

Manufacturer:

TST Rakor ve Tibbi Aletler San. Ve Tic. Ltd. Şti. Sanayi
Mahallesi, Şehit Cevdet Çelenk Cad. No:3
34912 Kurtköy –Pendik/İstanbul
Turkey

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**European Declaration of Conformity
to the Medical Device Directive, 93/42/EEC With 2007/47/EC**



General Name of the Products : Orthopedic Implants
Products : See page 2-3
Description : Implantable and long-term surgically invasive devices

Sterility : Sterile (With Radiation)/Non-Sterile

Classification / Rule : Class III & Class IIb Rule 8
(acc. to MDD – Annex IX)

Conformity Assessment Route: Annex II of the Medical Devices Directive 93/42/EEC with 2007/47/EC

Declaration :

1. TST Rakor ve Tibbi Aletler San. Ve Tic. Ltd. Şti. declares that the above product to which this declaration relates, bears the CE Marking, and is in conformity with the applicable requirements of the Council Directive MDD 93/42/EEC with 2007/47/EC, concerning medical devices, which allows its free distribution, sale and circulation in EEC. Standards that ISO 13485; TS EN ISO 14630; TS EN ISO 14155; Meddev 2.7.1; TS ISO 5832; TS EN ISO 14971; TS EN ISO 15223-1; EN ISO 10993; EN ISO 11607-1; EN ISO 11607-2; EN ISO 11737-1; EN ISO 11737-2; EN ISO 14937; EN ISO 16061; EN ISO 17664; EN ISO 17665-1; EN 27740; EN 62366; EN ISO 21534; EN ISO 21535 are applied. All of related standarts are in the TST.F.01/11 list of outsourced documents.

2. As required by the above mentioned Directive, this Declaration is supported by:

EC Certificate No: 1984-MDD-18-526(93/42/AT Annex II Section 3)
1984-MDD-18-527(93/42/AT Annex II Section 4)

Notified Body: Kiwa Certification Services Inc.
Address of Notified Body: ITOSB 9.Cadde No:15 Tepeören Tuzla - İstanbul – Turkey
Notified Body No: 1984

All supporting documentation is retained at the manufacturer's premises

The present EC Declaration of Conformity is applicable to all mentioned medical devices, manufactured by TST R. ve Tibbi Aletler, İstanbul, Turkey, and/or anyway realized under the Manufacturer's Certified Quality System control for validation period of CE certificate mentioned above

On behalf of TST R Tibbi Aletler,

Date/Location : 04.11.2021/İstanbul

Signature

Seda ARSLAN

Quality Assurance Manager

Product(s) included within the scope of the Declaration of Conformity for TST Orthopedic Implants Products Group:

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 (<i>Anatomic or straight, Locking or Non-locking, for pediatric or adult, Titanium or Stainless Steel</i>)	IIb
Screws	Cortex screws, Cortical screws, Cancellous/Spongious screws, Compression screws, Malleolar screws, Connection screws, Cannulated screws (<i>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</i>)	IIb
Pins	Calibrated or not calibrated, trocar, threaded or not threaded pins, Steinmann pins, Cerclage pins, Knowless pins, Rush pins, Threaded compression pins (<i>Titanium or Stainless Steel</i>)	IIb
Wedges	OWO block	IIb
U-Nails	Stepped or U-shaped or barbed (<i>Titanium or Stainless Steel or CoCrMo</i>)	IIb
Wires	Bayonet or trocar wires, threaded or not threaded Kirschner wires, Ender wires (<i>Titanium or Stainless Steel</i>)	IIb
Cable+Swage	CrNi or CoCrMo or Titanium	IIb
Washers	Compression washers, threaded compression pin washers, screw washers (<i>Titanium or Stainless Steel</i>)	IIb
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 (<i>InterLocking or not interLocking, low profile or not low profile, Pediatric or adult</i>)	IIb
Hooks	Laminar or Pedicular hooks (<i>Pediatric or adult</i>) Connector hooks	IIb
Plates	Anterior, servical plates (<i>Locking or Non-locking, pediatric or adult</i>)	IIb
Blockers	Screw caps, Nuts	IIb
Cages	Servical Plate Cages, Servical cages, other region cages	IIb
Mesh	Spinal mesh	IIb
Bridges	Spinal bridges	IIb
Connectors-Clamps	Single or double connectors, Polyaxial connectors, Multidirectional and multiaxial connectors, Transverse connector clamps (<i>Angled or not angled, Pediatric or adult</i>)	IIb
Rods	Sacral rods, Transverse rods, Straight rods, Curved rods (<i>pediatric or adult</i>)	IIb
External Fixator System		
Product Group	Models	Class
Fixators	Femur Fixator (<i>Ilizarov Fixator, LRS, DAF (dynamic multiaxial Fixator), UMEF [Ultra Modular External Fixator], MAMEF [Modular Adjustable Multiaxial External Fixator]</i>), Tibia Fixator (<i>Ilizarov Fixator, OWO-FIX, LRS, UMEF, MAMEF</i>) Humerus Fixator (<i>Ilizarov Fixator, Elbow Fixator, DAF, UMEF</i>) Ulna-Radius Fixator(<i>Ilizarov Fixator, Elbow Fixator, UMEF</i>) El-Bilek Fixator(<i>Colles Fixator</i>) Parmak Fixator, (<i>Mini Fixator</i>) Mandibula Fixator (<i>Mini Fixator</i>) Pelvis Fixator (<i>DAF</i>) (<i>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</i>)	IIb
Clamps	For Femur, tibia, humerus, ulna, radius (<i>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</i>)	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
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-	IIb

	drilling or not, conical or not, or Trocar pointed, Titanium or Stainless Steel, coated or not coated), Connector screws	
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 (<i>half hinge</i>), 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
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 (<i>Locking or Non-locking, elastic or rigid, for pediatric or adult, Titanium or Stainless Steel</i>)	IIb
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 (<i>Locking or Non-locking, Titanium or Stainless Steel</i>)	IIb
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
	Anatomic Press Fit Cups, Press Fit Cup Screws, Acetabulum Screws	III
	Inserts for Anatomic Press Fit Cup	III
	Plugs	IIb
	Centralizers	IIb



Approved by

Seda ARSLAN

Quality Assurance Manager