

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.

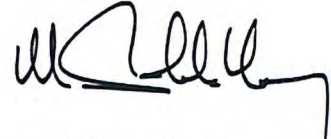
Organization:**OSİMLANT TIBBİ MALZEMELER VE MEDİKAL
TİCARET LİMİTED ŞİRKETİ**

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: 11 May 2021
Revision Number: 06
Expiry Date: 27 May 2024



Muhteşem Gökhan Yücel
Head of Notified Body

11 May 2021, Istanbul, Turkey

Enclosure of the EC Certificate:

Page 1/2

Full Quality Assurance System according to

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

Certificate Number: 1984-MDD-15-320, Revision Number: 06

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



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Enclosure of the EC Certificate:**Page 2/2****Full Quality Assurance System according to****Medical Devices Directive 93/42/EEC Annex-II Section 3****Certificate Number: 1984-MDD-15-320, Revision Number: 06**

Concerned medical devices;

Product: Sterile and Non Sterile Spinal Cages

TALOS PEEK TLIF Cage
ZELOS PEEK-TITANIUM PLIF Cage
TERRACOTTA Trabecular Titanium Lumbar Interbody TLIF Cage
TERRACOTTA Trabecular Titanium Lumbar Interbody PLIF Cage
TERRACOTTA-C Trabecular Titanium Cervical Cage
SENTINUS-C Cervical Corpectomy Mesh Cage
SENTINUS-L Lumbar Corpectomy Mesh Cage
X-XP Corpectomy Cage
ANTENOR Stand Alone ALIF 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

11 May 2021, Istanbul, Turkey