

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:

**OSİMLANT 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



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



Enclosure of the EC Certificate:

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

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

Concerned medical devices;

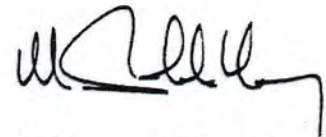
Product: Sterile and Non Sterile Spinal Cages

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



Muhtesem Gökhan Yücel
Head of Notified Body

02 December 2020, Istanbul, Turkey



UYGUNLUK BEYANI

Declaration of Conformity

"OSIMPLANT" 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 "OSIMPLANT" brand are completely under our responsibility also produced 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 İnvasiv, Perkütan Vida Spinal Fiksasyon Sistemi/ *CERES Minimally Invasive, Percutaneous Screw Spinal Fixation System*

STRATOS Interspinöz Fiksator 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*



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 Poliaksiyel 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 Fiksatorler/ *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*



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 referenced*

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

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

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



UYGUNLUK BEYANI
Declaration of Conformity

"OSİMLANT" 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 "OSİMLANT" brand are completely under our responsibility also produced and checked according to the requirements of 93/42/ EEC*

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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*



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 referenced.

Uygunluk Değerlendirme Yolu:
Conformity Assesment Route :

MDD (93/42/EEC) EK II - Bölüm 3
MDD (93/42/EEC) ANNEX II- Section3

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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

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CE Belge No: 1984-MDD-15-320

CE Certificate No:





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

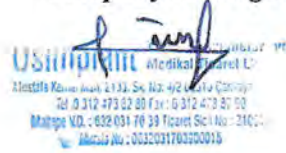
Ayrıca 93/42/EEC, EK-VII'e göre teknik bir dokümantasyon sistemi kurduğumuzu beyan ederiz.

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:



Şirket Müdürü /
Company Manager



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



Osmanlı
Türk
Mühür
Mühür
Mühür



CERTIFICATE



OSIMPLANT TIBBİ MALZEMELER VE MEDİKAL TİCARET LİMİTED ŞİRKETİ

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

DESIGN AND PRODUCTION OF SPINAL IMPLANTS

with a scope of

EN ISO 13485:2016

Has established a management system in accordance
with international Medical Devices Quality Management System Standard

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

Certificate No	: M 10028
Initial Certification Date	: 11 March 2013
Certification Date	: 04 March 2022
Expiration Date	: 03 March 2025

Kiwa Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cadde No. 15 Tepeören Tuzla
Istanbul / Turkey

Tel: + 90 216 593 25 75
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info@kiwa.com.tr
www.kiwa.com.tr

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

General Manager



TÜRKAK BDS NO
YS-441E-EC00