Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 1 din 06.10.2023

Solicitantul SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău
(adresa)
Tel./Fax: .+373-22-808517, +373-22-808719, fax +373-22-808519, e-mail biosistem.mld@gmail.com; info@biosistem-mld.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- SUTURĂ CHIRURGICALĂ

Se anexează următoarele acte:
Declaraţie pe proprie răspundere
CE certificate
Declaratie de conformitate
Scrisoare de imputernicire

Digitally signed by Poiata Vitalie
Date: 2023.10.06 15:00:22 EEST
Reason: MoldSign Signature
Location: Moldova

Data 06.10.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- SUTURĂ CHIRURGICALĂ

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 06.10.2023

21st Dec 2022

MANUFACTURERS AUTHORIZATION

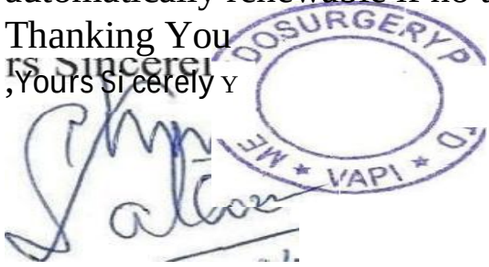
To whom so ever it may concern

This is to certify and confirm that we M/s Neril Endo Surgery Pvt Ltd situated at Third Floor, E1-E3, Meril Park, Survey No 135/b & 174/2, Muktanand Marg, Chala, Vapi 396191, Gujarat, India, hereby confirms that **Biosistem Mld SRL** is our Official business partner with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, is been authorized by Meril Endo Surgery Pvt Ltd to carry out the registration for all the Endo Surgery products manufactured by us.

This authorization is valid for 2years from the date of issuance and automatically renewable if no termination letter is issued.

Thanking You

,Yours Si cerely Y



Dhananjay Data'r'*
AGA: Quality Control

Meril Endo Surgery Private Limited
Survey No. 135/2/B, Nr. G. M. Bilakhia Stadium, Muktanand Marg, Chala, Vapi - 396191, Gujarat,
T: +91 260 3052100 F: *91 260 3052125

DECLARATION OF CONFORMITY

Manufacturer Name:	Meril Endo Surgery Pvt. Ltd.
Manufacturer Address:	Third Floor, E1-E3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat India.
Manufacturer SRN:	IN –MF -000010999
Authorized Representative Name:	Obelis S.A.
Authorized Representative Address:	Bd. Général Wahis 53, 1030 Brussels, Belgium Tel: +32. 2. 732. 59. 54 Fax: +32. 2. 732. 60. 03 E-mail: mail@obelis.net
Authorized Representative SRN:	BE-AR-000000106
Product Name:	**Meristeel™**- Non-absorbable Stainless Steel Surgical Suture U.S.P
Product Details:	**EMDN No:** H0102020101 **GMDN Code:** 15971 **Basic UDI-DI** 89042552MES_STC13Z8 **Product Code:** AS Per Annex I **Batch No:** XXXXX **Mfg. Date:** YYYY-MM **Expiry Date:** YYYY-MM **Intended Use:** MERISTEEL™ sutures are intended for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.

We, the manufacturer, hereby declare under sole responsibility that the above medical device conform to the applicable provisions of EC Directive 93/42/EEC Annex II, as amended by 2007/47/EEC concerning medical devices. All supporting documentation is retained under the premises of the manufacturer.

List of Standards Applied:	EU MDR 2017/745:2017, EN ISO 13485:2016, EN ISO 14971:2019, ISO/TR 24971:2020, EN 62366-1:2015, ISO/TR 62366-2:2016, USP 45 NF 40, EP 10th Edition, EN ISO 14630:2012, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-11:2018, EN ISO 10993-18:2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11137-1:2019, EN ISO 11137-2:2015, EN ISO 11737-1:2021, EN ISO 11373-2:2020, EN 556-1:2006, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 14644-3:2019, EN ISO 20417:2021, EN ISO 15223-1:2021, ASTM F 1980:2016, ASTM F 899:2020, ASTM F 138:2019, ASTM F 3014:2014, ASTM F 88:2021, ASTM F1886/F1886M:2016, ASTM D 1929:2015, ASTM D4169:2022, ASTM D999:2015, ASTM D5276:2019, MDCG 2020-6:2020, MDCG 2020-7:2020, MDCG 2020-8:2020, MDCG 2019-9:2022, MDCG 2021-24:2021, MDCG 2020-3:2020, MDCG 2022-21:2022, MDCG MEDDEV 2.4/1; Rev.9, MEDDEV 2.7.1; Rev.4, MEDDEV 2.12/1; Rev.8, MEDDEV 2.12/2; Rev.2.
Device Classification:	Class IIb as per Directive for medical devices 93/42/EEC Section 2.4, Rule 8.
Conformity Assessment Route:	Directive for medical devices 93/42/EEC Annex II, excluding section 4.
Quality System:	EN ISO 13485:2016/DIN EN-ISO 13485:2016 (Certificate No.: Q5 105557, 0003, Valid till: 29 March 2026).

Notifying Body Name:	Szutest Uygunluk Değerlendirme A.Ş.	
Notifying Body Address:	Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul Tel : +90 216 469 46 66	
Notifying Body No:	2195	
Signature:		
Name:	Umesh Sharma	
Designation	GM – QA/RA	
Date/Location:	**Date:** 11-05-2023	**Location:** Vapi, India

Annexure I

Sr. No.	Product Code	Brand Name	USP Size	Description
1.	STC050945	Meristeel	5	STEEL WIRE 5 X 75-55MM HC RC(75X2)
2.	STC070624	Meristeel	7	STEEL WIRE 7 X 75-50MM HC RC (75X2)
3.	STC653	Meristeel	5	STEEL WIRE 5 X 45-48MM HC CT (45X4)
4.	STC654	Meristeel	6	STEEL WIRE 6 X 45-48MM HC CT (45X4)
5.	STC9455	Meristeel	5	STEEL WIRE 5 X 45-44MM HC RB BP (45X4)
6.	STC9456	Meristeel	6	STEEL WIRE 6 X 45-44MM HC RB BP (45X4)
7.	STC9494	Meristeel	6	STEEL WIRE 6 X 75-44MM HC RB BP (75X2)
8.	STC9495	Meristeel	5	STEEL WIRE 5 X 75-44MM HC RB BP (75X2)
9.	STC9497	Meristeel	5	STEEL WIRE 5 X 45-48MM HC RB BP (45X4)
10.	STC9653	Meristeel	5	STEEL WIRE 5 X 45-48MM HC CT (45X1)
11.	STC9654	Meristeel	6	STEEL WIRE 6 X 45-48MM HC CT (45X1)
12.	STC9654CU	Meristeel	6	STEEL WIRE 6 X 45-48MM CU CT (45X6)
13.	STC05650	Meristeel	5	STEEL WIRE 5 X 45-48MM HC TC (45X4)
14.	STC650	Meristeel	2	STEEL WIRE 2 X 45-40MM HC TC (45X4)
15.	STC660	Meristeel	1	STEEL WIRE 1 X 45-40MM HC TC (45X4)
16.	STC661	Meristeel	1	STEEL WIRE 1 X 45-40MM HC BP (45X4)
17.	STC662	Meristeel	2	STEEL WIRE 2 X 45-40MM HC BP (45X4)
18.	STC664	Meristeel	4	STEEL WIRE 4 X 45-40MM HC BP (45X4)
19.	STC700	Meristeel	6	SS WIRE 6X45-48 HCCT(45X1)44 HCBP(45X3)
20.	STC600	Meristeel	0	STEEL WIRE 0 X 45-17MM HC BP (45X2)
21.	STC652	Meristeel	4	STEEL WIRE 4 X 45-48MM HC CT (45X4)
22.	STC9435	Meristeel	1	STEEL WIRE 1 X 45-35MM HC RB BLUNT
23.	STC9540	Meristeel	2	STEEL WIRE 2 X 45-40MM HC RB
24.	STC9656	Meristeel	6	STEEL WIRE 6 X 75-65MM HC RB BLUNT
25.	STC040651	Meristeel	4	STEEL WIRE 4 X 75-48MM HC TC (75X2)
26.	STC905	Meristeel	6	STEEL WIRE 6 X 75-48MM HC CT (75X1)
27.	STC902	Meristeel	6	STEEL WIRE 6 X 75-48MM HC CT (75X2)
28.	STC654RB	Meristeel	6	SS WIRE 6X45-48 HCCT(45X1)48 HCBP(45X3)
29.	STC655	Meristeel	7	STEEL WIRE 7 X 45-48MM HC CT (45X4)

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.