ORDIN DE PLATA NR.: 596 TIP.DOC. 1

DATA EMITERII:18 februarie 2021

PLATITI: 3700-00 LEI: Trei Mii Sapte Sute lei 00 ban
i

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

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

CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R) Institultul de Medicina Urgenta IMSP
CONTUL DE PLATI/CODUL IBAN
MD55VI022510300000002MDL
CODUL FISCAL :1003600152606 /

PRESTATORUL BENEFICIAR
B.C."VICTORIABANK"S.A.

CODUL BANCII:
:VICBMD2X :

DESTINATIA PLATII:Pentru garantia pentru: oferta la procedura de achizi?ie public:
a nr. ocds-b3wdp1-MD-1612167807161 din 2:
2.02.2021

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:18/02/2021
DATA EXECUTARII:

SEMNATURILE
EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb:

DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSq:

SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4:

DTIxMDEyODExMzgwNVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRA:
gYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkxOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv

(semnatura electronica)

L.S.

CONDUCATOR:

(semnatura manuala)

CONTABIL-SEF:

(semnatura manuala)

SEMNATURA PRESTATORUL

L.S.

Digitally signed by Poiata Vitalie
Date: 2021.02.19 13:24:55 EET
Reason: MoldSign Signature
Location: Moldova

MOTIVUL REFUZULUI

L.S.

# 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 MD95ML0000000002251429243**.

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

**„CAMERA ÎNREGISTRĂRII DE STAT" Î.S.**
**Secția fonduri speciale și informații curente**

# EXTRAS
## din Registrul de stat al persoanelor juridice

nr. **14419** din **11.07.2016**

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: **1010600028048.**
Data înregistrării de stat: **12.08.2010.**
Sediul: **MD-2001, str. Albișoara, 16/1, ap.(of.) 7, mun. Chișinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
**1 Activitatea farmaceutică;**
**2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
**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,**
Asociați:
**1. POIATA VITALIE , IDNP 0983103892591**
**cota 1803.60 lei, ce constituie 33,4 %**
**2. NASEDCHIN ALEXANDR , IDNP 2002001070747**
**cota 1798.20 lei, ce constituie 33,3 %**
**3. KOJEVNIKOV DMITRII , IDNP 0972305012362**
**cota 1798.20 lei, ce constituie 33,3 %.**

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: 11.07.2016.

Specialist principal **Lazari Aliona**
tel. 022-266-252

A A 7 * E A * 0 3 7 0 4 3 1 E A

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. | Alexandru Nasedchin | 2002001070747 |
| 3. | Dmitrii Kojevnikov | 0972305012362 |

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

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

# AT Tasarım İnceleme Belgesi

## 93/42/AT Tıbbi Cihaz Yönetmeliği, Ek II (4)

| | | |
|---|---|---|
| **Onaylanmış Kuruluş** | : | TÜRK STANDARDLARI ENSTİTÜSÜ (TSE) - NECATİBEY CAD. NO:112 BAKANLIKLAR ANKARA TÜRKİYE (NB 1783) |
| **Firma Adı** | : | MERIL ENDO SURGERY PVT. LTD. |
| **Firma Adresi** | : | THIRD FLOOR, E1-E3, MERIL PARK, SURVEY NO 135/B & 174/2, MUKTANAND MARG, CHALA, VAPI, GUJARAT, HİNDİSTAN |
| **Üretim Yeri** | : | THIRD FLOOR, E1-E3, MERIL PARK, SURVEY NO 135/B & 174/2, MUKTANAND MARG, CHALA, VAPI, GUJARAT, HİNDİSTAN |
| **Kapsam** | : | MERIZELLE™ EMİLEBİLİR CERRAHİ HEMOSTAT OXİDE REJENERE SELÜLOZ (STERİL) |
| **GMDN Kodu** | : | 38771 |
| **Sınıflandırma Kuralı** | : | Kural 8, Sınıf III |
| **İnceleme Rapor Numarası** | : | 1379-MDD-085/2019-01 |
| **İlk Belge Veriliş Tarihi** | : | 15.12.2017 |
| **Belge Geçerlilik Tarihi** | : | 15.12.2022 |
| **Tam Kalite Güvence Belgesi Numarası** | : | 1783-MDD-071 |

93/42/AT-Tıbbi Cihaz Yönetmeliği Ek-II Bölüm 4 gereklerine göre incelenmiş ve belgelendirilmiştir. Bu belge ekleriyle birlikte geçerlidir. Ekleriyle birlikte 2 sayfadır. Yukarıda belirtilen kapsamda bulunan ürünlerin piyasaya arzı için Tam Kalite Güvence (Ek II Bölüm 4 Hariç) belgesinin de olması gerekmektedir. Onaylanmış Kuruluş Tıbbi Cihaz Yönetmeliği'nin Ek II, Bölüm 5'e istinaden gerekli gözetimleri yapma hakkına sahiptir.

## Belge No: 1783- MDD-072

TÜRK STANDARTLARI ENSTİTÜSÜ DİREKTİFLER MÜDÜRLÜĞÜ DIRECTORATE OF DIRECTIVE TURKISH STANDARDS INSTITUTION 1923

**Sezai DOĞAN**

**Direktifler Müdürü**
**ANKARA Rev 01, 18/03/2020**

Belgenin geçerliliğini TSE'nin web sayfası: "https://basvuruportal.tse.org.tr/Genel/FirmaArama.aspx"den kontrol ediniz

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

# AT Tasarım İnceleme Belgesi Eki

## Belge No: 1783-MDD-072, Rev 01

### Ürün Tipi

MERIZELLE™ EMİLEBİLİR CERRAHİ HEMOSTAT OXİDE REJENERE SELÜLOZ (STERİL)

| Ürün Tipi | Ürün Kodu | Boyutlar |
|---|---|---|
| MERIZELLE™ Standard | ORC S214 | 2' x 14' |
| | ORC S48 | 4' x 8' |
| | ORC S23 | 2' x 3' |
| MERIZELLE™ Fibre | ORC F12 | 1' x 2' |
| | ORC F24 | 2' x 4' |
| | ORC F44 | 4' x 4' |
| MERIZELLE™ Woven | ORC W11 | 1' x 1' |
| | ORC W135 | 1' x 3.5' |
| | ORC W34 | 3' x 4' |

| BELGE TARİHÇESİ | | |
|---|---|---|
| **Tarih** | **Revizyon numarası** | **Revizyon Nedeni** |
| 15.12.2017 | Rev 00 | - |
| 18.03.2020 | Rev 01 | Şablon değişikliği |

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

# EC Design-Examination Certificate

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

| | | |
|---|---|---|
| **Notified Body** | : | TÜRK STANDARDLARI ENSTİTÜSÜ (TSE) - NECATİBEY CAD. NO:112 BAKANLIKLAR ANKARA TURKEY (NB 1783) |
| **Company Name** | : | MERIL ENDO SURGERY PVT. LTD. |
| **Company Address** | : | THIRD FLOOR, E1-E3, MERIL PARK, SURVEY NO 135/B & 174/2, MUKTANAND MARG, CHALA, VAPI, GUJARAT, INDIA |
| **Manufacturing Site** | : | THIRD FLOOR, E1-E3, MERIL PARK, SURVEY NO 135/B & 174/2, MUKTANAND MARG, CHALA, VAPI, GUJARAT, INDIA |
| **Scope** | : | MERIZELLE™ ABSORBABLE SURGICAL HEMOSTAT OXIDIZED REGENERATED CELLULOSE (STERILE) |
| **GMDN Code** | : | 38771 |
| **Classification Rule** | : | Rule 8, Class III |
| **Inspection Report Number** | : | 1379-MDD-085/2019-01 |
| **First Issue Date** | : | 15.12.2017 |
| **Validity Date** | : | 15.12.2022 |
| **Full Quality Assurance Certificate Number** | : | 1783-MDD-071 |

Above scope has been examined and certified according to the requirements of 93/42 / EC - Medical Device Directive Annex-II Section 4. This certificate is valid with its annexes. It is totally 2 pages, including this page. The products included in the scope mentioned above must also have a certificate of Full Quality Assurance (Annex II excluding Section 4). The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex II Section 5.

# Certificate No: 1783- MDD-072

**Sezai DOĞAN**

**Director of Directives**
**ANKARA Rev 01, 18/03/2020**

TÜRK STANDARTLARI ENSTİTÜSÜ DİREKTİFLER MÜDÜRLÜĞÜ 1783 DIRECTORATE OF DIRECTIVE TURKISH STANDARDS INSTITUTION

Please check the validity of certificate from TSE's web page "https://basvuruportal.tse.org.tr/Genel/FirmaArama.aspx?ref=en#open"

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

# EC Design Examination Certificate Annex

## Certificate No: 1783-MDD-072, Rev 01

### Product Type

MERIZELLE™ ABSORBABLE SURGICAL HEMOSTAT OXIDIZED REGENERATED CELLULOSE (STERILE)

| Product Type | Product Code | Sizes |
|---|---|---|
| MERIZELLE™ Standard | ORC S214 | 2' x 14' |
| | ORC S48 | 4' x 8' |
| | ORC S23 | 2' x 3' |
| MERIZELLE™ Fibre | ORC F12 | 1' x 2' |
| | ORC F24 | 2' x 4' |
| | ORC F44 | 4' x 4' |
| MERIZELLE™ Woven | ORC W11 | 1' x 1' |
| | ORC W135 | 1' x 3.5' |
| | ORC W34 | 3' x 4' |

| CERTIFICATE HISTORY | | |
|---|---|---|
| **Date** | **Revision Number** | **Reason of Revision** |
| 15.12.2017 | Rev 00 | - |
| 18.03.2020 | Rev 01 | Template change |

TÜRK STANDARTLARI ENSTİTÜSÜ * DİREKTİFLER MÜDÜRLÜĞÜ * DIRECTORATE OF DIRECTIVE * TURKISH STANDARDS INSTITUTION * 1783

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

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## 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.

SZUTEST

# EC DESIGN EXAMINATION CERTIFICATE

**According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices**

**Certificate Number: 2195-MED-1929401-D01**

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

**Model(s):**

| | |
|---|---|
| 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 |

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

Issued by Szutest, Notified Body 2195, this document certifies that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive.
The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

***This EC Design Examination 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

# EC DESIGN EXAMINATION CERTIFICATE

**According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices**

**Certificate Number: 2195-MED-1929401-D02**

**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):** **Non-Absorbable, Monofilament Polyamide Surgical Suture**

**Model(s):**

| | |
|---|---|
| FILAMIDE™ | Sterile Non-Absorbable Polyamide Surgical Suture |
| Aspiron™ | Sterile Non-Absorbable Polyamide Surgical Suture |

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

Issued by Szutest, Notified Body 2195, this document certifies that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive.
The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

***This EC Design Examination certificate is valid till 2024-05-26.***

Issue Date: 2019-10-21

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

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

# EC DESIGN EXAMINATION CERTIFICATE

**According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices**

**Certificate Number: 2195-MED-1929401-D03**

| | |
|---|---|
| **Manufacturer:** | **MERIL ENDO SURGERY PVT. LTD.**<br>Third Floor, E1-E3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi – 396 191, Gujarat, INDIA |
| **Product(s):** | **Non-Absorbable, Monofilament Polypropylene Surgical Suture** |
| **Model(s):** | FILAPROP™ P Sterile Non-Absorbable Polypropylene Surgical Suture with PTFE Pledget |
| **Reference Report No:** | MM0755-P001-R01, MM0755-P001-R02 |

Issued by Szutest, Notified Body 2195, this document certifies that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive.

The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

***This EC Design Examination certificate is valid till 2024-05-26.***

Issue Date: 2019-10-21

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY

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

# EC DESIGN EXAMINATION CERTIFICATE

**According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices**

**Certificate Number: 2195-MED-1929401-D04**

| | |
|---|---|
| **Manufacturer:** | **MERIL ENDO SURGERY PVT. LTD.**<br>Third Floor, E1-E3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi – 396 191, Gujarat, INDIA |
| **Product(s):** | **Non- Absorbable, Braided Coated Silk Surgical Suture** |
| **Model(s):** | FILASILK™ REEL Non-Sterile Non-Absorbable Silk Surgical Suture |
| **Reference Report No:** | MM0755-P001-R01, MM0755-P001-R02 |

Issued by Szutest, Notified Body 2195, this document certifies that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive.

The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

***This EC Design Examination 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

# 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<br>• Mitsu™ / Aspiron™ Polyglactin 910 and Mitsu FST™ / Aspiron™ Polyglactin 910 FST. Braided coated Poly (glycolide/l-lactide) suture<br>• Filaxyn™ / Aspiron™ Polydioxanone suture. Monofilament Poly (p-dioxanone) suture<br>• 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.:
**245506-2017-CE-IND-NA-PS Rev. 2.0**

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

Valid Until:
**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

# EC Design Examination Certificate

Certificate No.:
**245507-2017-CE-IND-NA-PS Rev. 2.0**

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

Valid Until:
**27 May 2024**

This is to certify that:

## Sutures – Absorbable

Manufactured by:

## 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
Has been assessed with respect to:

## Examination of the design of the product as described in Annex II section 4 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**

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 Design Examination Certificate

Certificate No.:
**245507-2017-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: 153230-2014-CE-IND-NA-D rev 2.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460) | 2017-11-15 |
| 1.0 | Editorial Changes | 2018-01-08 |
| 2.0 | **Recertification and reduction in scope** | 2019-07-16 |

Products covered by this Certificate:

| **Type of medical device and identification no.:** | **Medical Device Class:** | **GMDN code:** |
|---|---|---|
| Sutures – Absorbable | III | |

**Short description of the Medical Device:**

The absorbable surgical sutures are sterile, flexible strand prepared from synthetic polymers. These Sutures may either be in monofilament or multifilament form. They are capable of being absorbed by living mammalian tissue, but may be treated to modify its resistance to absorption. They are available dyed / undyed, needled (attached to standard stainless steel needles of varying types and sizes) / non needled and in a broad range of suture sizes and lengths. These sutures comply with the ‘Sterile Synthetic Absorbable suture’ requirements as per the United States Pharmacopoeia (U.S.P.) and European Pharmacopoeia (E.P.). However, they may be slightly oversize in diameter to U.S.P. requirement for some suture sizes.

Types of Absorbable Sutures:

i. **Polyglycolic Acid Suture (MEGASORB™/ASPIRON™ POLY GLYCOLIC ACID)**

Braided Polyglycolic Acid sutures are synthetic, sterile surgical suture coated with polycaprolactone and calcium stearate.

**MEGASORB™/ASPIRON™ POLY GLYCOLIC ACID**

MEGASORB™/ ASPIRON™ POLY GLYCOLIC ACID sutures are either undyed or dyed by adding D and C Violet No. 2. These sutures are intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery. Significant tensile strength i.e 70% - 80% of the original is retained until initil 14 days and 50% of the original is retained until initial 21 days.There is a subsequent loss between four to five weeks post implantation.

Complete absorption of MEGASORB suture usually takes place between 60 and 90 days.

ii. **Poly (glycolide l-lactide) suture (MITSU™ / ASPIRON™ POLYGLACTIN and MITSU FST™ / ASPIRON™ POLYGLACTIN FST)**

Braided coated synthetic absorbable sterile poly(glycolide/l-lactide) surgical suture. It is composed of a copolymer made from 90% glycolide and 10% L-lactide. MITSU sutures are coated with a mixture containing equal parts of copolymer of glycolide and lactide and calcium stearate. For MITSU FST™ / ASPIRON™ POLYGLACTIN FST, the rapid loss of strength is achieved by using polymer material with lower molecular weight than that of regular MITSU suture.

**MITSU™ / ASPIRON™ POLYGLACTIN**

These sutures are either undyed or dyed using D and C violet No. 2. These sutures are intended for use in general soft tissue approximation and/or ligation. MITSU can be used in ophthalmic surgery, and peripheral nerve anastomosis The safety and effectiveness of MITSU sutures in microsurgery and cardiovascular have not been established. For these sutures, Significant tensile strength i.e 75% of the original is retained until initial 14 days, 40% - 55% of the original is retained until initial 21 Days (6-0 and larger) & (7-0 and smaller) and 24% of the original is retained until initial 28 Days (6-0 and larger). There is a subsequent loss between four to five weeks post implantation. Complete absorption of MITSU suture usually takes place between 56 to 70 days..

**MITSU FST™ / ASPIRON™ POLYGLACTIN FST**

These sutures are used where only short term wound support is required and also where the rapid absorption of the suture is desirable. The rapid absorption profile is particularly useful for applications such as skin closure including episiotomy repair, paediatric surgery, closure of oral mucosa and also in ophthalmic surgery for conjunctivas sutures. Significant tensile strength i.e. 50% of the original is retained until initial 5 days. However, by approximately 10-14 days post implantation, the original tensile strength is completely lost. Complete absorption of MITSU FST suture usually takes place by 42 days.

**iii. Polydioxanone Suture (FILAXYN™/ ASPIRON™ POLYDIOXANONE)**

Polydioxanone Sutures are sterile, synthetic, monofilament suture composed of Poly (p-dioxanone). These sutures are undyed or dyed with D and C Violet No.2.

**FILAXYN™/ ASPIRON™ POLYDIOXANONE**

These sutures are intended for use in general soft tissue approximation including use in ophthalmic surgery. These sutures are particularly useful where an absorbable suture with prolonged wound support (up to 42 days) is required. Significant tensile strength i.e 75% of the original is retained until initial 14 days (4-0 & smaller), 78% of the original is retained until initial 14 days (3-0 & larger), 66% of the original is retained until initial 28 days (4-0 & smaller) and 69% of the original is retained until initial 28 days (3-0 & larger). 53% of the original is retained until initial 42 days (4-0 & smaller) and 57% of the original is retained until initial 42 days (3-0 & larger). There is a subsequent minimal absorption until about 90 post implantation day and complete absorption usually takes place between 180-220 days.

**iv. Poly (glycolide-co-caprolactone) suture (FILAPRON™/ ASPIRON™ POLYGLECAPRONE)**

These sutures are sterile, synthetic, monofilament sutures composed of poly (glycolide-co-caprolactone). poly (glycolide-co-caprolactone) sutures are either undyed or dyed using D and C violet No. 2.

# EC Design Examination Certificate

Certificate No.:
**245507-2017-CE-IND-NA-PS Rev. 2.0**

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

Valid Until:
**27 May 2024**

**FILAPRON™/ ASPIRON™ POLYGLECAPRONE**

Poly (glycolide-co-caprolactone) sutures are intended for use in general soft tissue approximation and/or ligation where an absorbable material is indicated. In dyed FILAPRON suture, significant tensile strength i.e 68% of the original is retained until initial 7 days and 41% of the original is retained until initial14 days. In undyed FILAPRON suture, significant tensile strength, i.e.: 76% of the original is retained until initial 7 days and 38% of original is retained until initial 14 days.There is a subsequent loss 28 days post implantation. Complete absorption of this suture usually takes place between 90 to 120 days.

# EC Design Examination Certificate

| Certificate No.: | Project No.: | Valid Until: |
|---|---|---|
| **245507-2017-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 inform Presafe of any intended change of the products detailed above and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

## Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

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

# EC Design Examination Certificate

Certificate No.:
**245508-2017-CE-IND-NA-PS Rev. 2.0**

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

Valid Until:
**27 May 2024**

This is to certify that:

## Sutures Non-absorbable

Manufactured by:

## 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

Has been assessed with respect to:

## Examination of the design of the product as described in Annex II section 4 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**

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# EC Design Examination Certificate

Certificate No.:
**245508-2017-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: 153231-2014-CE-IND-NA-D rev 3.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460) | 2017-11-15 |
| 1.0 | **Editorial Changes** | 2018-01-08 |
| 2.0 | **Recertification and reduction in scope** | 2019-07-16 |

Products covered by this Certificate:

| **Type of medical device and identification no.:** | **Medical Device Class:** | **GMDN code:** |
|---|---|---|
| Sutures-Non absorbable | III | |

# EC Design Examination Certificate

Certificate No.:
**245508-2017-CE-IND-NA-PS Rev. 2.0**

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

Valid Until:
**27 May 2024**

**Short description of the Medical Device:**

Non-absorbable surgical sutures are flexible strand of material that are suitably resistant to the action of living mammalian tissue hence are not absorbed by the tissue. They may either be in monofilament or multifilament form. They are available dyed / undyed, needled (attached to standard stainless steel needles of varying types and sizes) / non needled and in a broad range of suture sizes and lengths. These sutures comply with the 'Non absorbable suture' requirements as per the United States Pharmacopoeia (U.S.P.) and European Pharmacopoeia (E.P.). However, they may be slightly oversize in diameter to U.S.P. requirement for some suture sizes.

Types of Non - Absorbable Sutures:

i. **Polypropylene Suture (FILAPROP™/ ASPIRON™ POLYPROPYLENE BLUE)**

Polypropylene sutures are monofilament, synthetic, sterile surgical suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. These sutures are available undyed or dyed with phthalocyanine blue.

Polypropylene suture are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

# EC Design Examination Certificate

| Certificate No.: | Project No.: | Valid Until: |
|---|---|---|
| **245508-2017-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 inform Presafe of any intended change of the products detailed above and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

## Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

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