



GUVERNUL
REPUBLICII
MOLDOVA



SERVICIUL FISCAL DE STAT



CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ 1403048

Din
От 13.02.2024 14:03



DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare

Фискальный код / Идентификационный номер

1010600028048

Denumirea

Наименование

Societatea cu Răspundere Limitată BIOSISTEM MLD



**ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI
INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ
ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ
СИСТЕМЫ**

La data emiterii prezentului certificat restanța față de bugetul public național constituie

На дату выдачи данной справки задолженность перед национальным публичным бюджетом составляет

0 MDL



VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО

28.02.2024 14:03



Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответствии со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la **13.02.2024 14:03**

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022

Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022



Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are aceeași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц (mcabinet.gov.md) и подписан электронной подписью владельца портала и имеет такую же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлинности электронной подписи можно осуществить с помощью Государственной Службой Электронной Подписью (msign.gov.md)



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

Codul băncii MOLDM2X329.

Director

Nina Turcan

Director financiar



Nina Balmuș

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

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

EC Certificate



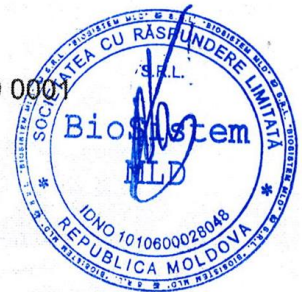
Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

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



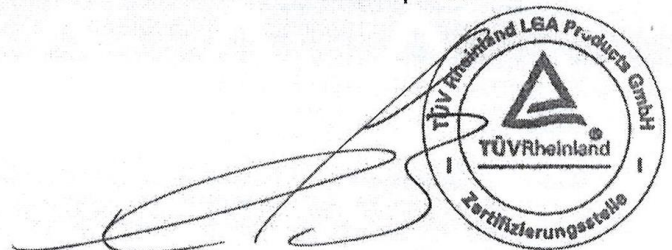
The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II,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

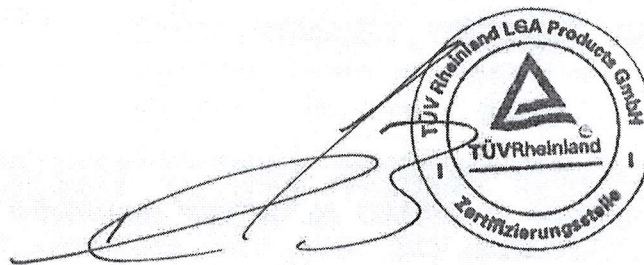
Registration No.: HD 1554225-1
Manufacturer: GRENA Ltd.
1000 Great West Road
Brentford, MIDDLESEX
TW8 9HH
United Kingdom

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.

DECLARATION OF CONFORMITY

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

Authorised representative MDML INTL LTD.
10 McCurtain Hill Clonakilly,
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

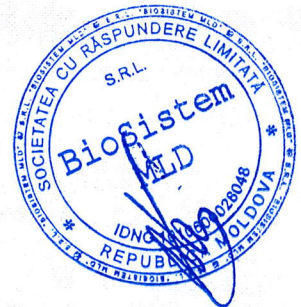
EC Approval number

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

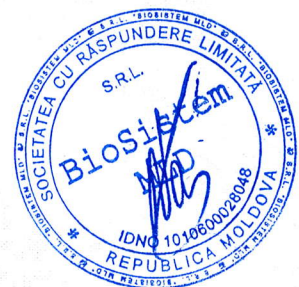
EC Approval number

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

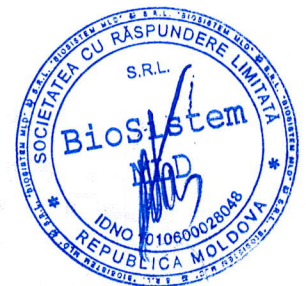
EC Approval number

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[®] 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

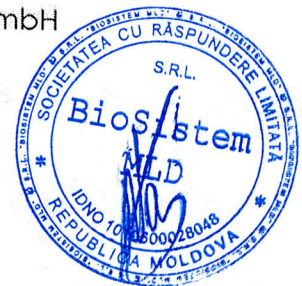
Notified Body
TÜV Rheinland LGA Products GmbH
Tillystrasse 2. D-90431 Nürnberg
Germany

EC Approval number
HD 1554225-1

Brentford, 08.06.2021

Rev 08


Wiesław Brodaczewski
Director



Liga²®
Titanium Ligating Clips



TITANIUM

Reliable Ligation

Ligating Clips

LigaV[®]

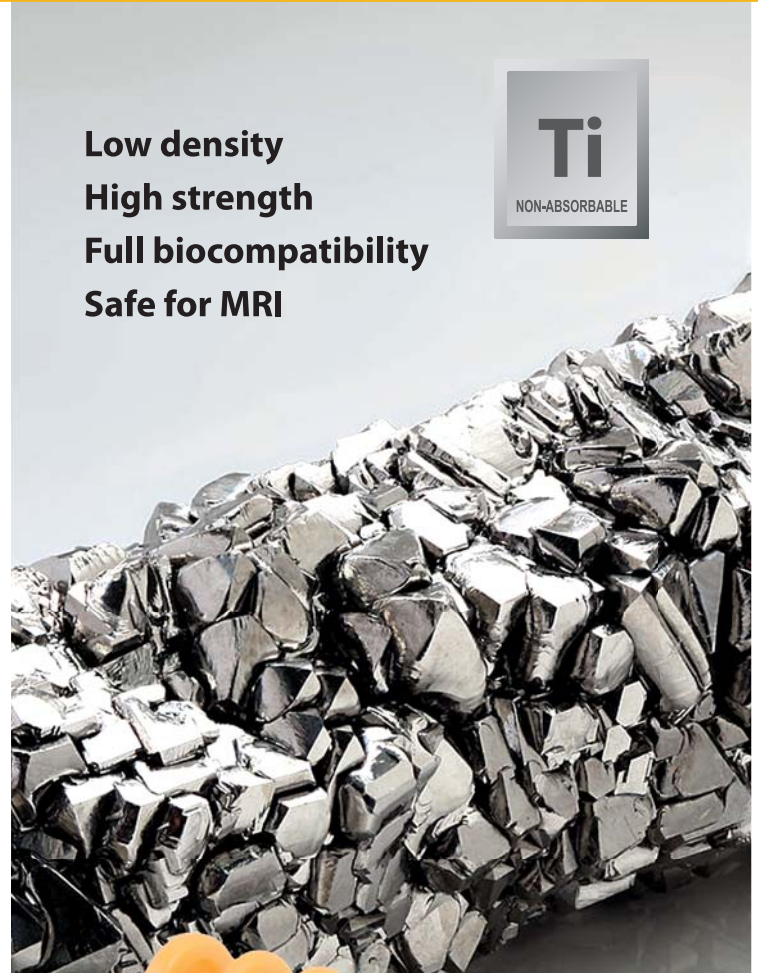
LigaV[®] Ligating clips are implantable medical devices. They are widely used in surgery for marking and ligating purposes. Medical practitioners value the product for its hemostatic features.

LigaV[®] 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[®] 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

Liga2[®]

The LigaV[®] 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® 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® titanium non-absorbable clips.

REF 0301-02ME	
Size	M
Colour	○
Shaft diameter (mm)	5
Trocar diameter (mm)	5
Working length (cm)	33
Loading	front - loaded
Box quantity (pcs)	1






REF 0301-02MLE	
Size	ML
Colour	●
Shaft diameter (mm)	10
Trocar diameter (mm)	10
Working length (cm)	33
Loading	front - loaded
Box quantity (pcs)	1



REF 0301-02LE	
Size	L
Colour	●
Shaft diameter (mm)	10
Trocar diameter (mm)	10
Working length (cm)	33
Loading	front - loaded
Box quantity (pcs)	1



Endoscopic Clip Appliers

-  M
-  ML
-  L

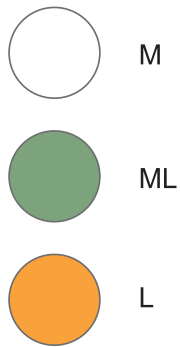


Endoscopic Clip Appliers

**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[®] 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[®] titanium non-absorbable clips.

REF 0301-02MEB

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



REF 0301-02MLEB

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



REF 0301-02LEB

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



Accessories

Accessories

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



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

Otorga la presente / Grants this

ACREDITACIÓN 12/PPI020

a

BioSystems, S.A. (PREVECAL)

Según criterios recogidos en la norma UNE-EN ISO/IEC 17043, para las actividades como **PROVEEDOR DE PROGRAMAS DE INTERCOMPARACIÓN** definidas en el ANEXO TÉCNICO nº 12/PPI020. According to the criteria in the standard UNE-EN ISO/IEC 17043 for the Proficiency Testing Provider activities defined in the Technical Annex Nº 12/PPI020.

Fecha de entrada en vigor / Coming into effect: 26/04/2019



D. José Manuel Prieto Barrio
Presidente

La acreditación mantiene su vigencia hasta notificación en contra. Este documento no tiene validez sin su correspondiente anexo técnico. La presente acreditación y su anexo técnico están sujetos a modificaciones, suspensiones temporales y retirada. Su vigencia puede confirmarse en www.enac.es.

The accreditation maintains its validity unless otherwise stated. The present accreditation is not valid without its corresponding technical annex. This accreditation and its technical annex could be reduced, temporarily suspended and withdrawn. The state of validity of it can be confirmed at www.enac.es.

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ENAC is signatory of the Multilateral Recognition Agreements established by the European co-operation for Accreditation (EA) and the International organizations of accreditation bodies, ILAC and IAF (www.enac.es)

Ref.: CPPI/11294 Fecha de emisión 30/07/2021
El presente documento anula y sustituye al de ref. CPPI/10429

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

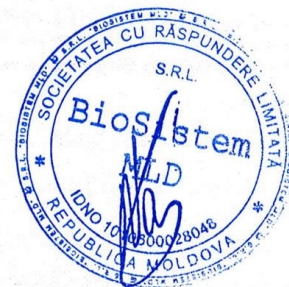

All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.



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

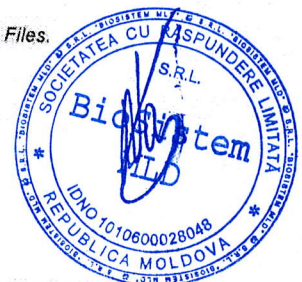
All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.



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

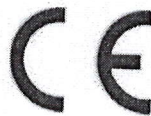
Classification

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

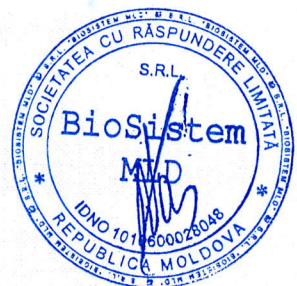
All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.



Brentford, 02.03.2020

Rev 2.1

Wiesław Brodaczewski
Director



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

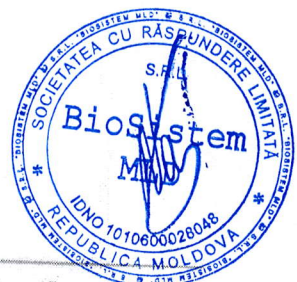
All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.



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.

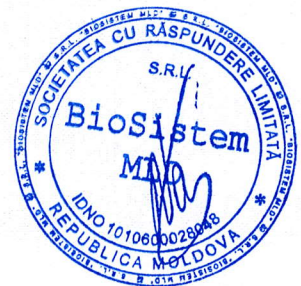
Standards Applied

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

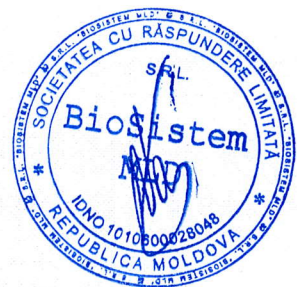
All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.

Brentford, 02.03.2020

Rev 4.1

CE

Wiesław Brodaczewski
Director



6M91021910

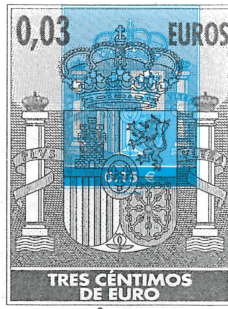
06/2019



JOSEP PEÑARROJA FA
ADVOCATE AND SOLICITOR
COMMISSIONER FOR OATHS
OFFICIAL TRANSLATOR
GRAN VIA 594 SA 2ª
08007 BARCELONA SPAIN



CLASE 8ª



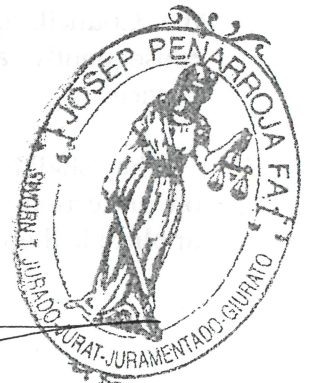
Traducción Jurada *Official translation*

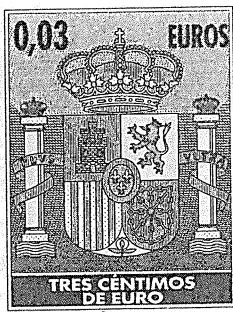
Josep Peñarroja Fa
Intérprete Jurado de Inglés
Official Translator of English

Certifica que la que antecede es traducción
fiel y completa al inglés de un documento
redactado en español.

Do hereby certify that the attached translation
is a true and accurate rendering into English
of a document in Spanish.

Barcelona, - 3 MAR 2020





0N9696073

CLASE 8.^a

Traducción Jurada

[Coat of arms
of Spain]**MINISTRY
OF HEALTH**[Logo]
Spanish Medicines and
Medical Devices Agency

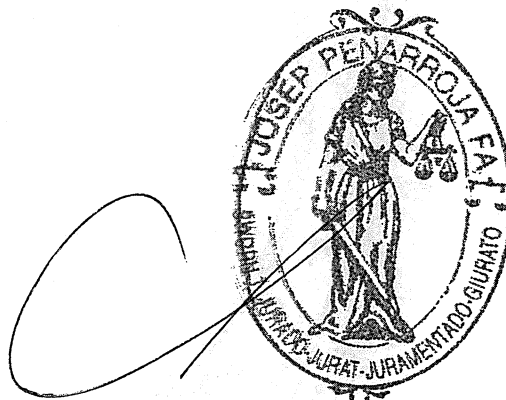
NOTIFICATION

OUR REF.: PS/DP/MFD
DATE: 19 February 2020
RE: Information to the recipient

RECIPIENT: **BIOSYSTEMS, S.A.**
C/ COSTA BRAVA, N.º 30
08030 BARCELONA (SPAIN)

With regard to the products listed below, produced by your company, considering that they are subject to external quality assessment procedures:

- PREVECAL BIOCHEMISTRY
- PREVECAL PROTEINS
- PREVECAL URINE
- PREVECAL RHEUMA
- PREVECAL BIOCHEMISTRY HUMAN
- PREVECAL ANA
- PREVECAL nDNA
- PREVECAL CELIAC
- PREVECAL ANCA
- PREVECAL COAGULATION
- PREVECAL VETERINARY



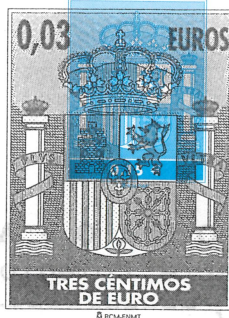
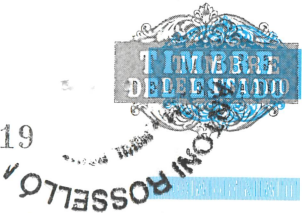
You are hereby advised that:

These products **do not** fall within the scope of Royal Decree 1662/2000, of 29 September, which transposes Directive 98/79/EC of the European Parliament and of the Council, of 27 October 1998, on in vitro diagnosis medical devices, and, consequently, are outside the sphere of competence of this Department of Medical Devices.

They shall be marketed as provided for under the general commercial laws, the laws on protection of users and consumers, and any other specific regulations which are applicable thereto.

0N98961929

06/2019



CLASE 8.^a

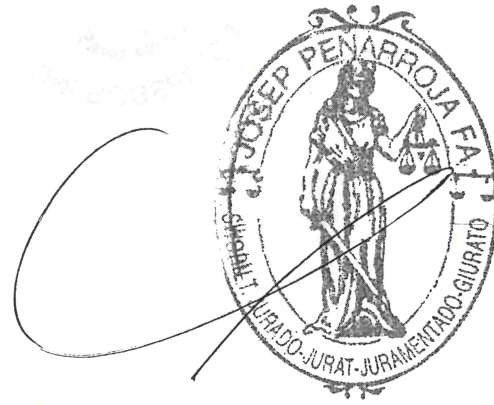
Traducción Jurada

THE HEAD OF THE DEPARTMENT
OF MEDICAL DEVICES
[Signature and seal of the Spanish Medicines
and Medical Devices Agency]
Carmen Ruiz-Villar Fernández-Bravo

E-MAIL:
mpizarro@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 50 09
FAX: 91 822 52 77

[There is a seal which states that the document has been recorded by the Spanish Ministry of Health, dated 20 February 2020]



TESTIMONIO.- ANTONIO ROSSELLÓ MESTRE, Notario del Ilustre Colegio de Cataluña, con residencia en Barcelona, -----

DOY FE: Que el presente testimonio es fiel reproducción, por fotocopia, del documento original, que me exhibe. Y para que conste libro el presente, extendido en dos folios de papel del Timbre del Estado, exclusivo para Documentos Notariales, serie FA, número el presente y el anterior correlativo en orden ascendente. -----

Barcelona a once de marzo de dos mil veinte. -----

Figura en el libro indicador con el N° 453/2020 de la Sección Segunda.-----



Antonio Roselló Mestre