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. 11 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:

- Mozec™ PEB PTA- Paclitaxel Eluting PTA Balloon Catheter

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 17:24:39 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 17:29:20 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:

- Mozec™ PEB PTA- Paclitaxel Eluting PTA Balloon Catheter

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: **Mozec™ PEB PTA – Paclitaxel Eluting PTA Balloon Catheter**
Product Details: GMDN Code **P 62551** Control No.: DOC/MO35P/Rev.10/ 14/12/2022
Batch No.: _____ Mfg. Date: _____
Batch Released Quantity: _____ 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.

A. **Mozec™ PEB PTA – Paclitaxel Eluting PTA Balloon Catheter**

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 Mozec™ PEB PTA – Paclitaxel Eluting PTA Balloon Catheter does not contain materials of human or animal origin.

List of Standard Applied: EN ISO 13485:2016/AC:2016; A11 2021, EN ISO 14971:2019 / A11:2021, IEC 62366-1:2015, EN ISO 15223-1:2021, ISO 20417:2021, 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 (E) Incorporating corrigendum November 2009, EN ISO 10993-11-2009, 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, ISO 11607-1:2020, ISO 11607-2 :2020, EN ISO/IEC 17050-1:2017, EN ISO/IEC 17050-2:2017, EN 868-5:2018, EN ISO 11737-1: 2018/ A1:2021, EN ISO 11135:2014, EN ISO 80369-7:2021, EN ISO 14155: 2020, ASTM F 1980 – 21, MDD 93/42/EEC/1993 , Directive 2007-47-EC, MDD 2001/83/EC, 6th Nov 2001 as amended by 2012/26/EU, MEDDEV 2.1/3, December 2009, MEDDEV 2.4/1 Rev.9, June 2010, MEDDEV 2.7/1, Rev.4June 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 of MDD/93/42/EEC on Medical devices as amended

Device Classification: Mozec™ PEB PTA – Paclitaxel Eluting PTA Balloon Catheter is a sterile single use, surgically invasive, transient use (<60 minutes) device and incorporates , and incorporates a Medicinal Product, as defined in Article 1 of Directive 65/65/EEC. Hence it is classified as class III Medical Device as per MDD/93/42/EEC, 14th June 1993 as amended by 2007/47/EC, Annexure IX, Rule 6 & Rule 13.

CE Certificate No.: EC certificate No. 1783-MDD-091, Rev 01 and EC Design Examination Certificate No. 1783-MDD-092, Rev 01

CE Certificate Issue Date: 06th June, 2018

CE Certificate Valid till: 06th June, 2023

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 903124166282
Email:ce@tse.org.tr, Website : www.tse.org.tr

Notifying Body No.: 1783

Signature:

MERIL LIFE SCIENCES PVT. LTD. VAPI

14/12/2022

Name: *Mr. Narendra Patel*
Designation: Head – QA
Date/Location: **Date:** _____ **Location:** Vapi, Gujarat, INDIA

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 Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara Türkiye (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	:	PACLITAXEL ELUTING PTA BALLOON CATHETER
GMDN Code	:	62551
Classification Rule	:	Rule 6 and Rule 13, Class III
Inspection Report Number	:	1207-MDD-069/2019-02
First Issue Date	:	06.06.2018
Validity Date	:	06.06.2023

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-091

Sezai DOĞAN

Director of Directives
ANKARA Rev01, 05/11/2020

Please check the validity of certificate from TSE's web page "https://basvuruportal.tse.org.tr/Genel/FirmaArama.aspx?ref=en#open"

TÜRK STANDARTLARI ENSTİTÜSÜ DİREKTİFLER MÜDÜRLÜĞÜ DIRECTORATE OF DIRECTIVE TURKISH STANDARDS INSTITUTION 1783

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-091, Rev 01

CERTIFICATE HISTORY		
Date	**Revision Number**	**Reason of Revision**
06.06.2018	Rev 00	-
5.11.2020	Rev 01	Design change and brand name addition

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-091, Rev 01

Product Type

PACLITAXEL ELUTING PTA BALLOON CATHETER

Brand Name

Mozec™ PEB PTA

Catalogue numbers for catheter usable length of 80 cm						
Balloon Diameter (mm)	Balloon Length (mm)					
	30	40	50	60	80	120
3.00	MO35P030030A	MO35P030040A	MO35P030050A	MO35P030060A	MO35P030080A	MO35P030120A
4.00	MO35P040030A	MO35P040040A	MO35P040050A	MO35P040060A	MO35P040080A	MO35P040120A
5.00	MO35P050030A	MO35P050040A	MO35P050050A	MO35P050060A	MO35P050080A	MO35P050120A
6.00	MO35P060030A	MO35P060040A	MO35P060050A	MO35P060060A	MO35P060080A	MO35P060120A
7.00	MO35P070030A	MO35P070040A	MO35P070050A	MO35P070060A	MO35P070080A	MO35P070120A
8.00	MO35P080030A	MO35P080040A	MO35P080050A	MO35P080060A	MO35P080080A	MO35P080120A
9.00	MO35P090030A	MO35P090040A	MO35P090050A	MO35P090060A	MO35P090080A	
10.00	MO35P100030A	MO35P100040A	MO35P100050A	MO35P100060A	MO35P100080A	

Catalogue numbers for catheter usable length of 135 cm						
Balloon Diameter (mm)	Balloon Length (mm)					
	30	40	50	60	80	120
3.00	MO35P030030B	MO35P030040B	MO35P030050B	MO35P030060B	MO35P030080B	MO35P030120B
4.00	MO35P040030B	MO35P040040B	MO35P040050B	MO35P040060B	MO35P040080B	MO35P040120B
5.00	MO35P050030B	MO35P050040B	MO35P050050B	MO35P050060B	MO35P050080B	MO35P050120B
6.00	MO35P060030B	MO35P060040B	MO35P060050B	MO35P060060B	MO35P060080B	MO35P060120B
7.00	MO35P070030B	MO35P070040B	MO35P070050B	MO35P070060B	MO35P070080B	MO35P070120B
8.00	MO35P080030B	MO35P080040B	MO35P080050B	MO35P080060B	MO35P080080B	MO35P080120B
9.00	MO35P090030B	MO35P090040B	MO35P090050B	MO35P090060B	MO35P090080B	
10.00	MO35P100030B	MO35P100040B	MO35P100050B	MO35P100060B	MO35P100080B	

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Catalogue numbers for catheter usable length of 80 cm						
Balloon Diameter (mm)	Balloon Length (mm)					
	30	40	50	60	80	120
3.00	PO35P030030A	PO35P030040A	PO35P030050A	PO35P030060A	PO35P030080A	PO35P030120A
4.00	PO35P040030A	PO35P040040A	PO35P040050A	PO35P040060A	PO35P040080A	PO35P040120A
5.00	PO35P050030A	PO35P050040A	PO35P050050A	PO35P050060A	PO35P050080A	PO35P050120A
6.00	PO35P060030A	PO35P060040A	PO35P060050A	PO35P060060A	PO35P060080A	PO35P060120A
7.00	PO35P070030A	PO35P070040A	PO35P070050A	PO35P070060A	PO35P070080A	PO35P070120A
8.00	PO35P080030A	PO35P080040A	PO35P080050A	PO35P080060A	PO35P080080A	PO35P080120A
9.00	PO35P090030A	PO35P090040A	PO35P090050A	PO35P090060A	PO35P090080A	
10.00	PO35P100030A	PO35P100040A	PO35P100050A	PO35P100060A	PO35P100080A	

Catalogue numbers for catheter usable length of 135 cm						
Balloon Diameter (mm)	Balloon Length (mm)					
	30	40	50	60	80	120
3.00	PO35P030030B	PO35P030040B	PO35P030050B	PO35P030060B	PO35P030080B	PO35P030120B
4.00	PO35P040030B	PO35P040040B	PO35P040050B	PO35P040060B	PO35P040080B	PO35P040120B
5.00	PO35P050030B	PO35P050040B	PO35P050050B	PO35P050060B	PO35P050080B	PO35P050120B
6.00	PO35P060030B	PO35P060040B	PO35P060050B	PO35P060060B	PO35P060080B	PO35P060120B
7.00	PO35P070030B	PO35P070040B	PO35P070050B	PO35P070060B	PO35P070080B	PO35P070120B
8.00	PO35P080030B	PO35P080040B	PO35P080050B	PO35P080060B	PO35P080080B	PO35P080120B
9.00	PO35P090030B	PO35P090040B	PO35P090050B	PO35P090060B	PO35P090080B	
10.00	PO35P100030B	PO35P100040B	PO35P100050B	PO35P100060B	PO35P100080B	

TÜRK STANDARTLARI ENSTİTÜSÜ * TURKISH STANDARDS INSTITUTION * DİREKTİFLER MÜDÜRLÜĞÜ DIRECTORATE OF DIRECTIVE 1763 TSE

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

Tam Kalite Güvence Belgesi

93/42/AT Tıbbi Cihaz Yönetmeliği, Ek II (4) hariç

Onaylanmış Kuruluş	:	Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara Türkiye (NB 1783)
Firma Adı	:	MERIL LIFE SCIENCES PVT. LTD.
Firma Adresi	:	MUKTANAND MARG, CHALA, VAPI-396191. GUJARAT, HİNDİSTAN
Üretim Yeri	:	MUKTANAND MARG, CHALA, VAPI-396191. GUJARAT, HİNDİSTAN
Kapsam	:	PAKLİTAKSEL SALINIMLI PTA BALON KATETER
GMDN Kodu	:	62551
Sınıflandırma Kuralı	:	Kural 6 ve Kural 13, Sınıf III
İnceleme Rapor Numarası	:	1207-MDD-069/2019-02
İlk Belge Veriliş Tarihi	:	06.06.2018
Belge Geçerlilik Tarihi	:	06.06.2023

Üreticinin kalite sistemi Tıbbi Cihaz Yönetmeliği Ek II'ye göre denetlenmiştir ve kalite sistemi Tıbbi Cihaz Yönetmeliği Ek II gereklerini karşılamaktadır. Onaylanmış Kuruluş Tıbbi Cihaz Yönetmeliğinin Ek II, 5. bölümüne istinaden gerekli gözetimleri yapma hakkına sahiptir. Bu belge kapsamında bulunan Sınıf III ürünler için, Tıbbi Cihaz Yönetmeliği Ek II, Bölüm 4'e göre düzenlenen Tasarım İnceleme Belgesi de gerekmektedir.

Belge No: 1783- MDD-091

Sezai DOĞAN

Direktifler Müdürü
ANKARA Rev 01, 05/11/2020

TÜRK STANDARTLARI ENSTİTÜSÜ * DİREKTİFLER MÜDÜRLÜĞÜ * DIRECTORATE OF DIRECTIVE * TURKISH STANDARDS INSTITUTION * 1783

Belgenin geçerliliğini TSE'nin web sayfası: "https://basvuruportal.tse.org.tr/Genel/FirmaArama.aspx"den kontrol ediniz

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

Tam Kalite Güvence Belgesi Belge Tarihçesi

93/42/AT Tıbbi Cihaz Yönetmeliği, Ek II (4) hariç

Belge No: 1783-MDD-091, Rev 01

BELGE TARİHÇESİ		
Tarih	**Revizyon numarası**	**Revizyon Nedeni**
06.06.2018	Rev 00	-
05.11.2020	Rev 01	Tasarım değişikliği ve marka ekleme

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

Tam Kalite Güvence Belgesi Kapsam Eki

93/42/AT Tıbbi Cihaz Yönetmeliği, Ek II (4) hariç

Belge No: 1783-MDD-091, Rev 01

Ürün Tipi

PAKLİTAKSEL SALINIMLI PTA BALON KATETER

Marka

Mozec™ PEB PTA

80 cm kullanılabilir uzunluğa sahip kateter için katalog numaraları

Balon çapı (mm) \ Mevcut balon uzunluğu (mm)	30	40	50	60	80	120
3.00	MO35P030030A	MO35P030040A	MO35P030050A	MO35P030060A	MO35P030080A	MO35P030120A
4.00	MO35P040030A	MO35P040040A	MO35P040050A	MO35P040060A	MO35P040080A	MO35P040120A
5.00	MO35P050030A	MO35P050040A	MO35P050050A	MO35P050060A	MO35P050080A	MO35P050120A
6.00	MO35P060030A	MO35P060040A	MO35P060050A	MO35P060060A	MO35P060080A	MO35P060120A
7.00	MO35P070030A	MO35P070040A	MO35P070050A	MO35P070060A	MO35P070080A	MO35P070120A
8.00	MO35P080030A	MO35P080040A	MO35P080050A	MO35P080060A	MO35P080080A	MO35P080120A
9.00	MO35P090030A	MO35P090040A	MO35P090050A	MO35P090060A	MO35P090080A	
10.00	MO35P100030A	MO35P100040A	MO35P100050A	MO35P100060A	MO35P100080A	

135 cm kullanılabilir uzunluğa sahip kateter için katalog numaraları

Balon çapı (mm) \ Mevcut balon uzunluğu (mm)	30	40	50	60	80	120
3.00	MO35P030030B	MO35P030040B	MO35P030050B	MO35P030060B	MO35P030080B	MO35P030120B
4.00	MO35P040030B	MO35P040040B	MO35P040050B	MO35P040060B	MO35P040080B	MO35P040120B
5.00	MO35P050030B	MO35P050040B	MO35P050050B	MO35P050060B	MO35P050080B	MO35P050120B
6.00	MO35P060030B	MO35P060040B	MO35P060050B	MO35P060060B	MO35P060080B	MO35P060120B
7.00	MO35P070030B	MO35P070040B	MO35P070050B	MO35P070060B	MO35P070080B	MO35P070120B
8.00	MO35P080030B	MO35P080040B	MO35P080050B	MO35P080060B	MO35P080080B	MO35P080120B
9.00	MO35P090030B	MO35P090040B	MO35P090050B	MO35P090060B	MO35P090080B	
10.00	MO35P100030B	MO35P100040B	MO35P100050B	MO35P100060B	MO35P100080B	

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80 cm kullanılabilir uzunluğa sahip kateter için katalog numaraları							
		Mevcut balon uzunluğu (mm)					
Balon çapı (mm)		30	40	50	60	80	120
	3.00	PO35P030030A	PO35P030040A	PO35P030050A	PO35P030060A	PO35P030080A	PO35P030120A
	4.00	PO35P040030A	PO35P040040A	PO35P040050A	PO35P040060A	PO35P040080A	PO35P040120A
	5.00	PO35P050030A	PO35P050040A	PO35P050050A	PO35P050060A	PO35P050080A	PO35P050120A
	6.00	PO35P060030A	PO35P060040A	PO35P060050A	PO35P060060A	PO35P060080A	PO35P060120A
	7.00	PO35P070030A	PO35P070040A	PO35P070050A	PO35P070060A	PO35P070080A	PO35P070120A
	8.00	PO35P080030A	PO35P080040A	PO35P080050A	PO35P080060A	PO35P080080A	PO35P080120A
	9.00	PO35P090030A	PO35P090040A	PO35P090050A	PO35P090060A	PO35P090080A	
	10.00	PO35P100030A	PO35P100040A	PO35P100050A	PO35P100060A	PO35P100080A	

135 cm kullanılabilir uzunluğa sahip kateter için katalog numaraları							
		Mevcut balon uzunluğu (mm)					
Balon çapı (mm)		30	40	50	60	80	120
	3.00	PO35P030030B	PO35P030040B	PO35P030050B	PO35P030060B	PO35P030080B	PO35P030120B
	4.00	PO35P040030B	PO35P040040B	PO35P040050B	PO35P040060B	PO35P040080B	PO35P040120B
	5.00	PO35P050030B	PO35P050040B	PO35P050050B	PO35P050060B	PO35P050080B	PO35P050120B
	6.00	PO35P060030B	PO35P060040B	PO35P060050B	PO35P060060B	PO35P060080B	PO35P060120B
	7.00	PO35P070030B	PO35P070040B	PO35P070050B	PO35P070060B	PO35P070080B	PO35P070120B
	8.00	PO35P080030B	PO35P080040B	PO35P080050B	PO35P080060B	PO35P080080B	PO35P080120B
	9.00	PO35P090030B	PO35P090040B	PO35P090050B	PO35P090060B	PO35P090080B	
	10.00	PO35P100030B	PO35P100040B	PO35P100050B	PO35P100060B	PO35P100080B	

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

EC Design-Examination Certificate

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

Notified Body	:	Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara Türkiye (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	:	PACLITAXEL ELUTING PTA BALLOON CATHETER
GMDN Code	:	62551
Classification Rule	:	Rule 6 and Rule 13, Class III
Inspection Report Number	:	1207-MDD-069/2019-02
First Issue Date	:	06.06.2018
Validity Date	:	06.06.2023
Full Quality Assurance Certificate Number	:	1783-MDD-091

Above scope has been examined and certified according to the requirements of 93/42 / EC - Medical Device Directive Annex-II Section 4. This certificate is valid with its annexes. It is totally ... pages, including this page. The products included in the scope mentioned above must also have a certificate of Full Quality Assurance (Annex II excluding Section 4). The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex II Section 5.

Certificate No: 1783- MDD-092

Sezai DOĞAN

Director of Directives
ANKARA Rev 01, 05/11/2020

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

EC Design Examination Certificate Annex

Certificate No: 1783-MDD-092, Rev 01

Product Type

PACLITAXEL ELUTING PTA BALLOON CATHETER

Brand Name

Mozec™ PEB PTA

Catalogue numbers for catheter usable length of 80 cm							
		Balloon Length (mm)					
Balloon Diameter (mm)		30	40	50	60	80	120
	3.00	MO35P030030A	MO35P030040A	MO35P030050A	MO35P030060A	MO35P030080A	MO35P030120A
	4.00	MO35P040030A	MO35P040040A	MO35P040050A	MO35P040060A	MO35P040080A	MO35P040120A
	5.00	MO35P050030A	MO35P050040A	MO35P050050A	MO35P050060A	MO35P050080A	MO35P050120A
	6.00	MO35P060030A	MO35P060040A	MO35P060050A	MO35P060060A	MO35P060080A	MO35P060120A
	7.00	MO35P070030A	MO35P070040A	MO35P070050A	MO35P070060A	MO35P070080A	MO35P070120A
	8.00	MO35P080030A	MO35P080040A	MO35P080050A	MO35P080060A	MO35P080080A	MO35P080120A
	9.00	MO35P090030A	MO35P090040A	MO35P090050A	MO35P090060A	MO35P090080A	
	10.00	MO35P100030A	MO35P100040A	MO35P100050A	MO35P100060A	MO35P100080A	

Catalogue numbers for catheter usable length of 135 cm							
		Balloon Length (mm)					
Balloon Diameter (mm)		30	40	50	60	80	120
	3.00	MO35P030030B	MO35P030040B	MO35P030050B	MO35P030060B	MO35P030080B	MO35P030120B
	4.00	MO35P040030B	MO35P040040B	MO35P040050B	MO35P040060B	MO35P040080B	MO35P040120B
	5.00	MO35P050030B	MO35P050040B	MO35P050050B	MO35P050060B	MO35P050080B	MO35P050120B
	6.00	MO35P060030B	MO35P060040B	MO35P060050B	MO35P060060B	MO35P060080B	MO35P060120B
	7.00	MO35P070030B	MO35P070040B	MO35P070050B	MO35P070060B	MO35P070080B	MO35P070120B
	8.00	MO35P080030B	MO35P080040B	MO35P080050B	MO35P080060B	MO35P080080B	MO35P080120B
	9.00	MO35P090030B	MO35P090040B	MO35P090050B	MO35P090060B	MO35P090080B	
	10.00	MO35P100030B	MO35P100040B	MO35P100050B	MO35P100060B	MO35P100080B	

TÜRK STANDARTLARI ENSTİTÜSÜ * TURKISH STANDARDS INSTITUTION * DİREKTİFLER KOORDİNATÖRLÜĞÜ DIRECTORATE OF DIRECTIVE 1783

Paximus™

Catalogue numbers for catheter usable length of 80 cm							
		Balloon Length (mm)					
Balloon Diameter (mm)		30	40	50	60	80	120
	3.00	PO35P030030A	PO35P030040A	PO35P030050A	PO35P030060A	PO35P030080A	PO35P030120A
	4.00	PO35P040030A	PO35P040040A	PO35P040050A	PO35P040060A	PO35P040080A	PO35P040120A
	5.00	PO35P050030A	PO35P050040A	PO35P050050A	PO35P050060A	PO35P050080A	PO35P050120A
	6.00	PO35P060030A	PO35P060040A	PO35P060050A	PO35P060060A	PO35P060080A	PO35P060120A
	7.00	PO35P070030A	PO35P070040A	PO35P070050A	PO35P070060A	PO35P070080A	PO35P070120A
	8.00	PO35P080030A	PO35P080040A	PO35P080050A	PO35P080060A	PO35P080080A	PO35P080120A
	9.00	PO35P090030A	PO35P090040A	PO35P090050A	PO35P090060A	PO35P090080A	
	10.00	PO35P100030A	PO35P100040A	PO35P100050A	PO35P100060A	PO35P100080A	

Catalogue numbers for catheter usable length of 135 cm							
		Balloon Length (mm)					
Balloon Diameter (mm)		30	40	50	60	80	120
	3.00	PO35P030030B	PO35P030040B	PO35P030050B	PO35P030060B	PO35P030080B	PO35P030120B
	4.00	PO35P040030B	PO35P040040B	PO35P040050B	PO35P040060B	PO35P040080B	PO35P040120B
	5.00	PO35P050030B	PO35P050040B	PO35P050050B	PO35P050060B	PO35P050080B	PO35P050120B
	6.00	PO35P060030B	PO35P060040B	PO35P060050B	PO35P060060B	PO35P060080B	PO35P060120B
	7.00	PO35P070030B	PO35P070040B	PO35P070050B	PO35P070060B	PO35P070080B	PO35P070120B
	8.00	PO35P080030B	PO35P080040B	PO35P080050B	PO35P080060B	PO35P080080B	PO35P080120B
	9.00	PO35P090030B	PO35P090040B	PO35P090050B	PO35P090060B	PO35P090080B	
	10.00	PO35P100030B	PO35P100040B	PO35P100050B	PO35P100060B	PO35P100080B	

CERTIFICATE HISTORY		
Date	**Revision Number**	**Reason of Revision**
06.06.2018	Rev 00	-
05.11.2020	Rev 01	Design change and brand name addition

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

AT Tasarım İnceleme Belgesi

93/42/AT Tıbbi Cihaz Yönetmeliği, Ek II (4)

Onaylanmış Kuruluş	:	Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara Türkiye (NB 1783)
Firma Adı	:	MERIL LIFE SCIENCES PVT. LTD.
Firma Adresi	:	MUKTANAND MARG, CHALA, VAPI-396191. GUJARAT, HİNDİSTAN
Üretim Yeri	:	MUKTANAND MARG, CHALA, VAPI-396191. GUJARAT, HİNDİSTAN
Kapsam	:	PAKLİTAKSEL SALINIMLI PTA BALON KATETER
GMDN Kodu	:	62551
Sınıflandırma Kuralı	:	Kural 6 ve Kural 13, Sınıf III
İnceleme Rapor Numarası	:	1207-MDD-069/2019-02
İlk Belge Veriliş Tarihi	:	06.06.2018
Belge Geçerlilik Tarihi	:	06.06.2023
Tam Kalite Güvence Belgesi Numarası	:	1783-MDD-091

93/42/AT-Tıbbi Cihaz Yönetmeliği Ek-II Bölüm 4 gereklerine göre incelenmiş ve belgelendirilmiştir. Bu belge ekleriyle birlikte geçerlidir. Ekleriyle birlikte ... sayfadır. Yukarıda belirtilen kapsamda bulunan ürünlerin piyasaya arzı için Tam Kalite Güvence (Ek II Bölüm 4 Hariç) belgesinin de olması gerekmektedir. Onaylanmış Kuruluş Tıbbi Cihaz Yönetmeliği'nin Ek II, Bölüm 5'e istinaden gerekli gözetimleri yapma hakkına sahiptir.

Belge No: 1783- MDD-092

Sezai DOĞAN

Direktifler Müdürü
ANKARA Rev 01, 05/11/2020

Belgenin geçerliliğini TSE'nin web sayfası: "https://basvuruportal.tse.org.tr/Genel/FirmaArama.aspx"den kontrol ediniz

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

AT Tasarım İnceleme Belgesi Eki

Belge No: 1783-MDD-092, Rev 01

Ürün Tipi

PAKLİTAKSEL SALINIMLI PTA BALON KATETER

Marka

Mozec™ PEB PTA

80 cm kullanılabilir uzunluğa sahip kateter için katalog numaraları						
	Mevcut balon uzunluğu (mm)					
Balon çapı (mm)	30	40	50	60	80	120
3.00	MO35P030030A	MO35P030040A	MO35P030050A	MO35P030060A	MO35P030080A	MO35P030120A
4.00	MO35P040030A	MO35P040040A	MO35P040050A	MO35P040060A	MO35P040080A	MO35P040120A
5.00	MO35P050030A	MO35P050040A	MO35P050050A	MO35P050060A	MO35P050080A	MO35P050120A
6.00	MO35P060030A	MO35P060040A	MO35P060050A	MO35P060060A	MO35P060080A	MO35P060120A
7.00	MO35P070030A	MO35P070040A	MO35P070050A	MO35P070060A	MO35P070080A	MO35P070120A
8.00	MO35P080030A	MO35P080040A	MO35P080050A	MO35P080060A	MO35P080080A	MO35P080120A
9.00	MO35P090030A	MO35P090040A	MO35P090050A	MO35P090060A	MO35P090080A	
10.00	MO35P100030A	MO35P100040A	MO35P100050A	MO35P100060A	MO35P100080A	

135 cm kullanılabilir uzunluğa sahip kateter için katalog numaraları						
	Mevcut balon uzunluğu (mm)					
Balon çapı (mm)	30	40	50	60	80	120
3.00	MO35P030030B	MO35P030040B	MO35P030050B	MO35P030060B	MO35P030080B	MO35P030120B
4.00	MO35P040030B	MO35P040040B	MO35P040050B	MO35P040060B	MO35P040080B	MO35P040120B
5.00	MO35P050030B	MO35P050040B	MO35P050050B	MO35P050060B	MO35P050080B	MO35P050120B
6.00	MO35P060030B	MO35P060040B	MO35P060050B	MO35P060060B	MO35P060080B	MO35P060120B
7.00	MO35P070030B	MO35P070040B	MO35P070050B	MO35P070060B	MO35P070080B	MO35P070120B
8.00	MO35P080030B	MO35P080040B	MO35P080050B	MO35P080060B	MO35P080080B	MO35P080120B
9.00	MO35P090030B	MO35P090040B	MO35P090050B	MO35P090060B	MO35P090080B	
10.00	MO35P100030B	MO35P100040B	MO35P100050B	MO35P100060B	MO35P100080B	

Paximus™

80 cm kullanılabilir uzunluğa sahip kateter için katalog numaraları						
	Mevcut balon uzunluğu (mm)					
Balon çapı (mm)	30	40	50	60	80	120
3.00	PO35P030030A	PO35P030040A	PO35P030050A	PO35P030060A	PO35P030080A	PO35P030120A
4.00	PO35P040030A	PO35P040040A	PO35P040050A	PO35P040060A	PO35P040080A	PO35P040120A
5.00	PO35P050030A	PO35P050040A	PO35P050050A	PO35P050060A	PO35P050080A	PO35P050120A
6.00	PO35P060030A	PO35P060040A	PO35P060050A	PO35P060060A	PO35P060080A	PO35P060120A
7.00	PO35P070030A	PO35P070040A	PO35P070050A	PO35P070060A	PO35P070080A	PO35P070120A
8.00	PO35P080030A	PO35P080040A	PO35P080050A	PO35P080060A	PO35P080080A	PO35P080120A
9.00	PO35P090030A	PO35P090040A	PO35P090050A	PO35P090060A	PO35P090080A	
10.00	PO35P100030A	PO35P100040A	PO35P100050A	PO35P100060A	PO35P100080A	

135 cm kullanılabilir uzunluğa sahip kateter için katalog numaraları						
	Mevcut balon uzunluğu (mm)					
Balon çapı (mm)	30	40	50	60	80	120
3.00	PO35P030030B	PO35P030040B	PO35P030050B	PO35P030060B	PO35P030080B	PO35P030120B
4.00	PO35P040030B	PO35P040040B	PO35P040050B	PO35P040060B	PO35P040080B	PO35P040120B
5.00	PO35P050030B	PO35P050040B	PO35P050050B	PO35P050060B	PO35P050080B	PO35P050120B
6.00	PO35P060030B	PO35P060040B	PO35P060050B	PO35P060060B	PO35P060080B	PO35P060120B
7.00	PO35P070030B	PO35P070040B	PO35P070050B	PO35P070060B	PO35P070080B	PO35P070120B
8.00	PO35P080030B	PO35P080040B	PO35P080050B	PO35P080060B	PO35P080080B	PO35P080120B
9.00	PO35P090030B	PO35P090040B	PO35P090050B	PO35P090060B	PO35P090080B	
10.00	PO35P100030B	PO35P100040B	PO35P100050B	PO35P100060B	PO35P100080B	

BELGE TARİHÇESİ

Tarih	Revizyon numarası	Revizyon Nedeni
06.06.2018	Rev 00	-
05.11.2020	Rev 01	Tasarım değişikliği ve marka ekleme

DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

Meril Life Sciences Pvt. Ltd.

Muktanand Marg, Chala,

Vapi-396191, Gujarat,

India

2023-06-02

Notified Body Confirmation Letter

Reference: 545101

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical device

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Meril Life Sciences Pvt. Ltd.

Muktanand Marg, Chala,

Vapi-396191, Gujarat,

India

SRN: IN-MF-000008308

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable

Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

i.A. Daniel Siuda

Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Evermine50/Peremo™ **89042249EECSSP6**	Class III		Turkish Standard Institution (TSE) - 1783 Certificate No: 1783-MDD-085 Rev03 (Full quality system certificate) Certificate No: 1783-MDD-086 Rev03 (EC Design examination certificate)
MOZEC™ PEB PTA/Paximus™ **89042249PEPBCO035GF**	**Class III**	**N/A**	Turkish Standard Institution (TSE) - 1783

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Full Quality assurance certificate Directive 93/42/EEC on Medical devices, Annex II excluding (4) Certificate No #1783-MDD-091; Rev 01 EC Design-Examination Certificate Directive 93/42/EEC on Medical Devices, Annex II (4) Certificate No #1783-MDD-092; Rev 01
Mozec PTA OTW 0.035” **89042249OPTABDC0357M**	**IIa**	**N/A**	DNV Product Assurance AS (DNV) - 2460 Full Quality assurance certificate Directive 93/42/EEC on Medical devices, Annex II excluding (4) Certificate No # 261394-2018-CE-IND-NA-PS Rev 1.0

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-05-24	545101-1	Initial issue
2023-05-31	545101-2	Addition of medical device MOZECT PEB PTA
2023-06-02	545101-3	Addition of medical device Mozec PTA OTW 0.035'' and adjustment of name of MOZEC PEB PTA/Paximus and removal of Mozec PEB reference Numbers
2023-06-02	545101-4	Addition of missing UDI for Evermine50/Peremo