



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	: ALVIMEDICA TIBBİ ÜRÜNLER SAN. DIŞ TİC. A.Ş.
Company Address	: İstanbul Trakya Serbest Bölgesi Ferhatpaşa SB Mahallesi Atatürk Bulvarı 34540 No:16 Çatalca-İstanbul, TÜRKİYE
Manufacturing Site	: İstanbul Trakya Serbest Bölgesi Ferhatpaşa SB Mahallesi Atatürk Bulvarı 34540 No:16 Çatalca-İstanbul, TÜRKİYE
Scope	: CORACTO™ RAPAMYCIN (SIROLIMUS) ELUTING CORONARY STENT SYSTEM (STERILE)
GMDN Code	: 58771
Classification Rule	: Rule 8 & 13, Class III
Inspection Report Number	: 720-MDD-037/2019-03
First Issue Date	: 10.03.2016
Validity Date	: 26.05.2024
Full Quality Assurance Certificate Number	: 1783-MDD-029

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-028

Frat HACIOĞLU

Director of Directives

ANKARA Rev04, 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>"

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

Bu belge hiçbir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazını ve silinti yapılamaz.
This certificate cannot be altered, partially duplicated or erased for misunderstanding.



TÜRK STANDARDLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

EC Design Examination Certificate Annex

Certificate No: 1783-MDD-028, Rev 04

Product Type

CORACTO™ RAPAMYCIN (SIROLIMUS) ELUTING CORONARY STENT SYSTEM

Catalogue Numbers							
Available Stent diameter (mm)	Available Stent length (mm)						
	9	13	17	21	24	28	32
2.50	3601005001	3601005011	3601005021	3601005031	3601005041	3601005051	
2.75	3601005061	3601005071	3601005081	3601005091	3601005101	3601005111	
3.00	3601005121	3601005131	3601005141	3601005151	3601005161	3601005171	3601005181
3.50	3601005191	3601005201	3601005211	3601005221	3601005231	3601005241	3601005251
4.00	3601005261	3601005271	3601005281	3601005291	3601005301	3601005311	3601005321

CERTIFICATE HISTORY

Date	Revision Number	Reason of Revision
10.03.2016	Rev 00	-
10.06.2016	Rev 01	Design change
08.01.2018	Rev 02	Editorial correction
20.01.2021	Rev 03	Design change and certificate renewal
25.05.2021	Rev 04	Change of number in address





TÜRK STANDARTLARI 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 Turkey (NB 1783)
Company Name	: ALVIMEDICA TIBBİ ÜRÜNLER SAN. DIŞ TİC. A.Ş.
Company Address	: İstanbul Trakya Serbest Bölgesi Ferhatpaşa SB Mahallesi Atatürk Bulvarı 34540 No:16 Çatalca-İstanbul, TÜRKİYE
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Scope	: CORACTO™ RAPAMYCIN (SIROLIMUS) ELUTING CORONARY STENT SYSTEM (STERILE)
GMDN Code	: 58771
Classification Rule	: Rule 8 & 13, Class III
Inspection Report Number	: 720-MDD-037/2019-03
First Issue Date	: 10.03.2016
Validity Date	: 26.05.2024

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-029




Fırat HACIOĞLU

Deputy Director of Directives

ANKARA Rev03, 25/05/2021

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TÜRK STANDARTLARI 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-029, Rev 03

CERTIFICATE HISTORY		
Date	Revision Number	Reason of Revision
10.03.2016	Rev 00	-
08.01.2018	Rev 01	Editorial correction
20.01.2021	Rev 02	Design change and certificate renewal
25.05.2021	Rev 03	Change of number in address





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-029, Rev 03

CORACTO™ RAPAMYCIN (SIROLIMUS) ELUTING CORONARY STENT SYSTEM

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