ORDIN DE PLATA NR.: 1215 TIP.DOC. 1

DATA EMITERII:10 martie 2022

PLATITI: 630-00 LEI: Sase Sute Treizeci lei 00 bani

PLATITOR: (R) 'BIOSISTEM MLD" SRL

CONTUL DE PLATI/CODUL IBAN
MD95ML000000002251429243
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. fil."Invest" Chisinau

CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R) IMSP SPITAL UL CLINIC MUNICIPAL "SFANTA T REIME"

CONTUL DE PLATI/CODUL IBAN
MD22ML000000000225166614
CODUL FISCAL :1003600152592 /

PRESTATORUL BENEFICIAR
BC"Moldindconbank"S.A.

CODUL BANCII:
:MOLDMD2X

DESTINATIA PLATII:Pentru garantia pentru: oferta la procedura de achizi?ie public: a nr. ocds-b3wdp1-MD-1644562976323 din 14.03.2022

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:10/03/2022
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzgwNVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkxOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv

L.S. (semnatura electronica)

CONDUCATOR: _____
(semnatura manuala)

CONTABIL-SEF: _____
(semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

Digitally signed by Poiata Vitalie
Date: 2022.03.11 18:13:56 EET
Reason: MoldSign Signature
Location: Moldova

Anexa nr.7.2 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existenţa restanţelor faţă de bugetul public naţional

Nr. / № A2203633 **din** / от 04.03.2022

1. Destinația / Назначение

Pentru participarea la proceduri de achiziții publice

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea / Наименование	**Codul fiscal / Numărul de identificare** / Фискальный код / Идентификационный номер
BIOSISTEM MLD S.R.L.	1010600028048
Adresa sediului de bază (strada, numărul) / Адрес основного месторасположения (улица, номер)	**Codul - Denumirea localității** / Код - Наименование населенного пункта
Albisoara nr.16 bl.1 of.7	0150-SEC.RISCANI

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat / Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет: **0,00** lei/лей.

4. Valabil pînă la / Действителен до 19.03.2022

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Şef DDF Rîşcani a DGDF — **Funcția**/Должность

Semnătura/Подпись

Petru GRICIUC — **Numele şi prenumele**/Фамилия и имя

L.Ş/ М.П.

Executor: **Claudia GOJAN**
Numele şi prenumele/Фамилия и имя

Tel.(022)823102

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 04.03.2022 ora 9:10:55
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,00)

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: MOLDMD2X329

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: MOLDMD2X329

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000022514292 43**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

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

semnătura

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

MD 0101250

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. **8506** din **28.04.2021**

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 şi codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

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

Obiectul principal de activitate:

1 Activitatea farmaceutică;

2 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;

3 Acordarea asistenţei medicale de către instituţiile medico-sanitare private;

4 Comerţul cu ridicata al calculatoarelor, echipamentelor periferice şi software-ului;

5 Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul;

6 Consultaţii în domeniul sistemelor de calcul.

Capitalul social: **5400** lei.

Administrator: POIATA VITALIE,

Asociaţi:

1. POIATA VITALIE 33,40 %

2. NASEDCHIN ALEXANDR 33,30 %

3. KOJEVNIKOV DMITRII 33,30 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 28.04.2021.

Specialist coordonator
tel. 022-207-840

Lazari Aliona

"AGENŢIA SERVICII PUBLICE" IDNO 1002600024700 REPUBLICA MOLDOVA CHIŞINĂU 003

EB 0358735

Date cu caracter personal. **Operator: I.P. "Agenţia Servicii Publice" IO 0000059**

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Lista fondatorilor Biosistem-mld SRL

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

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) – Italy
www.gimaitaly.com

EXPORT DIVISION
tel. +39 02 953854209/221/225
fax +39 02 95380056
export@gimaitaly.com

Gessate, 7 February 2012

CONFORMITY OF GIMA PRODUCTS

According to the annex VII of the Council Directive 93/42/EEC

as amended by the European Directive 2007/47/EEC concerning medical devices

GIMA declares that all medical devices illustrated on

GIMA INTERNATIONAL CATALOGUE

meet the provisions of the following Council Directive (when applicable)

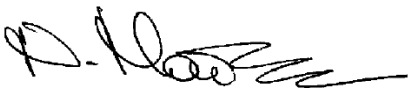
93/42/EEC AS AMENDED BY THE EUROPEAN DIRECTIVE 2007/47/EEC

as below:

A) For all products classified in **CLASS I**, we have in our company a technical file as required from annex VII, and it is available a certificate of conformity signed by the responsible inside the EU (generally GIMA).

B) For all products in CLASS IIa and IIb it is available, or it will be available in one month, a declaration of conformity signed by an official European Notified Body or the ISO 9002 certificate of the manufacturer.

GIMA S.p.A.
Q.A. Department
Nicola Manzoni



CERTIFICATE

Reg. Number	10164 - A	Valid From	2021-10-14
First issue date	2012-10-15	Last change date	2021-10-14
Valid Until	2024-10-14	IAF Sector	29 a

Quality Management System Certificate

ISO 9001:2015

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Trade, packaging and service of medical devices (MD), in vitro diagnostic products (IVD), personal protective equipments (PPE), biocides, veterinary items, medical accessories furniture and aids.

Chief Operating Officer
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwa.it

GIMA S.p.A.
Registered Headquarters
- Via Grossi, 2 20121 Milano - Italia

Certified Sites
- Via Marconi, 1 20060 Gessate (MI) - Italia

CERTIFICATE

Reg. Number	10164 - M	Valid From	2021-10-14
First issue date	2012-10-15	Last change date	2021-10-14
Valid until	2024-10-14		

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Management of design and production, packaging and service of:
General non-active, non-implantable medical devices (except: injection, infusion, transfusion and dialysis; disinfecting, cleaning, rinsing; IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except: extra-corporal circulation, infusion and haemopheresis; stimulation or inhibition, rehabilitation devices and active prostheses; IVF, ART; software; medical gas supply systems and parts thereof), Monitoring devices, Devices for imaging and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices (IVD).
Trade and service of: General non-active, non-implantable medical devices (except: IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except IVF, ART), Devices for imaging (except ionizing radiation), Monitoring devices, Devices for radiation therapy and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices(IVD)

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwa.it

GIMA S.p.A.
Registered Headquarters
- Via Grossi, 2 20121 Milano Italia

Certified Sites
- Via Marconi, 1 20060 Gessate (MI) - Italia

SGQ N° 007A

GRENA®

VAT no. GB 821 2900 64

1000 Great West Road, Brentford, Middlesex TW8 9HH,.UK Phone +44 131 208 207 6 Fax +44 131 777 80 77

DECLARATION OF CONFORMITY

Manufacturer

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

Product(s)

Disposable circular staplers with related surgical instruments (class IIb, rule 8)
Disposable linear staplers and cartridges for linear staplers (class IIb, rule 8)
Disposable bone marrow aspiration needles (class IIa, rule 6)
Disposable bone marrow biopsy needles (class IIa, rule 6)
Disposable staples cartridges for reusable linear staplers (class IIb, rule 8)
Disposable staples cartridges for reusable circular staplers (class IIb, rule 8)
Disposable endoscopic linear cutting staplers (class IIa, rule 6)
Cartridges for disposable endoscopic linear cutting staplers (class IIb, rule 8)
Surgical meshes (class IIb, rule 8)
Disposable automatic clip appliers with clips (class IIb, rule 8)
LigaV® – Titanium ligating clips (class IIb, rule 8)
VClip® – Titanium ligating clips (class IIb, rule 8)
Click'a-V® – Polymer ligating clips (class IIb, rule 8)
Disposable endoscopic instruments:
- Disposable grasper with ratchet atraumatic fenestrated (class IIb, rule 9)
- Disposable grasper with ratchet-Allis (class IIb, rule 9)
- Disposable grasper with ratchet-Maxi Grip (class IIb, rule 9)
- Disposable toothed grasper with ratchet (class IIb, rule 9)
- Disposable grasper with ratchet –Babcock (class IIb, rule 9)
- Disposable Metzenbaum scissors-curved (class IIb, rule 9)
- Disposable scissors-straight (class IIb, rule 9)
- Disposable scissors-hook (class IIb, rule 9)
- Disposable dissector-Maryland (class IIb, rule 9)
- Disposable dissector with ratchet- Maryland (class IIb, rule 9)
- Disposable endoscopic dissector 3mm – Maryland, non-ratcheted
- Disposable endoscopic dissector 3mm – Maryland, ratcheted
- Disposable endoscopic grasper 3mm – atraumatic fenestrated
- Disposable endoscopic scissors 3mm – curved

Limited use endoscopic instruments:
- Limited use dissector- Maryland (class IIb, rule 9)
- Limited use dissector with ratchet- Maryland (class IIb, rule 9)
- Limited use Metzenbaum scissors- curved (class IIb, rule 9)
- Limited use scissors-straight (class IIb, rule 9)
- Limited use scissors-hook (class IIb, rule 9)
- Limited use grasper with ratchet atraumatic fenestrated (class IIb, rule 9)
- Limited use disposable grasper with ratchet-Allis (class IIb, rule 9)
- Limited use grasper with ratchet-Maxi Grip (class IIb, rule 9)
- Limited use toothed grasper with ratchet (class IIb, rule 9)
- Limited use grasper with ratchet –Babcock (class IIb, rule 9)

Reusable endoscopic surgical instruments (class IIb, rule 9)
Disposable linear cutting staplers and cartridges for cutting staplers (class IIb, rule 8)
Disposable trocars with accessories (class IIa, rule 7)
Sterile disposable skin staplers (class IIa, rule 7)
Thoracentesis/paracentesis sets (class IIa, rule 6)
Suction cannulas and suction sets (class IIa, rule 7)
Suction-irrigation sets (class IIa, rule 6)
Disposable skin staples removers (class I sterile, rule 1)
Chest drainage systems (class I sterile, rule 1)
Connecting tubes (class I sterile, rule 1)
Retrieval bags (class IIa, rule 6)
Veress needles (class IIa, rule 6)
Silicone slings (class IIa, rule 6)
Arida® absorbing pads (class I, rule 1)
Arida® absorbing pads – sterile (class I sterile, rule 1)
Solidifying agent (class I, rule 1)
Open surgery and endoscopic clip appliers (class I, rule 6)
Vomit bags (class I, rule 1)

Grena Limited – Incorporated in England & Wales – Company No. 04793131

GRENA®

VAT no. GB 821 2900 64

1000 Great West Road, Brentford, Middlesex TW8 9HH,.UK Phone +44 131 208 207 6 Fax +44 131 777 80 77

Classification According to Annex IX of 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. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied

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

Notified Body

CE 0197

TÜV Rheinland LGA Products GmbH
Lillystrasse 2
90431 Nürnberg
Germany

EC Certificate(s)

HD 60040590 0001
DD 60040589 0001

Brentford, 09.05.2014

Wiesław Brodaczewski
Director

Grena Limited – Incorporated in England & Wales – Company No. 04793131

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1554225-1

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

Scope: Design and development, production and distribution of disposable and reusable medical devices for surgical and patient care procedures.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84952920-70
Effective date: 2021-04-23
Expiry date: 2022-04-13
Issue date: 2021-04-23

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierstelle

Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1554225-1

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

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	GRENA Ltd. 1000 Great West Road Brentford, MIDDLESEX TW8 9HH United Kingdom	Design and development, production and distribution of disposable and reusable medical devices for surgical and patient care procedures.
/02	Grena Ltd. Chelsea Street, Chelsea House Nottingham NG7 7HP United Kingdom	Design and development, production and distribution of disposable and reusable medical devices for surgical and patient care procedures. Especially: production, purchasing, logistics and distribution of disposable and reusable medical devices.

Report No.: 84952920-70
Effective date: 2021-04-23
Expiry date: 2022-04-13
Issue date: 2021-04-23

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

10/020 h 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

SZUTEST

EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number: 2195-MED-1929401

Manufacturer: **MERIL ENDO SURGERY PVT. LTD.**
Third Floor, E1-E3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi – 396 191, Gujarat, INDIA

Product(s):

(1) Non-Absorbable, Braided Coated Poly(Ethylene Terephthalate) Surgical Suture

(2) Non-Absorbable, Monofilament Polyamide Surgical Suture

(3) Non-Absorbable, Monofilament Polypropylene Surgical Suture

(4) Non- Absorbable, Braided Coated Silk Surgical Suture

(5) Non-Absorbable, Monofilament Stainless Steel Surgical Suture

Model(s): Product specifications are stated on the second page.

Reference Report No: MM0755-P001-R01, MM0755-P001-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

This EC certificate is valid till 2024-05-26.

Issue Date: 2019-10-21

Rukiye BALKAN
Deputy General Manager

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

Certificate Number: 2195-MED-1929401

Product Specifications

Product Categories	Type (Models)	Generic Name
(1) Non-Absorbable, Braided Coated Poly(Ethylene Terephthalate) Surgical Suture	MERICRON XL™	Sterile Non-Absorbable Poly(Ethylene Terephthalate) Surgical Suture
	Aspiron™	Sterile Non-Absorbable Poly(Ethylene Terephthalate) Surgical Suture
	MERICRON XL™ P	Sterile Non-Absorbable Poly(Ethylene Terephthalate) Surgical Suture with PTFE Pledget
(2) Non-Absorbable, Monofilament Polyamide Surgical Suture	FILAMIDE™	Sterile Non-Absorbable Polyamide Surgical Suture
	Aspiron™	Sterile Non-Absorbable Polyamide Surgical Suture
(3) Non-Absorbable, Monofilament Polypropylene Surgical Suture	FILAPROP™ P	Sterile Non-Absorbable Polypropylene Surgical Suture with PTFE Pledget
(4) Non- Absorbable, Braided Silk Surgical Suture	FILASILK™ REEL	Non-Sterile Non-Absorbable Silk Surgical Suture
(5) Non-Absorbable, Monofilament Stainless Steel Surgical Suture	MERISTEEL™	Sterile Non-Absorbable Stainless Steel Surgical Suture

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

EC Certificate
Full Quality Assurance System

Certificate No.:
245506-2017-CE-IND-NA-PS Rev. 2.0

Project No.:
PRJC-499089-2014-MSL-IND

Valid Until:
27 May 2024

This is to certify that the quality system of:

Meril Endo Surgery Pvt Ltd

Third Floor, E1- E3, Meril Park, Survey No 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, Gujarat, India - 396191

For design, production and final product inspection/testing of:

Sterile / non - sterile surgical sutures with and without needle

Has been assessed with respect to:

The conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 16 July 2019

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Cathrine Wisbech

Cathrine Wisbech

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.:
245506-2017-CE-IND-NA-PS Rev. 2.0

Project No.:
PRJC-499089-2014-MSL-IND

Valid Until:
27 May 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Supersedes DNVGL (NB 0434) Certificate no: 151561-2014-CE-IND-NA Rev 3.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-11-15
1.0	Remove of Polypropylene Mesh	2018-01-08
2.0	**Recertification and reduction in scope**	2019-07-16

Products covered by this Certificate:

Product Description	Product Name	Class
Absorbable Sutures	• Megasorb™ / Aspiron™ Polyglycolic acid Braided coated Polyglycolic acid suture • Mitsu™ / Aspiron™ Polyglactin 910 and Mitsu FST™ / Aspiron™ Polyglactin 910 FST. Braided coated Poly (glycolide/l-lactide) suture • Filaxyn™ / Aspiron™ Polydioxanone suture. Monofilament Poly (p-dioxanone) suture • Filapron™ / Aspiron™ Polyglecaprone 25 suture. Monofilament poly (glycolide-co-caprolactone) suture	III*
Non-Absorbable Sutures	• Filaprop™ / Aspiron™ Polypropylene Blue Monofilament Polypropylene Suture	III**

EC Certificate
Full Quality Assurance System

Certificate No.: **245506-2017-CE-IND-NA-PS Rev. 2.0**

Project No.: **PRJC-499089-2014-MSL-IND**

Valid Until: **27 May 2024**

*Design assessment is covered by a separate EC-Design Examination Certificate No.: 245507-2017-CE-IND-NA-PS Rev. 2
**Design assessment is covered by a separate EC-Design Examination Certificate No.: 245508-2017-CE-IND-NA-PS Rev. 2

Sites covered by this certificate

Site Name	Address
Meril Endo Surgery Pvt Ltd	Third Floor, E1- E3, Meril Park, Survey No 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, Gujarat, India - 396191

EU Representative

OBELIS S.A

Bd. Général Wahis, 53, 1030 Brussels, Belgium. Tel: +32.2.732.59.54. Fax: +32.2.732.60.03

E-mail: **mail@obelis.net**, **www.obelis.net**

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
245506-2017-CE-IND-NA-PS Rev. 2.0	**PRJC-499089-2014-MSL-IND**	**27 May 2024**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 105557 0001 Rev. 00

Holder of Certificate:

Meril Endo Surgery Pvt. Ltd.
Third floor, E1- E3, Meril Park
Survey No 135/2/B & 174/2, Muktanand Marg, Chala
396191 Vapi, Gujarat
INDIA

Facility(ies):

Meril Endo Surgery Pvt. Ltd.
Third floor, E1- E3, Meril Park , Survey No 135/2/B & 174/2, Muktanand Marg, Chala, 396191 Vapi, Gujarat, INDIA

Meril Endo Surgery Pvt. Ltd
Type A-2, Shed No. 11, Survey No. 725/P, Phase – I, GIDC, 396195 Vapi, Gujarat, INDIA

Meril Endo Surgery Pvt. Ltd
Plot No 688/10 & 11, Siddivinayak Industrial Estate, Somnath Road, 396210 Daman, INDIA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate:

Design, Development, Production, Testing, Storage, Sales and Distribution of Sterile / Non-sterile Endo Surgical Products e.g., Bulk and Finished Surgical Sutures, Polytetrafluroethylene Pledgets, Sutures with Polytetrafluroethylene Pledgets, Contraceptive Devices, Surgical Meshes, Mesh Fixation Devices, Bone Wax, Umbilical Cotton Tape, Surgical Kits, Surgical Staplers and Staples, Tourniquet Devices, Disposable Endoscopic Trocars, Ligating Clips, Surgical Haemostats, Skin Adhesives, Surgical Adhesives, Sealants & Surgical Needles"

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: IND2019074
Valid from: 2020-03-30
Valid until: 2023-03-29

Date, 2020-03-30

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany