



TÜRK STANDARTLARI 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	: SIROLIMUS ELUTING CORONARY SIDE BRANCH STENT SYSTEM
GMDN Code	: 58771
Classification Rule	: Rule 8 and Rule 13, Class III
Inspection Report Number	: 1539-MDD-098/2019-02
First Issue Date	: 26.02.2019
Validity Date	: 26.02.2024
Full Quality Assurance Certificate Number	: 1783-MDD-112

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 2 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-113

Sezai DOĞAN

Director of Directives
ANKARA Rev01, 16/10/2020



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

www.tse.org.tr / Necatibey Cad. No: 112 Bakanlıklar - ANKARA / +90 312 416 62 00

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This certificate cannot be altered, partially duplicated or erased for misunderstanding.



TÜRK STANDARTLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

EC Design Examination Certificate Annex

Certificate No: 1783-MDD-113, Rev 01

Product Type

SIROLIMUS ELUTING CORONARY SIDE BRANCH STENT SYSTEM

Brand Name

BioMime™ Branch

Stent diameters (from proximal to distal) (mm)	Stent length (mm)			
	16	19	24	29
2.50-2.50	BBR25025016	BBR25025019	BBR25025024	BBR25025029
3.00-2.50	BBR30025016	BBR30025019	BBR30025024	BBR30025029
3.50-2.50	BBR35025016	BBR35025019	BBR35025024	BBR35025029
3.50-3.00	BBR35030016	BBR35030019	BBR35030024	BBR35030029
4.00-3.50	BBR40035016	BBR40035019	BBR40035024	BBR40035029

CERTIFICATE HISTORY

Date	Revision Number	Reason of Revision
26.02.2019	Rev 00	-
16.10.2020	Rev 01	Scope extension





TÜRK STANDARTLARI ENSTITÜSÜ

TURKISH STANDARDS INSTITUTION -

Certifikát ES o skúške dizajnu

Smernica 93/42/EHS o zdravotníckych pomôckach, príloha II (4)

Notifikovaná osoba	Türk Standardlari Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanliklar Ankara Turecko (NB 1783)
Názov spoločnosti	SPOLOČNOSŤ MERIL LIFE SCIENCES PVT. LTD.
Adresa spoločnosti	MUKTANAND MARG CHALA, VAPI-396191. GUJARAT INDIA
Výrobná lokalita	MUKTANAND MARG CHALA, VAPI-396191. GUJARAT INDIA
Rozsah	SYSTEM STENTU VEDĽAJŠEJ KORONÁRNEJ VETVY UVOĽŇUJÚCI SIROLIMUS
Kód GMDN	58771
Klasifikačné pravidlo	Pravidlo 8 a pravidlo 13, trieda III
Číslo správy o inšpekcii	1539-MDD-098/2019-02
Dátum prvého vydania	26.02.2019
Dátum platnosti	26.02.2024
Číslo certifikátu o kompletnom systéme zabezpečovania kvality:	1783-MDD-112

Uvedený rozsah bol preskúmaný a certifikovaný podľa požiadaviek v oddiele 4 prílohy 11 k smernici 93/42/EHS o zdravotníckych pomôckach. Tento certifikát je platný s prílohami. Sú to celkom 2 strany vrátane tejto. Výrobky zahrnuté do uvedeného rozsahu musia mať okrem toho certifikát o kompletnom systéme zabezpečovania kvality (príloha 11 s výnimkou oddielu 4). Notifikovaná osoba má právo vykonávať potrebné kontroly v súlade s oddielom 5 prílohy 11 k smernici o zdravotníckych pomôckach.

Certifikát č.: 1783-MDD-113



Sezai DOGAN

Riaditeľ oddelenia

smerníc

ANKARA Rev01, 16.10.2020

Platnosť certifikátu si môžete overiť na webovej stránke TSE <https://basvuruportal.tse.org.tr/Genes/FirmaAraina.aspx?ref=en#open>.

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TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION -

Príloha k certifikátu ES o skúške dizajnu

Certifikát č.: 1783-MDD-113, Rev 01

Typ výrobku

SYSTEM STENTU VEDĽAJŠEJ KORONÁRNEJ VETVY UVOĽŇUJÚCI SIROLIMUS

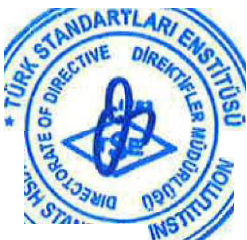
Názov značky

BioMime** Branch

Priemery stentu (od proximálneho po distálny)	Dĺžka stentu (mm)			
	16	19	24	29
2,50 – 2,50	BBR25025016	BBR25025019	BBR25025024	BBR25025029
3,00 – 2,50	BBR30025016	BBR30025019	BBR30025024	BBR30025029
3,50 – 2,50	BBR35025016	BBR35025019	BBR35025024	BBR35025029
3,50 – 3,00	BBR35030016	BBR35030019	BBR35030024	BBR35030029
4,00 – 3,50	BBR40035016	BBR40035019	BBR40035024	BBR40035029

HISTÓRIA CERTIFIKÁTU

Dátum	Číslo revízie	Dôvod revízie
26.02.2019	Rev 00	-
16.10.2020	Rev 01	Rozšírenie rozsahu



Strana 1/1

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