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. 7 din 01.10.2023

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:

- MIRUS™ STERILE DISPOSABLE SKIN STAPLER
- MIRUS™ ENDO CUTTER
- MIRUS™ LINEAR CUTTER
- MIRUS™ LINEAR STAPLER
- MONIK™

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

Digitally signed by Poiata Vitalie
Date: 2023.09.29 14:09:03 EEST
Reason: MoldSign Signature
Location: Moldova

Data 01.10.2023 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:

- MIRUS™ STERILE DISPOSABLE SKIN STAPLER
- MIRUS™ ENDO CUTTER
- MIRUS™ LINEAR CUTTER
- MIRUS™ LINEAR STAPLER
- MONIK™

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 01.10.2023

21st Dec 2022

MANUFACTURERS AUTHORIZATION

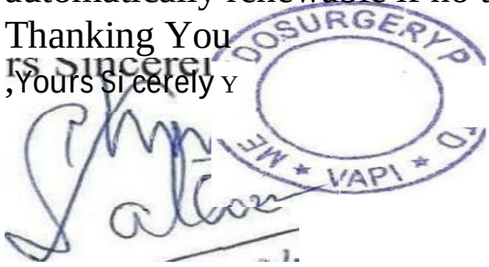
To whom so ever it may concern

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/TCR/01
Rev-03

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:	**MONIK™** - Disposable Endoscopic Trocar
Product Details:	GMDN code: 61425 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. All supporting documentation is retained under premises of the manufacturer.

List of Standard Applied:	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 11135:2014, EN ISO 11137-1:2015 & EN ISO 11137-2:2015, EN ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013,EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 15223-1:2016, EN 1041:2008, ASTM F1980:2016, MEDDEV 2.7/1 Rev.04, MDD/93/42/EEC.
Conformity Assessment Route:	Directive for medical devices 93/42/EEC, Annex II, excluding section 4.
Device Classification:	Class IIa as per Directive for medical devices 93/42/EEC Rule 6
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, 0001, Valid till: 29 March 2023).
CE Certificate:	CE Certificate no: 2195-MED-2012001, Valid till: 26 May 2024.
Notifying Body:	Szutest 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**: 10-08-2020 **Location**: Vapi, Gujarat, INDIA

Meril
Endo Surgery

DECLARATION OF CONFORMITY

Document No. ME/DOC/MEC/01
Rev-04

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-396 191, Gujarat India. Plot. No. 688 / 10 &11 Siddhivinayak Industrial Estate, Somnath Road, Daman – 396210, India.
Product Name:	**MIRUS™ ENDO CUTTER**- Sterile Disposable Endoscopic Linear Cutter
Product Details:	GMDN code: 59871 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. All supporting documentation is retained under premises of the manufacturer.

List of Standard Applied:	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 11137-1:2015 & EN ISO 11137-2:2015, EN ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013,EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 15223-1:2016, EN 1041:2008, ASTM F1980:2016, MEDDEV 2.7/1 Rev.04, MDD/93/42/EEC.
Conformity Assessment Route:	Directive for medical devices 93/42/EEC, Annex II, excluding section 4.
Device Classification:	Class IIa as per Directive for medical devices 93/42/EEC Rule 6. Class B as per Medical Device Rule-2017, India.
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, 0001, Valid till: 29 March 2023).
CE Certificate:	CE Certificate no: 2195-MED-2012001, Valid till: 26 May 2024.
Notifying Body:	Szutest 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**: 10-08-2020 **Location**: Vapi, Gujarat, INDIA

Meril
Endo Surgery

DECLARATION OF CONFORMITY

Document No. ME/DOC/MLC/01
Rev-04

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-396 191, Gujarat India. Plot. No. 688 / 10 &11 Siddhivinayak Industrial Estate, Somnath Road, Daman - 396210 India.
Product Name:	**MIRUS™ LINEAR CUTTER** - Sterile Disposable Linear Cutter
Product Details:	GMDN code: 59870 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. All supporting documentation is retained under premises of the manufacturer.

List of Standard Applied:	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 11135:2014, EN ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-7:2008, EN ISO 10993-10:2013, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 15223-1:2016, EN 1041:2008, ASTM F1980:2016, MEDDEV 2.7/1 Rev.04, MDD/93/42/EEC.
Conformity Assessment Route:	Directive for medical devices 93/42/EEC, Annex II, excluding section 4.
Device Classification:	Class IIa as per Directive for medical devices 93/42/EEC, Rule 6. Class B as per Medical Device Rule-2017, India.
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, 0001, Valid till: 29 March 2023).
CE Certificate:	CE Certificate no: 2195-MED-2012001, Valid till: 26 May 2024.
Notifying Body:	Szutest 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
Date/Location:	**Date**: 10-08-2020 **Location**: Vapi, Gujarat, INDIA

Meril
Endo Surgery

DECLARATION OF CONFORMITY

Document No. ME/DOC/MLS/01
Rev-04

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-396 191, Gujarat India. Plot. No. 688 / 10 &11 Siddhivinayak Industrial Estate, Somnath Road, Daman – 396210, India.
Product Name:	**MIRUS™ LINEAR STAPLER** - Sterile Disposable Linear Stapler
Product Details:	GMDN code: 59873 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. All supporting documentation is retained under premises of the manufacturer.

List of Standard Applied:	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 11137-1:2015 & EN ISO 11137-2:2015, EN ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013,EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 15223-1:2016, EN 1041:2008, ASTM F1980:2016, MEDDEV 2.7/1 Rev.04, MDD/93/42/EEC.
Conformity Assessment Route:	Directive for medical devices 93/42/EEC, Annex II, excluding section 4.
Device Classification:	Class IIa as per Directive for medical devices 93/42/EEC Rule 6. Class B as per Medical Device Rule-2017, India.
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, 0001, Valid till: 29 March 2023).
CE Certificate:	CE Certificate no: 2195-MED-2012001, Valid till: 26 May 2024.
Notifying Body:	Szutest 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
Date/Location:	**Date**: 10-08-2020 **Location**: Vapi, Gujarat, INDIA

Meril
Endo Surgery

DECLARATION OF CONFORMITY

Document No. ME/DOC/MSS/01
Rev-05

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-396 191, Gujarat India. Plot. No. 688 / 10 &11 Siddhivinayak Industrial Estate, Somnath Road, Daman – 396210, India.
Product Name:	**MIRUS™ STERILE DISPOSABLE SKIN STAPLER** - Sterile Disposable Skin Stapler
Product Details:	GMDN code: 35884 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. All supporting documentation is retained under premises of the manufacturer.

List of Standard Applied:	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 11135:2014, EN ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-7:2008, EN ISO 10993-10:2013, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 15223-1:2016, EN 1041:2008, ASTM F138:2013, EN ISO 5832-1:2019, ASTM F1980:2016, MEDDEV 2.7/1 Rev.04, MDD/93/42/EEC.
Conformity Assessment Route:	Directive for medical devices 93/42/EEC, Annex II, excluding section 4.
Device Classification:	Class IIa as per Directive for medical devices 93/42/EEC Rule 7. Class B as per Medical Device Rule, 2017 India.
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, 0001, Valid till: 29 March 2023).
CE Certificate:	CE Certificate no: 2195-MED-2012001, Valid till: 26 May 2024.
Notifying Body:	Szutest 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**: 10-08-2020 **Location**: Vapi, Gujarat, INDIA

SZUTEST

EC CERTIFICATE

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

Full Quality Assurance System

Certificate Number: 2195-MED-2012001

Manufacturer: **MERIL ENDO SURGERY PVT. LTD.**
Head Office & Factory I: Third Floor, E1-E3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi – 396 191, Gujarat, INDIA
Factory II: Plot. No. 688 / 10 &11, Siddhivinayak Industrial Estate, Somnath Road, Daman – 396210, INDIA

Product(s): **Sterile Single Use Endo Mechanical Products**

Model(s):
1. MIRUS™ Endoscopic Linear Cutter and Reloads
2. MIRUS™ Linear Stapler and Reloads
3. MIRUS™ Linear Cutter and Reloads
4. MIRUS™ Circular Stapler
5. MIRUS™ Hemorrhoids Stapler
6. MIRUS™ Disposable Skin Stapler
7. MONIK™ Disposable Endoscopic Trocar

Reference Report No: MM0755-P002-R01, MM0755-P002-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: 2020-04-29

Rukiye BALKAN
Deputy General Manager