CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-15-320

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

OSİMPLANT TIBBİ MALZEMELER VE MEDİKAL TİCARET LİMİTED ŞİRKETİ

Mustafa Kemal Mah. 2133. Sk. No: 4/2 Çankaya /Ankara/Turkey

Products: Sterile and Non Sterile Spinal Fixation Systems, Sterile and Non Sterile Spinal Cages, Sterile Vertebroplasty and Kyphoplasty Kits

The products defined at the enclosure which is the part of this certificate and contains two pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.4306.08
Date of first issue: 02 January 2015
Date of last issue: 02 December 2020
Revision Number: 04
Expiry Date: 27 May 2024

02 December 2020, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

CERTIFICATE

kiwa

Enclosure of the EC Certificate:

Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-15-320, Revision Number: 04

Concerned medical devices;

Product: Sterile and Non Sterile Spinal Fixation Systems

OSI Spinal Fixation System
ON PLUS Spinal Fixation System
VESTA Cement Injectable Screw Spinal Fixation System
JUVE Pediatric Spinal Fixation System
CERES Minimally Invasive, Percutaneous Screw Spinal Fixation System
STRATOS Interspinous Fixator Spinal Fixation System
PORTHOS Posterior Cervical Spinal Fixation System
ULTIO Laminoplasty Posterior Cervical Spinal Fixation System
AURA Anterior Cervical Plate System
ATLAS Odontoid Screw
ATHENA MIS and Open Modular Pedicle Screw System

Product: Sterile and Non Sterile Spinal Cages

ARION Expandable Bladed Cervical PEEK Cage
EOS Bladed Cervical PEEK Cage
BIA Cervical PEEK Cage
TITANOPEEK ACF Stand Alone Cervical Cage System
ARIA Expandable PEEK PLIF Cage
FIDES Angular PEEK TLIF Cage

Muhteşem Gökhan Yücel
Head of Notified Body

02 December 2020, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

CERTIFICATE

Enclosure of the EC Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-15-320, Revision Number: 04

Concerned medical devices;

Product: Sterile and Non Sterile Spinal Cages

TALOS PEEK TLIF Cage
ZELOS PEEK-TITANIUM PLIF Cage
SENTINUS-C Cervical Corpectomy Mesh Cage
SENTINUS-L Lumbar Corpectomy Mesh Cage
X-XP Corpectomy Cage

Product: Sterile Vertebroplasty and Kyphoplasty Kits

ON PLUS Gauge
ON PLUS Needle Beveled Type
ON PLUS Bone Filler
ON PLUS Osteo Introducer
Kischner Wire
ON PLUS Spacer (Drill)
ILOS Spine Kit

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

02 December 2020, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

OSIMPLANT
Spine Restoration Technology

UYGUNLUK BEYANI
Declaration of Conformity

"OSİMPLANT" markasına ait olarak tamamen kendi sorumluluğumuz altında üretmiş olduğumuz bu ürünlerin 93/42/ EEC yönetmeliğinin gereksinimlerine göre üretilip kontrol edildiğini beyan ederiz. / *We declare that, these products which belong to "OSİMPLANT" brand are completely under our responsibility also producted and checked according to the requirements of 93/42/ EEC.*

Üretici firma / *Manufacturer:* Osimplant Tıbbi Malzemeler Medikal Tic.Ltd.Şti.

Üretici Adresi / *Manufacturer Address:* Mustafa Kemal Mah. 2133. Sk. No:4/2 Royale Office Çankaya/ Ankara 06510

Tel / *Phone :* +90 312 473 82 80 **Faks** / *Fax :* +90 312 473 8190
Web: http://osimplant.com.tr/ **E-Mail:** info@osimplant.com.tr

Ürün Adı / *Product Name:*

Steril ve Steril Olmayan Spinal Fiksasyon Sistemleri/*Sterile and Non-sterile Spinal Fixation Systems*
OSI Spinal Fiksasyon Sistemi/ *OSI Spinal Fixation System*
ON PLUS Spinal Fiksasyon Sistemi / *ON PLUS Spinal Fixation System*
VESTA Sement Enjekte Edilebilir Vida Spinal Fiksasyon Sistemi / *VESTA Cement Injectable Screw Spinal Fixation System*
ARTHOS Titanyum Plazma Kaplı Vida Spinal Fiksasyon Sistemi/ *ARTHOS Titanium Plasma Coated Screw Spinal Fixation System*
JUVE Pediatrik Spinal Fiksasyon Sistemi/ *JUVE Pediatric Spinal Fixation System*
CERES Minimal İnvaziv, Perkütan Vida Spinal Fiksasyon Sistemi/ *CERES Minimally Invasive, Percutaneous Screw Spinal Fixation System*
STRATOS Interspinöz Fiksatör Spinal Fiksasyon Sistemi/ *STRATOS Interspinous Fixator Spinal Fixation System*
PORTHOS Posterior Servikal Spinal Fiksasyon Sistemi/ *PORTHOS Posterior Cervical Spinal Fixation System*
ULTIO Laminoplasti Posterior Servikal Spinal Fiksasyon Sistemi/ *ULTIO Laminoplasty Posterior Cervical Spinal Fixation System*
AURA Anterior Servikal Plak Sistem/ *AURA Anterior Cervical Plate System*
ATLAS Odontoid Vida/*ATLAS Odontoid Screw*

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HERAKLES Mini Plak Ve Vida Kraniyel Sistemler/ *HERAKLES Mini Plate and Screw Cranial Systems*
ATHENA MIS Perkütan Spinal Stabilizasyon Sistem/ *ATHENA MIS Percutaneous Spinal Stabilization System*

Ürün Tipleri */Product Types:*

Steril ve Steril Olmayan Monoaksiyel Vidalar, Steril ve Steril Olmayan Poliaksiyel Vidalar, Steril ve Steril Olmayan Monoaksiyel Redüksiyon Vidalar, Steril ve Steril Olmayan Poliaksiyel Redüksiyon Vidalar, Steril ve Steril Olmayan Monoaksiyel Sement Enjekte Edilebilir Vidalar, Steril ve Steril Olmayan Poliaksiyel Sement Enjekte Edilebilir Vidalar, Steril ve Steril Olmayan Titanyum Plazma Kaplama Vidalar, Steril ve Steril Olmayan Titanyum Plazma Kaplama Redüksiyon Vidalar, Steril ve Steril Olmayan Sakroiliak Poliaksiyal Vidalar, Steril ve Steril Olmayan Perkütan Vidalar, Steril ve Steril Olmayan Minimal Invaziv Vidalar, Steril ve Steril Olmayan Odontoid Vidalar, Steril ve Steril Olmayan Laminoplasti Vidaları, Steril ve Steril Olmayan Servikal Vidalar, Steril ve Steril Olmayan Lamina Kancalar, Steril ve Steril Olmayan Pedikül Kancalar, Steril ve Steril Olmayan Offset Kancalar, Steril ve Steril Olmayan Rodlar, Steril ve Steril Olmayan Konnektörler, Steril ve Steril Olmayan Kortikal Vidalar, Steril ve Steril Olmayan Plaklar, Steril ve Steril Olmayan Mikro Plaklar, Steril ve Steril Olmayan Mikro Vidalar, Steril ve Steril Olmayan Domino Konnektörler, Steril ve Steril Olmayan İnterspinöz Fiksatörler/ *Sterile and Non-Sterile Monoaxial Screws, Sterile and Non-Sterile Polyaxial Screws, Sterile and Non-Sterile Monoaxial Reduction Screws, Sterile and Non-Sterile Polyaxial Reduction Screws, Sterile and Non-Sterile Monoaxial Cement Injectable Screws, Sterile and Non-Sterile Polyaxial Cement Injectable Screws, Sterile and Non-Sterile Titanium Plasma Coated Screws, , Sterile and Non-Sterile Titanium Plasma Coated Reduction Screws, Sterile and Non-Sterile Sacroiliac Polyaxial Screws, Sterile and Non- Sterile Percutaneous Screws, Sterile and Non-Sterile Minimal Invasive Screws, Sterile and Non-Sterile Odontoid Screws, Sterile and Non-Sterile Laminoplasty Screws, Sterile and Non-Sterile Cervical Screws, Sterile and Non-Sterile Lamina Hooks, Sterile and Non-Sterile Pedicle Hooks, Sterile and Non-Sterile Offset Hooks, Sterile and Non-Sterile Rods, Sterile and Non-Sterile Connectors, Sterile and Non-Sterile Cortical*

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Screws, Sterile and Non-Sterile Plates, Sterile and Non-Sterile Micro Plates, Sterile and Non-Sterile Micro Screws, Sterile and Non-Sterile Domino Connectors, Sterile and Non-Sterile Interspinous Fixators

Ürün Sınıfı / *Class of Product:*

Sınıf IIb - Kural 8
Class IIb - Rule 8

GMDN Kodu/ GMDN Adı:

61325/ Kemik-vidası iç omurga sabitleme sistemi, steril olmayan
61324/ Kemik-vidası iç omurga sabitleme sistemi, steril
46653/ Spinal fiksasyon plakası biyobozunur olmayan
61533/Interspinöz spinal fiksasyon İmplant
46642/ Kranyofasiyal fiksasyon plakası, biyobozunur olmayan

GMDN Code/GMDN Name:

61325/ Bone-screw internal spinal fixation system nonsterile
61324/ Bone-screw internal spinal fixation system sterile
46653/ Spinal Fixation Plate non-bioabsorbable
61533/Interspinous Spinal Fixation Implant
46642/ Craniofacial fixation plate, non-biodegradable

Uygulanan Standart ve Yönetmelikler / *Applicable Harmonized Standards and directives:*
Standartlar listesi referans alındı. / *Standard list is referanced*

Uygunluk Değerlendirme Yolu: MDD (93/42/EEC) EK II- Bölüm 3
Conformity Asssesment Route: MDD (93/42/EEC) ANNEX II- Section3

Onaylanmış Kuruluş Adı / *Name of Notified Body:* Kiwa Belgelendirme Hizmetleri A.Ş.

Onaylanmış Kuruluş Adresi / *Address of Notified Body:*
(İTOSB) İstanbul Tuzla Organize Sanayi Bölgesi Tepeören Mevkii 34957 Tuzla-İstanbul Türkiye

Tel/*Phone:* +90 216 593 25 75 **Faks/***Fax:* +90 216 593 25 74

OSIMPLANT
Spine Restoration Technology

UYGUNLUK BEYANI
Declaration of Conformity

"OSİMPLANT" markasına ait olarak tamamen kendi sorumluluğumuz altında üretmiş olduğumuz bu ürünlerin 93/42/ EEC yönetmeliğinin gereksinimlerine göre üretilip kontrol edildiğini beyan ederiz. / *We declare that, these products which belong to "OSİMPLANT" brand are completely under our responsibility also producted and checked according to the requirements of 93/42/ EEC*

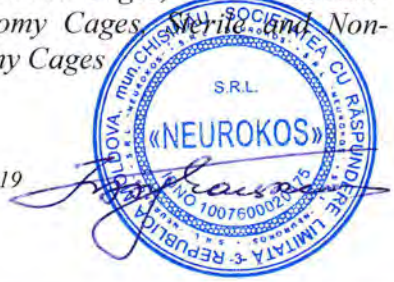
Üretici firma / *Manufacturer*: Osimplant Tıbbi Malzemeler Medikal Tic.Ltd.Şti.

Üretici Adresi/ *Manufacturer Address*: Mustafa Kemal Mah. 2133. Sk. 4/2 Royale Office Çankaya / Ankara-Turkey 06510

Tel / *Phone* : +90 312 473 82 80 **Faks / *Fax*** : +90 312 473 8190
Web: http://osimplant.com.tr/ **E-Mail:** info@osimplant.com.tr

Ürün Adı / *Product Name* : Steril ve Steril Olmayan Spinal Kafesler/*Sterile and Non-Sterile Spinal Cages*
Lomber Kafesler / *Lumbar Cages*
Servikal Kafesler / *Cervical Cages*
Korpektomi Kafesler / *Corpectomy Cages*
Trabeküler Kafesler/ *Trabecular Cages*

Ürün Tipleri /*Product Types:* Steril ve Steril Olmayan Servikal PEEK Kafesler, Steril ve Steril Olmayan Titanyum Kafesler, Steril ve Steril Olmayan Lomber Interbody Kafesler, Steril ve Steril Olmayan Trabeküler Kafesler, Steril ve Steril Olmayan Genişleyebilir Kafesler, Steril ve Steril Olmayan Bıçaklı Kafesler, Steril ve Steril Olmayan Genişleyebilir Bıçaklı Kafesler, Steril ve Steril Olmayan Servikal Korpektomi Kafesler, Steril ve Steril Olmayan Lomber Korpektomi Kafesler / *Sterile and Non-Sterile Cervical PEEK Cages, Sterile and Non-Sterile Titanium Cages, Sterile and Non-Sterile Lumbar Interbody Cages, Sterile and Non-Sterile Trabecular Cages, Sterile and Non-Sterile Expandable Cages, Sterile and Non-Sterile Bladed Cages, Sterile and Non-Sterile Expandable Bladed Cages, Sterile and Non-Sterile Cervical Corpectomy Cages, Sterile and Non-Sterile Lumbar Corpectomy Cages*



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Spine Restoration Technology

Ürün Sınıfı / *Class of Product:*	Sınıf IIb - Kural 8 *Class IIb - Rule 8*
GMDN Kodu/ GMDN Adı:	38161/ Spinal Kafes 57805/ Spinal Füzyon Kafesler, Steril Olmayan 60762/ Polimerik Omurga Füzyon Kafesi, Steril Olmayan 60847/ Polimer Omurga Füzyon Kafesi, Steril 38161/ Metalik Spinal Füzyon Kafesler-Steril 57805/ Metalik Spinal Füzyon Kafesler-Steril Olmayan
GMDN Code/GMDN Name:	*38161/ Spinal Cage* *57805/ Spinal Fusion Cages, Non-Sterile* *60762/ Polymeric Spinal Fusion Cage, Non-Sterile* *60847/ Polymer Spinal Fusion Cage, Sterile* *381611 Metallic Spinal Fusion Cages Sterile* *578051 Metallic Spinal Fusion Cages Non-Sterile*

Uygulanan Standart ve Yönetmelikler / ***Applicable Harmonized Standards and directives:***
Standartlar listesi referans alındı. / *Standard list is referanced.*

Uygunluk Değerlendirme Yolu: ***Conformity Asssesment Route :***	MDD (93/42/EEC) EK II - Bölüm 3 *MDD (93/42/EEC) ANNEX II- Section3*
Onaylanmış Kuruluş Adı / ***Name of Notified Body*:**	Kiwa Belgelendirme Hizmetleri A.Ş.
Onaylanmış Kuruluş Adresi / ***Address of Notified Body* :**	(İTOSB) İstanbul Tuzla Organize Sanayi Bölgesi Tepeören Mevkii 34957 Tuzla-İstanbul Türkiye
Tel/Phone: +90 216 593 25 75	**Faks/Fax:** +90 216 593 25 74

CE Belge No: 1984-MDD-15-320
CE Certificate No:

OSIMPLANT

UYGUNLUK BEYANI
Declaration of Conformity

"OSİMPLANT" markasına ait olarak tamamen kendi sorumluluğumuz altında üretmiş olduğumuz bu ürünlerin 93/42/ EEC yönetmeliğinin gereksinimlerine göre üretilip kontrol edildiğini beyan ederiz. / *We declare that, these products which belong to "OSİMPLANT" brand are completely under our responsibility also producted and checked according to the requirements of 93/42/ EEC*

Üretici firma / Manufacturer: Osimplant Tıbbi Malzemeler Medikal Tic.Ltd.Şti.

Ofis Adres / Office Address: Mustafa Kemal Mah. 2133. Sk. 4/2 Royale Office Çankaya / Ankara-Turkey 06510

Üretim ve Tasarım Adresi: İkitelli O.S.B. Mutfak Eşyaları San. Sit. M4 Blok No:47 Başakşehir / İSTANBUL

Tel / Phone : +90 312 473 82 80 **Faks / Fax** : +90 312 473 8190
Web: http://osimplant.com.tr/
E-Mail: info@osimplant.com.tr

Ürün Adı / *Product Name:* ENSTRÜMAN SETLER
INSTRUMENTS SETS

Ürün Sınıfı: Sınıf-I Diğer (steril ve ölçme fonksiyonu olmayan)
Class of Product: *Class-I Other (without sterile and measuring function)*

Uygunluk Değerlendirme Yolu: MDD (93/42/EEC) EK IX
Conformity Assessment Route: *MDD (93/42/EEC) ANNEX IX*

Yukarıda belirtilen ürünlerin Avrupa Tıbbi Cihaz Direktifi 93/42/EEC, EK-VII uyarınca üretildiğini beyan ederiz.
We, the manufacturer hereby declare that, the above mentioned products are manufactured in accordance with European Medical Device Directive 93/42/EEC, ANNEX-VII.

Ürünler Tıbbi Cihaz Direktifi 93/42/EEC, EK-I Temel Gereksinimlerine uygundur ve CE işareti ile piyasaya sürülebilir. Cihazların MDD (Tıbbi Cihaz Direktifi) 93/42/EEC, EK-VII'e uygun olduğunun değerlendirilmesi münhasır sorumluluğumuz altında gerçekleşmiştir.
Products are suitable for Essential Requirements of Medical Device Directive 93/42/EEC, ANNEX-I and could be marketable with CE mark. The evaluation of the conformity of products

OSIMPLANT

according to MDD 93/42/EEC (European Medical Device Directive), ANNEX-VII is made under the responsibility of Osimplant exclusively.

Ayrıca 93/42/EEC, EK-VII'e göre teknik bir dokümantasyon sistemi kurduğumuzu beyan ederiz.
Besides, we hereby declare that we have established a technical documentation system according to 93/42/EEC, ANNEX-VII.

Deklarasyon Düzenlenme Tarihi: 15 / 01 / 2019
Date of Issuance of Declaration:

SOCIETATEA CU RĂSPUNDERE LIMITATĂ «NEUROKOS» S.R.L. mun. CHIŞINĂU, REPUBLICA MOLDOVA

Şirket Müdürü /
Company Manager

Osimplant Medikal Ticaret Ltd.

Referans Kodu/*Reference Code*	Ürün Adı/*Product Name*	GMDN Kodu/*GMDN Code*
OSI-1020	OSI Spinal Fixation System Instrument Set	16349
PORTHOS-1010	PORTHOS Posterior Cervical System Instrument Set	16349
SENTINUS-1095	SENTINUS Corpectomy Mesh Cage Instrument Set	16349
AURA-1050	AURA Cervical Plate System Instrument Set	16349
X/XP-1060	X-XP Mesh Corpectomy Cage Instrument Set	16349
BIA-1046	BIA Cervical Cage Instrument Set	16349
TITANOPEEK-1031	TITANOPEEK-C Stand Alone Cervical Cage Instrument Set	16349
ARION-1070	ARION Expandable Cervical Bladed Cage Instrument Set	16349
COMBO-1011	ZELOS&FIDES Combined Instrument Set	16349
ULTIO-1040	ULTIO Laminoplasty System Instrument Set	16349
ONPLUS-1021	ON PLUS Spinal Fixation System Instrument Set	16349
HERAKLES-1015	HERAKLES Micro Plate and Screw Instrument Set	16349
JUVE-1030	JUVE Pediatric Spinal System Instrument Set	16349
ATLAS-1022	ATLAS Odontoid Screw Instrument Set	16349
TALOS-1075	TALOS TLIF Cage Instrument Set	16349
EOS-1035	EOS Cervical Bladed Cage Instrument Set	16349
PAN-1033	PAN Cervical Disc Prosthesis Instrument Set	16349
PALES-1023	PALES Transfacet Pedicle Screw System Instrument Set	16349
ARIA-1080	ARIA Expandable PLIF Cage Instrument Set	16349
ZELOS-1085	ZELOS PLIF Cage Instrument Set	16349
FIDES-1065	FIDES Angular TLIF Cage Instrument Set	16349
STRATOS-1032	STRATOS Interspinous Fixation System Instrument Set	16349

CERTIFICATE

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OSIMPLANT

OSİMPLANT TIBBİ MALZEMELER VE MEDİKAL TİCARET LİMİTED ŞİRKETİ

MUSTAFA KEMAL MAHALLESİ 2133. SOKAK NO: 4/2 ÇANKAYA – ANKARA – TURKEY

with a scope of

DESIGN AND PRODUCTION OF SPINAL IMPLANTS

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded"
"7.5.3" "7.5.4"

EN ISO 13485:2016

Certificate No	: M 10028
Initial Certification Date	: 11 March 2013
Certification Date	: 20 February 2019
Expiration Date	: 19 February 2022

General Manager

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

TÜRKAK
Medical Device Q.M.S.
TS EN ISO/IEC 17021-1
AB-0006-YS
TÜRKAK BDS NO
YS-E870-0BC4

Last Modified: 20 February 2019 - R 04

CERTIFICATE

kiwa

OSIMPLANT

OSİMPLANT TIBBİ MALZEMELER VE MEDİKAL TİCARET LİMİTED ŞİRKETİ

MUSTAFA KEMAL MAHALLESİ 2133. SOKAK NO: 4/2 ÇANKAYA – ANKARA – TURKEY

with a scope of

DESIGN AND PRODUCTION OF SPINAL IMPLANTS

Has established a quality management system in accordance with international standard.

" Following elements of the standard are excluded "

" None "

ISO 9001:2015

Certificate No	: M 10027
Initial Certification Date	: 11 March 2013
Certification Date	: 01 October 2018
Expiration Date	: 30 September 2021

General Manager

MOLDOVA, mun.CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ «NEUROKOS» S.R.L. IDNO 1007600021

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

Last Modified: 10 January 2019 - R 04

TÜRKAK
Quality Management System
TS EN ISO/IEC 17021-1
AB-0006-YS

TÜRKAK BDS NO
YS-C4BF-F2B1