

Manufacturer:

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

Document No/Revision No/Date:

TST.F.43.05/00/20.11.2017

Content Revision No/Date:

REV 18/24.01.2020

**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
Description : Supporting equipments for implanting surgically medical device
Sterility : Non-Sterile
Classification / Rule : Class I Rule 6
(acc. to MDD – Annex IX)
Conformity Assessment Route: Annex VII 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 14971; EN 62366 are applied. All of related standarts are in the TST.F.01/11 list of outsourced documents.

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.

On behalf of TST R Tibbi Aletler,

Date/Location : 24.01.2020 /İstanbul
Signature

Seda ARSLAN

Quality Assurance Manager

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

Product Groups	Types	GMDN
Instruments	Staple Impactors	10458
	Chisel	10825
	Design Tray	12143
	Impactors- Extractors	12696
	Head Extractor	13180
	Containers	13730
	Awls	15275
	Taps for Cannulated Screws	16462
	Taps	17507
	Impactors- Hammers	32312
	Drills- Reamers	32390
	Reduction Tools	32854
	Impactors- Holders	32856
	Cable Passer	32864
	Wrenches	32871
	Rod Pushers	32886
	Inserters	33968
	Sleeves	34004
	Positioners	35095
	Connection tools	35166
	Reamers - Rasps	35297
	Retractors	35315
	Trials	36313
	Elevators	38168
	Tensioners	47715
	Benders	44795
	Cutters	44805
	Graft inserters	44869
	Markers	45170
	Guide Wires	46165
	Holders/ Grippers	46751
	Trochars	47457
	Trials - Inserters	47807
	Templates	47815
	Guides	47847
	Screwdrivers/Tips	33968

Approved by

Seda ARSLAN

Quality Assurance Manager

