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. 12 din 13.10.2023

Solicitantul SRL Biosistem mld, cu sediul str. Albişoara 16/1 of.7, or. Chişinău
(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:

- Myra™ BMS - Balloon Expandable 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 17:24:54 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 17:27:50 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:

- Myra™ BMS - Balloon Expaпdaьle 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.

Meril

DECLARATION OF CONFORMITY

Manufacturer's Name:	**MERIL LIFE SCIENCES PVT. LTD.**
Manufacturer's Address:	Muktanand Marg, Chala, Vapi - 396191 Gujarat, India.
Product Name:	**Myra™ BMS – Balloon Expandable Peripheral Stent System**
Product Details:	GMDN Code P 47932 Control No.: DOC/MYB/Rev.11/23.12.2022 Batch No.: _____ Mfg. Date: _____ Batch Released Quantity: _____ Expiry Date: _____

Conforms to the applicable national and international standards.

1. We declare that our products as listed below, comply to the requirements to Medical device Directive 93/42/EEC as amended by directive 2007/47/EC and this declaration is sole responsibility of company.
   A. **Myra™ BMS – Balloon Expandable 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 and 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.

List of Standard Applied:	MDD/93/42/EEC as amended by Directive 2007/47/EC, EN ISO 13485:2016/AC:2016; A11:2021, ISO 13485:2016, EN ISO 14971:2019/A11:2021, EN ISO 15223-1:2021, ISO 20417:2021, EN ISO 25539-2:2020, EN ISO 10555-1:2013/A1:2017, EN ISO 10993-1:2020, EN ISO 11135:2014/A1:2019, EN ISO 11607-1:2020, EN ISO 11607-2:2020, ASTM F 1980:2016, ICH Q1 A(R2).
Conformity Assessment Route:	Annex: II. of MDD/93/42/EEC on Medical Devices as amended.
Device Classification:	As per MDD/93/42/EEC of 14th June 1993, Annexure IX, Rules 8, **Myra™ BMS – Balloon Expandable Peripheral Stent System** is surgically invasive devices intended for long term use. Hence it is Classified as Class IIb medical device. The product is CE marked.
EC Certificate No.:	10000380498-PA-NA-IND
EC Certificate Issue Date:	06 October 2020
EC Certificate Valid till:	27 May 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:	DNV Product Assurance AS, Veritasveien 1, N-1363 Høvik, Norway Tel: +47 67 57 88 00 www.dnv.com (NB 2460)
Signature:	
Name:	Mr. Narendra Patel
Designation:	Head – QA
Date/Location:	**Date**: 23/12/2022 **Location**: Vapi, Gujarat, INDIA.

MERIL LIFE SCIENCES PVT. LTD. VAPI

CE 2460

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10000380498-PA-NA-IND	PRJC-517914-2015-MSL-IND	27-May-2024

This is to certify that the quality system of:

Meril Life Sciences Private Limited

Muktanand Marg, Chala, Vapi-396191, Gujarat, India

For design, production and final product inspection/testing of:
STERILE PERIPHERAL STENT SYSTEM

Has been assessed with respect to:
THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING 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, 06 October 2020

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Certificate No.:
10000380498-PA-NA-IND

Project No.:
PRJC-517914-2015-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	Certification	06 October 2020

Products covered by this Certificate:

<table>
<tr><th>Product Description</th><th>Product Name</th><th>Class</th></tr>
<tr><td>Myra™ BMS – Balloon Expandable Peripheral Stent System</td><td>Myra™ BMS –Balloon Expandable Peripheral Stent System
<table>
<tr><td colspan="6">Catalogue numbers</td></tr>
<tr><td rowspan="2">Stent Diameter (mm)</td><td colspan="5">Stent Length (mm)</td></tr>
<tr><td>17</td><td>27</td><td>37</td><td>47</td><td>57</td></tr>
<tr><td>5.00</td><td>MYB05017A</td><td>MYB05027A</td><td>MYB05037A</td><td>MYB05047A</td><td>MYB05057A</td></tr>
<tr><td>6.00</td><td>MYB06017A</td><td>MYB06027A</td><td>MYB06037A</td><td>MYB06047A</td><td>MYB06057A</td></tr>
<tr><td>7.00</td><td>MYB07017A</td><td>MYB07027A</td><td>MYB07037A</td><td>MYB07047A</td><td>MYB07057A</td></tr>
<tr><td>8.00</td><td>MYB08017A</td><td>MYB08027A</td><td>MYB08037A</td><td>MYB08047A</td><td>MYB08057A</td></tr>
<tr><td>9.00</td><td>MYB09017A</td><td>MYB09027A</td><td>MYB09037A</td><td>MYB09047A</td><td>MYB09057A</td></tr>
<tr><td>10.00</td><td>MYB10017A</td><td>MYB10027A</td><td>MYB10037A</td><td>MYB10047A</td><td>MYB10057A</td></tr>
<tr><td colspan="6">For usable length 800mm</td></tr>
<tr><td colspan="6">Catalogue numbers</td></tr>
<tr><td rowspan="2">Stent Diameter (mm)</td><td colspan="5">Stent Length (mm)</td></tr>
<tr><td>17</td><td>27</td><td>37</td><td>47</td><td>57</td></tr>
<tr><td>5.00</td><td>MYB05017B</td><td>MYB05027B</td><td>MYB05037B</td><td>MYB05047B</td><td>MYB05057B</td></tr>
<tr><td>6.00</td><td>MYB06017B</td><td>MYB06027B</td><td>MYB06037B</td><td>MYB06047B</td><td>MYB06057B</td></tr>
<tr><td>7.00</td><td>MYB07017B</td><td>MYB07027B</td><td>MYB07037B</td><td>MYB07047B</td><td>MYB07057B</td></tr>
<tr><td>8.00</td><td>MYB08017B</td><td>MYB08027B</td><td>MYB08037B</td><td>MYB08047B</td><td>MYB08057B</td></tr>
<tr><td>9.00</td><td>MYB09017B</td><td>MYB09027B</td><td>MYB09037B</td><td>MYB09047B</td><td>MYB09057B</td></tr>
<tr><td>10.00</td><td>MYB10017B</td><td>MYB10027B</td><td>MYB10037B</td><td>MYB10047b</td><td>MYB10057B</td></tr>
<tr><td colspan="6">For usable length 1350 mm</td></tr>
</table></td><td>IIb</td></tr>
</table>

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Meril Life Sciences Pvt. Ltd.	Muktanand Marg, Chala, Vapi-396191, Gujarat, India

EU Representative

Obelis S A , Bd., General Wahis 53, 1030, Brussels, Belgium.

Certificate No.:	Project No.:	Valid Until:
10000380498-PA-NA-IND	PRJC-517914-2015-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 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