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. 13 din 13.10.2023

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:

- Promesa™ BMS Self-Expanding Nitinol Peripheral Stent System

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

Digitally signed by Poiata Vitalie
Date: 2023.10.13 17:24:24 EEST
Reason: MoldSign Signature
Location: Moldova

Data 13.10.2023 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	

Digitally signed by Kojevnikov Dmitrii
Date: 2023.10.13 17:28:51 EEST
Reason: MoldSign Signature
Location: Moldova

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:

- Promesa™ BMS Self-Expanding Nitinol Peripheral Stent System

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 13.10.2023

"To whomever it may concern"

Date: 17th November 2022.

MANUFACTURERS AUTHORIZATION

We, Meril Life Sciences Pvt. Ltd. manufacturer of medical products with principal place of business at Muktanand Marg, Chala, Vapi – 396191, Gujarat, India. hereby confirm that Biosistem mld SRL with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, is authorized by the company Meril Life Sciences Pvt. Ltd, to carry out the State Registration in Republic of Moldova of our products.

This authorization is valid for 1 year from the date of issuance and automatically renewable if no termination letter issued.

For and on behalf of Manufacturer or Producer

Signed: Chhagan Donode

Dated: 17th November 2022.

In the capacity of: Vice President

And duly authorised to sign this Authorisation on behalf of: Meril Life Sciences Pvt. Ltd.

DECLARATION OF CONFORMITY

Manufacturer's Name:	**MERIL LIFE SCIENCES PVT. LTD.**
Manufacturer's Address:	Muktanand Marg, Chala, Vapi - 396191 Gujarat, India.
Product Name:	**Promesa™ BMS Self-Expanding Nitinol Peripheral Stent System**
Product Details:	GMDN Code P 47932 Control No.: DOC/PRB/Rev.11/14/12/2022 Batch No.: _____ Mfg. Date: _____ Batch Size: _____ Expiry Date: _____

Conforms to the applicable national/ international Standards.

1 We declare that our products as listed below, comply with the requirements to Medical device Directive 93/42/EEC as amended by directive 2007/47/EC and this declaration is sole responsibility of company. We also declare that the product listed below has no relation with other directives.

A. **Promesa™ BMS Self-Expanding Nitinol Peripheral Stent System**

2. Company undertakes to manufacture the products as per National/ International Standards and following quality management system as per EN ISO 13485:2016/ ISO 13485:2016.
3. Company authorizes the notified body to carry out necessary inspection and agrees to supply the required information & data/documents from time to time.
4. Company agrees to make available all relevant Documents & Data of the products to the National and competent Authority for a period ending 15 (Fifteen) years after the last product has been manufactured.
5. Company or his authorized representative shall fulfill the obligations imposed by Annex II (Full Quality Assurance system) of Medical Device Directive 93/42/EEC as amended & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.
6. Company undertakes to keep up to date a systematic procedure to review experience gained during post production phase and to implement appropriate means to apply any necessary corrective action taking account of the nature & risk in relation to the product.
7. Company undertakes to notify immediately any malfunction /deterioration of the performance of the device to the appropriate authority and shall recall such devices already placed in the market.
8. Company shall fulfill the obligations imposed by Annex I of Medical Device Directive 93/42/EEC as amended & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.
9. Company declares that **Promesa™ BMS Self-Expanding Nitinol Peripheral Stent System** does not contain any medicinal substance, material of human and animal origin.

List of Standard Applied:	EN ISO 13485: 2016 /A11:2021, EN ISO 14971:2019 / A11:2021, EN ISO 62366-1:2015, EN ISO 15223-1:2021, ISO 20417:2021, 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 (E) Incorporating corrigendum November 2009, EN ISO 10993-11-2018, EN ISO 10993-12-2021, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO-14644-3:2019, EN ISO-14644-4:2001, EN ISO 10555-1: 2013+A1:2017, EN ISO 10555-4:2013, EN ISO 25539-2:2020, EN ISO 11607-1:2020, EN ISO 11607-2 :2020, EN ISO/IEC 17050-1:2010, EN ISO/IEC 17050-2:2004, EN 868-5:2018, EN ISO 11135:2014, EN ISO 11737-1-2018, EN ISO 80369-7:2021, EN ISO 14155:2020, ASTM F 1980 – 2016, MDD 93/42/EEC/1993 , Directive 2007-47-EC, MEDDEV 2.4/1 Rev.9, June 2010, MEDDEV 2.7/1, Rev.4 June 2016 & Appendix 1, ICH Harmonized Tripartite Guidelines Q1A(R2) February 2003, MEDDEV 2.12-1 Rev 8, MEDDEV 2.12/2 Rev 2.
Conformity Assessment Route:	Annex: II. (excluding Section 4) of MDD/93/42/EEC on Medical Devices as amended.
Device Classification:	The stent of Promesa BMS Self-Expanding Nitinol Peripheral Stent System is a sterile, single use, surgically invasive device consisting a stent as long-term use (permanent implant, > 30 days) and the delivery system as transient use (less than 24 hours) as defined in Article 1 of Directive 2001/83/EC. As per MDD/93/42/EEC, 14th June 1993, Annexure IX, Rule 6 and Rule 8 Promesa™ BMS Self-Expanding Nitinol Peripheral Stent System is classified as class IIb Medical Device.
CE Certificate No.:	EC certificate No. 1783-MDD-111, Rev No. 04.
CE Certificate Issue Date:	25 May 2021
CE Certificate Valid till:	26 February 2024
European Authorized Representative:	Obelis s.a., Bd. General Wahis 53, 1030 Brussels, Belgium. Tel: +32. 2. 732. 59. 54, Fax: +32. 2. 732. 60. 03, E-mail: mail@obelis.net
Notifying Body:	Turkish Standards institution (TSE) NecatibeyCad.No.112,06100 Bakanliklar Ankara Country : Turkey Phone:00 903124166499, Fax:00 903124166628,Email:ce@tse.org.tr,Website : www.tse.org.tr
Notifying Body No.:	1783
Signature:	
Name:	Mr. Narendra Patel
Designation:	Head – QA
Date/Location:	**Date**: _____ **Location**: Vapi, Gujarat, INDIA

MERIL LIFE SCIENCES PVT. LTD. VAPI

CE 1783

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

Full Quality Assurance Certificate

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

Notified Body	:	TÜRK STANDARDLARI ENSTİTÜSÜ (TSE) - NECATİBEY CAD. NO:112 BAKANLIKLAR ANKARA TURKEY (NB 1783)
Company Name	:	MERIL LIFE SCIENCES PVT. LTD
Company Address	:	MUKTANAND MARG, CHALA, VAPI-396191. GUJARAT, INDIA
Manufacturing Site	:	MUKTANAND MARG, CHALA, VAPI-396191. GUJARAT, INDIA
Scope	:	SELF EXPANDING NITINOL PERIPHERAL STENT SYSTEM (STERILE)
GMDN Code	:	47932
Classification Rule	:	Rule 8, Class IIB
Inspection Report Number	:	1722-MDD-114/2020-02
First Issue Date	:	26.02.2019
Validity Date	:	26.02.2024

The manufacturer's quality system is inspected in accordance with Annex II of the Medical Device Directive and the quality system meets the requirements of Medical Device Directive Annex II. The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex II Section 5. For Class III products covered by this certificate, a EC Design Examination Certificate issued in accordance with Medical Device Directive Annex II Section 4 is also required.

Certificate No: 1783- MDD-111

TÜRK STANDARDLARI ENSTİTÜSÜ DİREKTİFLER MÜDÜRLÜĞÜ DIRECTORATE OF DIRECTIVE TURKISH STANDARDS INSTITUTION

Fırat HACIOĞLU
Deputy Director of Directives
ANKARA Rev 04, 25/05/2021

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

Full Quality Assurance Certificate Certification History

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

Certificate No: 1783-MDD-111, Rev 04

CERTIFICATE HISTORY		
Date	**Revision Number**	**Reason of Revision**
26.02.2019	Rev 00	-
02.09.2019	Rev 01	Template change
06.03.2020	Rev 02	Design change
20.05.2021	Rev 03	Design change
25.05.2021	Rev 04	Editorial correction

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

Full Quality Assurance Certificate Scope Attachment

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

Certificate No: 1783-MDD-111, Rev 04

Promesa™ BMS Size Matrix (Handle)

(OTW 0.035" 80cm)				
Nominal Stent Length (mm)	Unconstrained stent Diameter (mm)			
	7.00	8.00	9.00	10.00
30	PRB0700030A	PRB0800030A	PRB0900030A	PRB1000030A
40	PRB0700040A	PRB0800040A	PRB0900040A	PRB1000040A
60	PRB0700060A	PRB0800060A	PRB0900060A	PRB1000060A
80	PRB0700080A	PRB0800080A	PRB0900080A	PRB1000080A
100	PRB0700100A	PRB0800100A	PRB0900100A	PRB1000100A
120	PRB0700120A	PRB0800120A	PRB0900120A	PRB1000120A
150	PRB0700150A	PRB0800150A	-	-
180	PRB0700180A	PRB0800180A	-	-

(OTW 0.035" 120cm)						
Nominal Stent Length (mm)	Unconstrained stent Diameter (mm)					
	5.00	6.00	7.00	8.00	9.00	10.00
30	PRB0500030B	PRB0600030B	PRB0700030B	PRB0800030B	PRB0900030B	PRB1000030B
40	PRB0500040B	PRB0600040B	PRB0700040B	PRB0800040B	PRB0900040B	PRB1000040B
60	PRB0500060B	PRB0600060B	PRB0700060B	PRB0800060B	PRB0900060B	PRB1000060B
80	PRB0500080B	PRB0600080B	PRB0700080B	PRB0800080B	PRB0900080B	PRB1000080B
100	PRB0500100B	PRB0600100B	PRB0700100B	PRB0800100B	PRB0900100B	PRB1000100B

120	PRB0500120B	PRB0600120B	PRB0700120B	PRB0800120B	PRB0900120B	PRB1000120B
150	PRB0500150B	PRB0600150B	PRB0700150B	PRB0800150B	-	-
180	PRB0500180B	PRB0600180B	PRB0700180B	PRB0800180B	-	-