



CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-18-526

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:

TST RAKOR ve TIBBİ ALETLER SANAYİ ve TİCARET LİMİTED ŞİRKETİ

Sanayi Mahallesi, Şehit Cevdet Çelenk Caddesi No:3 34912
Kurtköy, Pendik, İstanbul, Turkey

Products: Plate–Screw System, Spinal System, External Fixator System, Intramedullary Nails, Hip Prosthesis

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

Report Number: M.3345.09
Date of first issue: 04 June 2018
Date of last issue: 18 October 2019
Revision Number: 01
Expiry Date: 03 June 2021

Design Examination according to Medical Devices Directive 93/42/EEC Annex-II Section 4 certificate is also mandatory for class III devices covered by this certificate.

Muhteşem Gökhan Yücel
Head of Notified Body

18 October 2019, Istanbul, Turkey

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Concerned medical devices;

Product: Plate – Screw System

Product Group	Models	Class
Plates	Pelvic-Acetabulum plates, Femur plates, Tibia plates, Fibula plates, Calcaneus plates, Face plates (mandibular plates, mini plates), Clavicle plates, Scapula plates, Sternum plates, Humerus plates, Ulna-radius plates, Metacarpus and finger plates, Metatarsus and finger plates (Anatomic or straight, Locking or Non-locking, for pediatric or adult, Titanium or Stainless Steel)	IIb
Screws	Cortex screws, Cortical screws, Cancellous/Spongious screws, Compression screws, Malleolar screws, Connection screws, Cannulated screws (Self-tapping or not selftapping, self drilling or not self drilling, Low profile or not low profile, Locking or non-locking, Titanium or Stainless Steel)	IIb
Pins	Calibrated or not calibrated, trocar, threaded or not threaded pins, Steinmann pins, Cerclage pins, Knowless pins, Rush pins, Threaded compression pins (Titanium or Stainless Steel)	IIb
Wedges	OWO block	IIb
U-Nails	Stepped or U-shaped or barbed (Titanium or Stainless Steel or CoCrMo)	IIb
Wires	Bayonet or trocar wires, threaded or not threaded Kirschner wires, Ender wires (Titanium or Stainless Steel)	IIb
Cable+Swage	CrNi or CoCrMo or Titanium	IIb
Washers	Compression washers, threaded compression pin washers, screw washers (Titanium or Stainless Steel)	IIb



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Product: Spinal System

Product Group	Models	Class
Screws	Polyaxial or Monoaxial screws, Servical screws, Sacral screws, Sacral bolt, Expandable screws, Iliac screws, Iliac bolt, Spondilolistezis screws, Dynamic screws-HA coated or not (InterLocking or not interLocking, low profile or not low profile, Pediatric or adult)	IIb
Hooks	Laminar or Pedicular hooks (Pediatric or adult) Connector hooks	IIb
Plates	Anterior, servical plates (Locking or Non-locking, pediatric or adult)	IIb
Blockers	Screw caps, Nuts	IIb
Bridges	Spinal bridges	IIb
Connectors-Clamps	Single or double connectors, Polyaxial connectors, Multidirectional and multiaxial connectors, Transverse connector clamps (Angled or not angled, Pediatric or adult)	IIb
Rods	Sacral rods, Transverse rods, Straight rods, Curved rods (pediatric or adult)	IIb

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Product: External Fixator System

Product Group	Models	Class
Fixators	Femur Fixator (Ilizarov Fixator, LRS, DAF (dynamic multiaxial Fixator), UMEF [Ultra Modular External Fixator], MAMEF [Modular Adjustable Multiaxial External Fixator]), Tibia Fixator (Ilizarov Fixator, OWO-FIX, LRS, UMEF, MAMEF) Humerus Fixator (Ilizarov Fixator, Elbow Fixator, DAF, UMEF) Ulna-Radius Fixator (Ilizarov Fixator, Elbow Fixator, UMEF) El-Bilek Fixator (Colles Fixator) Parmak Fixator, (Mini Fixator) Mandibula Fixator (Mini Fixator) Pelvis Fixator (DAF) (Lengthening, Deformity correction fixator, Bone segment transportation fixator, Articulated or not articulated, Mono or poly axial or plane, Segmental or not segmental, Titanium, Aluminium or Fiber Carbon)	IIb
Clamps	For Femur, tibia, humerus, ulna, radius (135° and or any other angled clamps, double, T, Hybrid connector clamp, Multi axial connector clamp, Rod-rod clamp, Double schanz clamp, Ilizarov clamps, Pilon clamps, UMEF clamps)	IIb
Plates	Threaded pointed or not threaded pointed connector plates, Twisted plates, Curved plates, Stainless Steel, Aluminium or fiber Carbon	IIb
Rings	C Rings, 5\8 C Rings, Half Rings, Foot Rings, Omega rings, Aluminium or Stainless Steel or Fiber Carbon	IIb
Arches	Femoral arches 90°, 120° Stainless Steel, Aluminium or Fiber Carbon	IIb
Nuts	Nuts M6, Quadragonal nuts, Teflon nuts, Bushing	IIb

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Product: External Fixator System

Product Group	Models	Class
Bolts	Bolts M6, Cannulated, Hexagonal, Single or Multiple, Polyaxial (Polygonal or threaded), Slotted, Serrated, Angled, Universal pin fixation bolts	IIb
Screws	Schanz screws (cortical or cancellous, calibrated or not calibrated, self-cutting or not, self-drilling or not, conical or not, or Trocar pointed, Titanium or Stainless Steel, coated or not coated), Connector screws	IIb
Rods	Threaded Rods, Cannulated threaded rods, Slotted Rods, Telescopic rods, Stainless Steel or Aluminium or fiber Carbon rods	IIb
Washers	Conical or not conical washers, Couple washers, Serrated washers, Slotted washers, Special washers	IIb
Supports, Connectors	Male supports, Female supports (half hinge), Universal half hinge, Multiangled universal half hinge, Half pin supporting cube, Oblique support connector	IIb
Wires	Olive wires	IIb
Sockets	Threaded Sockets	IIb
Blocks	Translation rotation block	IIb
Stirrups	Kirschner stirrups, Steinmann stirrups	IIb

Product: Intramedullary Nails

Product Group	Models	Class
Nail Locking Screws- Compression Screws- End Caps	Proximal Locking Screws, Distal Locking Screws, Lag Screws, Compression Screws, Set Screws, "DSBLS" Screws, Cannulated screws, End Caps (Locking or Non-locking, Titanium or Stainless Steel)	IIb

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Product: Intramedullary Nails

Product Group	Models	Class
Nails	Clavicular Intramedullary Nails, Humeral Intramedullary Nails, Radial Intramedullary Nails, Ulnar Intramedullary Nails, Femoral Intramedullary Nails, Tibial Intramedullary Nails, Fibular Intramedullary Nails, Arthrodesis Intramedullary Nails (Locking or Non-locking, elastic or rigid, for pediatric or adult, Titanium or Stainless Steel)	IIb

Product: Hip Prosthesis

Product Group	Models	Class
Stems	Calcar Replacement Stems	III
	Supra Art-1 Stems	III
	Volumed Modular Stems	III
	Arthrom Stems, Arthrom Bodies, Arthrom Junction Bolts	III
Acetabular Components	Modular Heads	III
	Acetabular Cups	III
	Bipolar Heads	III
	Unipolar Heads, A. Unipolar Heads, A. Unipolar Rings	III
	Press Fit Cups, Anatomic Press Fit Cups, Press Fit Cup Screws, Acetabulum Screws	III
	Inserts for Press Fit Cup, Inserts for Anatomic Press Fit Cup	III
	Plugs	IIb
	Centralizers	IIb

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

18 October 2019, Istanbul, Turkey