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

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 2 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 15:00:15 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

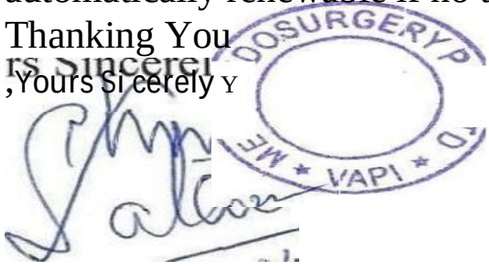
To whom so ever it may concern

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

Meril
Endo Surgery

DECLARATION OF CONFORMITY

Document No. ME/DOC/PGC/01
Rev-10

Manufacturer's Name:	**MERIL ENDO SURGERY PVT. LTD.**
Manufacturer's Address:	Third Floor, E1-E3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat India.
Product Name:	**FILAPRON™ -** Absorbable Poly (Glycolide-Co-Caprolactone) Surgical Suture U.S.P.
Product Details:	Product code: _____ Batch No.: _____ Mfg. Date : _____ Expiry Date: _____

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.

List of Standard Applied:	EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2019, EN ISO 11135-1:2007, EN ISO 10993-1:2020, EN ISO 10993-3:2014, EN ISO 10993-4:2017, EN ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-7:2008, ISO 10993-10:2013, EN ISO 10993-11:2018, EN ISO 11607-1 :2020, EN 20417:2021, ASTM F 1980:2016, MEDDEV 2.5.5; Rev. 3, MEDDEV 2.4/1; Rev.9, MEDDEV 2.7.1; Rev.4, MEDDEV 2.12/1; Rev.8, MEDDEV 2.12/2; Rev.2, United States Pharmacopoeia - 43 -National Forrnulary-38, EUROPEAN PHARMACOPOEIA-10 thEdition.
Conformity Assessment Route:	Directive for medical devices 93/42/EEC, Annex II, including section 4
Device Classification:	Class III as per Directive for medical devices 93/42/EEC Section 2.4, Rule 8.
Authorized 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
Quality System:	EN ISO 13485:2016/DIN EN -ISO 13485:2016 (Certificate No.: Q5 105557 0003 Rev.01 , Valid till: 29 March 2026).
CE Certificate:	CE Certificate no.: 245506-2017-CE-IND-NA-PS, Valid till: 27 May 2024.
Notifying Body:	DNV Product Assurance AS, Veritasveien 3, N-1363, Hovik, Norway. www.presafe.com
Notifying Body No.:	2460
Signature:	
Name:	UMESH SHARMA
Designation:	GM – QA
Date/Location:	**Date**:24-04-2023 **Location**: Vapi, Gujarat, INDIA

EC CERTIFICATE
Full Quality Assurance System

Certificate no.:
245506-2017-CE-IND-NA-PS

Initial certification date:
15 November 2017

Valid Until:
27 May 2024

This is to certify that the management system of

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

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

Sterile / non - sterile surgical sutures with and without needle

has been assessed and found to comply with respect to:

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

Place and date:
Høvik,19 May 2021

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer

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**	**Issued 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
3.0	Editorial Changes and blockchain information	2021-05-19

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/llactide) suture • Filaxyn™ / Aspiron™ Polydioxanone suture. Monofilament Poly (p-dioxanone) suture • Filapron™ / Aspiron™ Polyglecaprone 25 suture. Monofilament poly (glycolide-cocaprolactone) suture	III*
Non-Absorbable Sutures	• Filaprop™ / Aspiron™ Polypropylene Blue Monofilament Polypropylene Suture	III**

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 245506-2017-CE-IND-NA-PS

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

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

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 the Notified Body of any intended updating of the quality system and the Notified Body 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. Notified Body 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.