
REF numbers	0207-RS01OMNXF, 0207-RS01OMNXFB, 0207-RS02OMNXF, 0207-RS02OMNXFB
Classification	Class I, Rule 6.2 according to Annex IX of the EC 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. The conformity assessment procedure was performed according to the Annex VII of the Directive. All supporting documentation is retained under the premises of the manufacturer, including Product Release Reports.

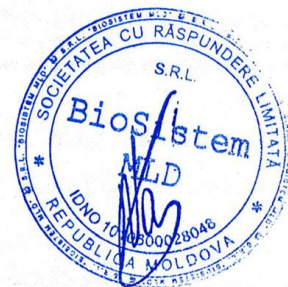
Standards Applied

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



Brentford, 02.03.2020

Rev 1.1

Wiesław Brodaczewski
Director

DECLARATION OF CONFORMITY

Manufacturer

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

Authorised representative

MDML INTL LTD.
10 McCurtain Hill Clonakilty
Co. Cork, P85 K230
Republic of Ireland

Product

Click'aV[®] Ligating Clip Applier

REF numbers	0301-04L20	0301-04M20	0301-04MLE	0301-04XLEN
	0301-04L27	0301-04M27	0301-04MLEA20	0301-04XLEA20
	0301-04L27A70	0301-04M27A70	0301-04MLEA20B	0301-04XLEA20B
	0301-04LE	0301-04ME	0301-04MLEA20I	0301-04XLEA20I
	0301-04LEN	0301-04MEA20	0301-04MLEA20IB	0301-04XLEA20IB
	0301-04LEA20	0301-04MEA20B	0301-04MLEA45	0301-04XLEA45
	0301-04LEA20B	0301-04MEA20I	0301-04MLEA45I	0301-04XLEA45I
	0301-04LEA20I	0301-04MEA20IB	0301-04MLEA45IB	0301-04XLEA45IB
	0301-04LEA20IB	0301-04MEA45	0301-04MLEB	0301-04XLEB
	0301-04LEA45	0301-04MEA45I	0301-04MLEHS	0301-04XLEBN
	0301-04LEA45I	0301-04MEA45IB	0301-04MLEI	0301-04XLEHS
	0301-04LEA45IB	0301-04MEB	0301-04MLEIB	0301-04XLEI
	0301-04LEB	0301-04MEHS	0301-04MMLEHS	0301-04XLEIB
	0301-04LEBN	0301-04MEI	0301-04MMLEHSB	0301-04XXLEN
	0301-04LEI	0301-04MEIB	0301-04XL20	0301-04XXLEBN
	0301-04LEIB	0301-04ML20	0301-04XL27	0301-04XXL20
	0301-04LXLEHS	0301-04ML27	0301-04XL27A70	
	0301-04LXLEHSB	0301-04ML27A70	0301-04XLE	

Classification

Class I, Rule 6.2 according to Annex IX of the EC 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. The conformity assessment procedure was performed according to the Annex VII of the Directive. All supporting documentation is retained under the premises of the manufacturer, including Product Release Reports.

Standards Applied

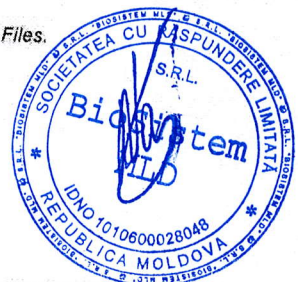
All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.



Wiesław Brodaczewski
Director

Brentford, 17.06.2021

Rev 08



DECLARATION OF CONFORMITY

Manufacturer

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

Authorised representative

MDML INTL LTD.
10 McCurtain Hill Clonakilty
Co. Cork, P85 K230
Republic of Ireland

Product

OMNIFinger™ Articulating Click'aV® Ligating Clip Applier

REF numbers

0301-04MEOMN, 0301-04MEOMNB, 0301-04MEOMNX,
0301-04MEOMNBX, 0301-04MLEOMN, 0301-04MLEOMNB,
0301-04MLEOMNX, 0301-04MLEOMNBX,
0301-04LEOMN, 0301-04LEOMNB, 0301-04LEOMNX,
0301-04LEOMNBX, 0301-04XLEOMN, 0301-04XLEOMNB,
0301-04XLEOMNX, 0301-04XLEOMNBX

Classification

Class I, Rule 6.2 according to Annex IX of the EC
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. The conformity assessment procedure was performed according to the Annex VII of the Directive. All supporting documentation is retained under the premises of the manufacturer, including Product Release Reports.

Standards Applied

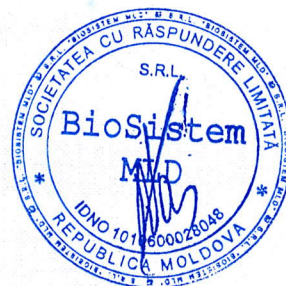
All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.



Brentford, 02.03.2020

Rev 2.1

Wiesław Brodaczewski
Director



Grena Ltd. 1000 GREAT WEST ROAD, BRENTFORD, MIDDLESEX, TW8 9HH, UK

Tel./ Fax +44 115 9704 800

DECLARATION OF CONFORMITY

Manufacturer

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

Authorised representative

MDML INTL LTD.
10 McCurtain Hill Clonakilty
Co. Cork, P85 K230
Republic of Ireland

Product

LigaV[®] Ligating Clip Appliers,

REF numbers

0301-02L20	0301-02M28	0301-02MLEB
0301-02L28	0301-02ME	0301-02S15
0301-02LE	0301-02MEB	0301-02S185
0301-02LEB	0301-02ML20	0301-02S19
0301-02M15	0301-02ML275A45	0301-02S20
0301-02M185	0301-02ML28	0301-02S28
0301-02M19	0301-02MLEA25	0301-02SE
0301-02M20	0301-02MLE	

Classification

Class I, Rule 6.2 according to Annex IX of the
EC 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. The conformity assessment procedure was performed according to the Annex VII of the Directive. All supporting documentation is retained under the premises of the manufacturer, including Product Release Reports.

Standards Applied

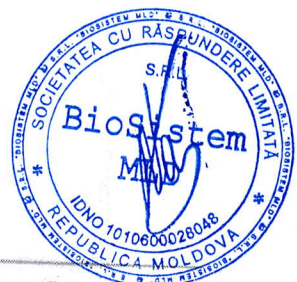
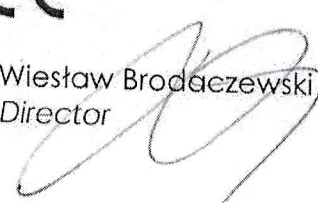
All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.



Brentford, 03.12.2020

Rev.06

Wiesław Brodaczewski
Director



DECLARATION OF CONFORMITY

Manufacturer

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

Authorised representative

MDML INTL LTD.
10 McCurtain Hill Clonakilty
Co. Cork, P85 K230
Republic of Ireland

Product

OMNIFinger™ Articulating Vclip® Ligating Clip Applier
OMNIFinger™ Articulating LigaV® Ligating Clip Applier

REF numbers

0301-07MEOMN, 0301-07MEOMNB, 0301-07MLEOMN,
0301-07MLEOMNB, 0301-07LEOMN, 0301-07LEOMNB
0301-02MEOMN, 0301-02MEOMNB, 0301-02MLEOMN,
0301-02MLEOMNB, 0301-02LEOMN, 0301-02LEOMNB

Classification

Class I, Rule 6.2 according to Annex IX of the EC
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. The conformity assessment procedure was performed according to the Annex VII of the Directive. All supporting documentation is retained under the premises of the manufacturer, including Product Release Reports.

Standards Applied

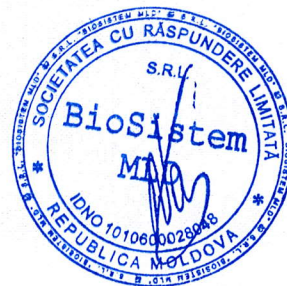
All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.



Brentford, 02.03.2020

Rev 1.1

Wiesław Brodaczewski
Director



DECLARATION OF CONFORMITY

Manufacturer

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

Authorised representative

MDML INTL LTD.
10 McCurtain Hill Clonakilty
Co. Cork, P85 K230
Republic of Ireland

Product

Vclip[®] Ligating Clip Applier,

REF numbers

0301-07L20	0301-07ML28	0301-07SE
0301-07L28	0301-07MLE	0301-07XS15
0301-07LE	0301-07MLEB	0301-07XS20
0301-07LEB	0301-07MLES	0301-07XS28
0301-07M15	0301-07SM15	0301-07S20A25
0301-07M20	0301-07SM20	0301-07M20A25
0301-07M28	0301-07SM28	0301-07ML20A25
0301-07ME	0301-07S15	0301-07L20A25
0301-07MEB	0301-07S20	0301-07MLEA25
0301-07ML20	0301-07S28	

Classification

Class I, Rule 6.2 according to Annex IX of the
EC 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. The conformity assessment procedure was performed according to the Annex VII of the Directive. All supporting documentation is retained under the premises of the manufacturer, including Product Release Reports.

Standards Applied

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



Brentford, 02.03.2020

Rev 4.1

Wiesław Brodaczewski
Director

