

## Date generale despre ofertant

<b>SRL Biosistem mld</b>
<b>Administrator:</b> Poiata Vitalie
<b>Adresa poștală:</b> str. Albișoara 16/1 of.7, or. Chișinău
<b>Tel./Fax:</b> .+373-22-808517, +373-22-808719, fax +373-22-808519
<b>E-mail:</b> biosistem.mld@gmail.com; info@biosistem-mld.com
<b>Cod IBAN:</b> MD95ML000000002251429243
<b>Banca:</b> BC "Moldindconbank" S.A. fil. Invest
<b>Codul băncii:</b> MOLDMD2X329
<b>Cod fiscal:</b> 1010600028048
<b>Cod TVA:</b> 0607490

Cu respect,

Vitalie Poiata

Administrator



# 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: MOLDM2X329

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: MOLDM2X329

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 MOLDM2X329.

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





## 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**

## **Lista fondatorilor Biosistem-mld SRL**

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

**Liga<sup>2</sup>**®  
**Titanium Ligating Clips**



**TITANIUM**

**Reliable Ligation**

## Ligating Clips

### *LigaV*<sup>®</sup>

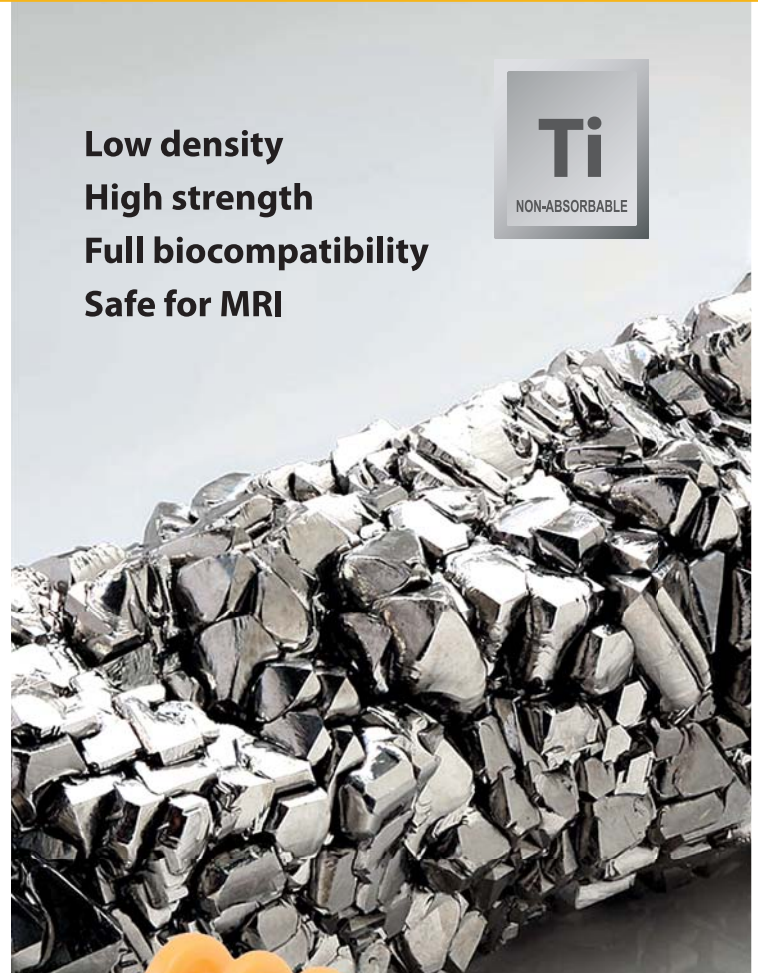
LigaV<sup>®</sup> Ligating clips are implantable medical devices. They are widely used in surgery for marking and ligating purposes. Medical practitioners value the product for its hemostatic features.

LigaV<sup>®</sup> manufactured by Grena Ltd., comes with inner and outer serration which enhances its function. The outer serration helps to grip the clip in the applicator's jaws; the inner serration enables its proper nourishment.

The product is offered in 4 standard sizes ensuring every user will be able to find appropriate clip for the given tissue. The LigaV<sup>®</sup> clips are delivered in colour coded cartridges to ensure easy and intuitive identification. A cartridge includes 4 or 6 clips that ensure economical and comfortable use. The product is disposable, sterilised with EO.

Clip applicators with proper sized jaws depending on the clip should be used. Clip applicators are made of highest quality surgical grade steel. Handle rings are color coded matching cartridge hue.

**Low density**  
**High strength**  
**Full biocompatibility**  
**Safe for MRI**



## Ligating Clips

### *LigaV*<sup>®</sup>

The LigaV<sup>®</sup> ligating clips are manufactured of a medical grade titanium which ensures proper level of biocompatibility. The applied technology guarantees the product meets the requirements of even the most demanding clinical institutes.



# TITANIUM



# Ligating Clips

## Ligating Clips

**Cost-effective alternative  
for simple procedures**








4 clips per cartridge





### Key features

- 4 sizes to ligate tissue structures,
- made of apyrogenic titanium,
- easy loading system,
- clips delivered in color-coded cartridges for easy identification,
- 4 or 6 clips per cartridge to ensure economical and comfortable use of the product,
- V-shaped,
- color-coded applicator rings for easy identification



REF	Clip size	Compatible with applicators (jaws grip) (mm)	Product specification	Colour	Pcs per cartridge	Pcs cartridges per box
0301-01S	Small	0,59-0,75	V-shaped titanium ligating clips		6	50
0301-01M	Medium	0,84-1,00			6	50
0301-01ML	Medium-Large	1,16-1,32			6	20
0301-01ML04	Medium-Large	1,16-1,32			4	20
0301-01L	Large	1,26-1,42			6	20

## Open Surgery Clip Appliers

-  S
-  M
-  ML
-  L



Open Surgery Clip Appliers

**Ergonomic and effective approach  
in endoscopic procedures**

# Open Surgery Clip Appliers

## Open Surgery Clip Appliers

### Key features

- available for Small, Medium, Medium-Large and Large non-absorbable LigaV® clips to be used on large spectrum of tissue sizes,
- 15cm, 20cm and 28cm clip,
- non-detachable design for easier maintenance and durability, appliers with proper sized jaws made of high quality stainless steel,
- colour-coded rings matching cartridge hue,
- compatible with corresponding sizes of LigaV® titanium non-absorbable clips.



REF	Clip size	Applier length	Pcs per box
0301-02S15*	Small	15	1
0301-02S20	Small	20	1
0301-02S28*	Small	28	1
0301-02M15*	Medium	15	1
0301-02M20	Medium	20	1
0301-02M28*	Medium	28	1
0301-02ML20	Medium-Large	20	1
0301-02ML28	Medium-Large	28	1
0301-02L20	Large	20	1
0301-02L28	Large	28	1



\* Manufactured on request.

# Endoscopic Clip Appliers

## Endoscopic Clip Appliers

### Key features

- available for Medium, Medium-Large and Large non-absorbable LigaV<sup>®</sup> clips to be used on large spectrum of tissue sizes,
- jaws activated by front handle for better stability,
- 360° shaft rotation by index finger allows one-hand operation,
- flushing port facilitates easy cleaning, thus eliminating potential contamination,
- made of high quality stainless steel,
- colour coded size matching cartridge hue,
- compatible with corresponding sizes of LigaV<sup>®</sup> titanium non-absorbable clips.

#### REF 0301-02ME

<b>Size</b>	M
<b>Colour</b>	○
<b>Shaft diameter (mm)</b>	5
<b>Trocar diameter (mm)</b>	5
<b>Working length (cm)</b>	33
<b>Loading</b>	front - loaded
<b>Box quantity (pcs)</b>	1



#### REF 0301-02MLE

<b>Size</b>	ML
<b>Colour</b>	●
<b>Shaft diameter (mm)</b>	10
<b>Trocar diameter (mm)</b>	10
<b>Working length (cm)</b>	33
<b>Loading</b>	front - loaded
<b>Box quantity (pcs)</b>	1

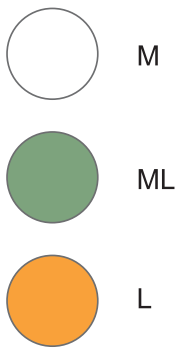


#### REF 0301-02LE

<b>Size</b>	L
<b>Colour</b>	●
<b>Shaft diameter (mm)</b>	10
<b>Trocar diameter (mm)</b>	10
<b>Working length (cm)</b>	33
<b>Loading</b>	front - loaded
<b>Box quantity (pcs)</b>	1



## Endoscopic Clip Appliers

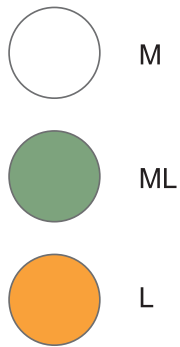


Endoscopic Clip Appliers

**Ergonomic and effective approach  
in endoscopic procedures**



## Endoscopic Clip Appliers



Bariatric Endoscopic Clip Appliers - 45 cm

**Extra length for bariatric surgery**

# Endoscopic Clip Appliers

## Bariatric Endoscopic Clip Appliers

### Key features

- 45 cm long shaft,
- available for Medium, Medium-Large and Large non-absorbable LigaV<sup>®</sup> clips to be used on large spectrum of tissue sizes,
- jaws activated by front handle for better stability,
- 360° shaft rotation by index finger allows one-hand operation,
- flushing port facilitates easy cleaning, thus eliminating potential contamination,
- made of high quality stainless steel,
- colour coded size matching cartridge hue,
- compatible with corresponding sizes of LigaV<sup>®</sup> titanium non-absorbable clips.

#### REF 0301-02MEB

<b>Size</b>	M
<b>Colour</b>	○
<b>Shaft diameter (mm)</b>	5
<b>Trocar diameter (mm)</b>	5
<b>Working length (cm)</b>	45
<b>Box quantity (pcs)</b>	1



#### REF 0301-02MLEB

<b>Size</b>	ML
<b>Colour</b>	●
<b>Shaft diameter (mm)</b>	10
<b>Trocar diameter (mm)</b>	10
<b>Working length (cm)</b>	45
<b>Box quantity (pcs)</b>	1



#### REF 0301-02LEB

<b>Size</b>	L
<b>Colour</b>	●
<b>Shaft diameter (mm)</b>	10
<b>Trocar diameter (mm)</b>	10
<b>Working length (cm)</b>	45
<b>Box quantity (pcs)</b>	1



## Accessories

# Accessories

REF	Product	Clip size	Pcs per box
0301-05CB	Cartridge base	S, M, ML, L	1





## New International Initiative

**GRENA<sup>DG</sup>**  
*Think Medical*

**Grena forges Talents!**



**Who's next?**

**Visit us**

**<http://talents.grena.co.uk>**

## 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.

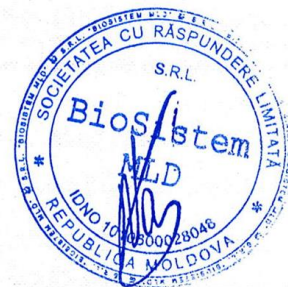
**Standards Applied**

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<sup>®</sup> 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**

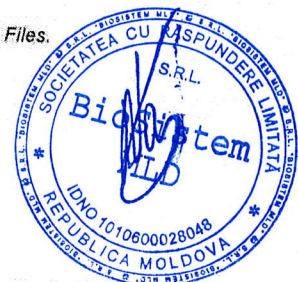
All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.



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**

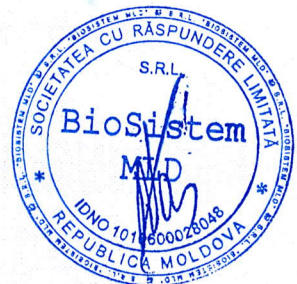

All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.



Brentford, 02.03.2020

Rev 2.1

Wiesław Brodaczewski  
Director



## 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**

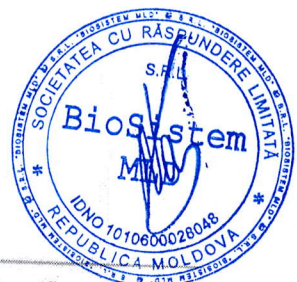
All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.

CE

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.*

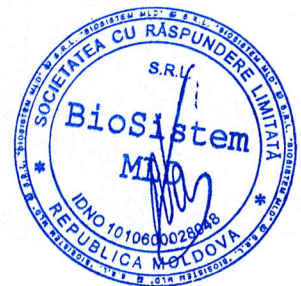
**Standards Applied**

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<sup>®</sup> 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**

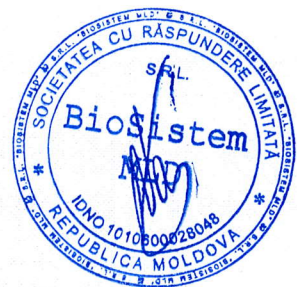
All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.

CE

Brentford, 02.03.2020

Rev 4.1

Wiesław Brodaczewski  
Director



# EC Certificate



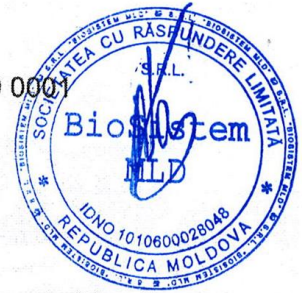
**Full Quality Assurance System**  
**Directive 93/42/EEC on Medical Devices, Annex II excluding (4)**

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



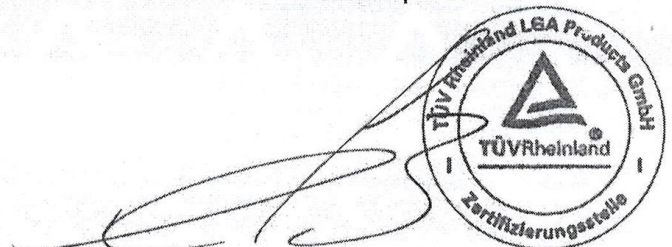
The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, 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.

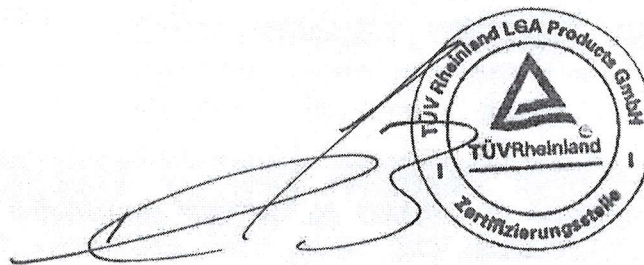


Report No.: 84953323-70

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.

## 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

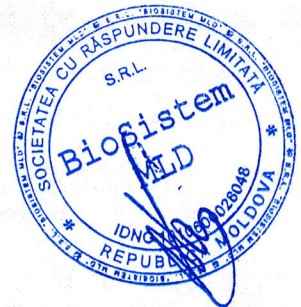
EC Approval number

HD 1554225-1

Brentford, 01.02.2023

Rev 07

Wiesław Brodaczewski  
Director



## 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.

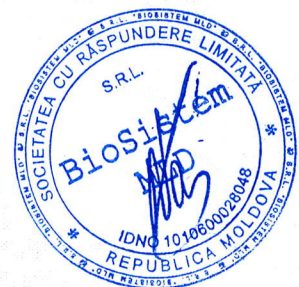
### CE 0197

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

**EC Approval number** HD 1554225-1

Brentford, 31.05.2021  
Rev 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

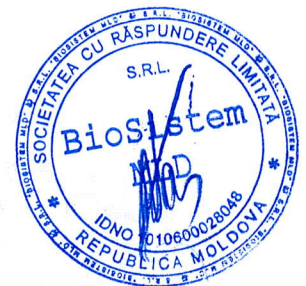
**Notified Body** TÜV Rheinland LGA Products GmbH  
Tillystrasse 2. D-90431 Nürnberg  
Germany

**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<sup>®</sup> Ligating Clips,  
VClip<sup>®</sup> 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

