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Accreditation Scope

 Test TS EN ISO/IEC 17025 AB-1535-T	LABİOTEK BİYOTEKNOLOJİ LABORATUVARLARI PROTEZ SANAYİ VE TİCARET LİMİTED ŞİRKETİ	
	Accreditation Nr: AB-1535-T Revision Nr: 01 Date: 13.12.2022	
As a Testing Laboratory		
Address: SÖĞÜTÖZÜ MAHALLESİ SÖĞÜTÖZÜ CADDESİ NO:43 (TOBB EKONOMİ VE TEKNOLOJİ ÜNİVERSİTESİ YERLEŞKESİ)		Phone : 03122924506 Fax : E-Mail : info@labiotech.com.tr Website : www.labiotech.com.tr

Tested Materials / Products	Name of Test	Testing Method (National, International standards, in house methods)
Intramedullary Fixation Devices	Test Method for Static Four-Point Bend Test	ASTM F 1264- ANNEX A.1
Intramedullary Fixation Devices	Test Method for Static Torsional Testing of Intramedullary Fixation Devices	ASTM F 1264- ANNEX A.2
Intramedullary Fixation Devices	Test Method for Bending Fatigue Testing of Intramedullary Fixation Devices	ASTM F 1264- ANNEX A.3
Intramedullary Fixation Devices	Test Method for Bending Fatigue Testing of IMFD Locking Screws	ASTM F 1264- ANNEX A.4
Metallic Bone Plates	Standard Test Method for Single Cycle Bend Testing of Metallic Bone Plates	ASTM F 382 - ANNEX A.1
Metallic Bone Plates	Standard Test Method for Determining the Bending Fatigue Properties of Metallic Bone Plates	ASTM F 382 - ANNEX A.2
Metallic Medical Bone Screws	Test Method for Determining The Torsional Properties of Metallic Bone Screws	ASTM F 543 - ANNEX A.1
Metallic Medical Bone Screws	Test Method for Determining The Axial Pullout Strength of Medical Bone Screws	ASTM F 543 - ANNEX A.3
Endosseous Dental Implant	Dynamic Fatigue Test	TS EN ISO 14801-5
Spinal Arthrodesis Implants	Flexion/Extansion Moment Test Axial Gripping Capacity Test Axial Torque Gripping Capacity Test	ASTM F1798-21



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Tested Materials / Products	Name of Test	Testing Method (National, International standards, in house methods)
Intervertebral Body Fusion Devices	Static Compression Test Dynamic Compression Test Static Torsion Test	ASTM F 2077-22
Spinal Artificial Discs	Static Compression Test Dynamic Compression Test Static Torsion Test	ASTM F 2346-18
Intervertebral Body Fusion Devices	Subsidence Test	ASTM F 2267-04(2018)
Metal Tibial Tray Components of Total Knee Joint Replacements	Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	ASTM F1800-19e1
Modular Prostheses	Axial Disassembly Test for Taper Connections of Modular Prostheses	ASTM F 2009-20
Implantable Strands and Cables	Standard Specification for Metallic Implantable Strands and Cables	ASTM F 2180-17
Endosseous Dental Implants	Torsion Test of Implant Body/Connecting Part Joints of Endosseous Dental Implant Systems	ISO TS 13498:2011
Orthodontic Anchor Screws	Fracture Torque Test of Orthodontic Anchor Screws	ISO 19023:2018
Stainless Steel Needle Tubing	Test Method for Stiffness of Tubing	TS EN ISO 9626:2016-ANNEX B
Stainless Steel Needle Tubing	Test Method for Resistance of Tubing to Breakage	TS EN ISO 9626:2016-ANNEX C
Stainless Steel Needle Tubing	Test Method for Resistance to Corrosion	TS EN ISO 9626:2016-ANNEX D
Absorbable Plates and Screws	Axial Pullout Test of Absorbable Bone Screws	ASTM F2502-17-ANNEX A3



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Tested Materials / Products	Name of Test	Testing Method (National, International standards, in house methods)
Absorbable Plates and Screws	Static Bending Test of Absorbable Bone Plates	ASTM F2502-17-ANNEX A4
Absorbable Plates and Screws	Torsion Test of Absorbable Bone Screws	ASTM F 2502-17-ANNEX A1
Modular Acetabular Devices	Axial Disassembly Test	ASTM F 1820-22-4.2
Modular Acetabular Devices	Offset Pullout or Lever Out Disassembly Test	ASTM F1820-22-4.3
Modular Acetabular Devices	Torque Out Disassembly Test	ASTM F1820-22-4.4
External Skeletal Fixation Devices	Test Method For Determining In-Plane Compressive Properties Of Circular Ring Or Ring Segment Bridge Elements	ASTM F1541-17-A3
External Skeletal Fixation Devices	Four-Point Bending Test for External Fixator Pins	ASTM F1541-17-A5.8.1
External Skeletal Fixation Devices	Torsion Test for External Skeletal Fixator Pins	ASTM F1541-17-A5.8.2
External Skeletal Fixation Devices	Axial Load Test for External Skeletal Fixator-Bone Constructs	ASTM F1541-17-A7.10.15
External Skeletal Fixation Devices	Torsion Test for External Skeletal Fixator-Bone Constructs	ASTM F1541-17-A7.10.17
External Skeletal Fixation Devices	Fatigue Test for External Skeletal Fixator-Bone Constructs	ASTM F1541-17-A.7.10.18
Metallic Angled Orthopedic Fracture Devices	Static Compression Bending Test	ASTM F 384-17-A1
Metallic Angled Orthopedic Fracture Devices	Bending Fatigue Test	ASTM F 384-17-A2



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Tested Materials / Products	Name of Test	Testing Method (National, International standards, in house methods)
Spinal Implant Constructs	Static Compression Bending Test	ASTM F1717-21-8.1.1
Spinal Implant Constructs	Static Tension Bending Test	ASTM F1717-21-8.1.2
Spinal Implant Constructs	Static Torsional Test	ASTM F1717-21-8.1.3
Spinal Implant Constructs	Dynamic Compression Bending Test (Fatigue Test)	ASTM F1717-21-8.2
Sterile Hypodermic Needles for Single Use	Test Methods for Sterile Hypodermic Needles for Single Use	ISO 7864:2016- ANNEX E
Sterile Hypodermic Needles for Single Use	Test Method for Measuring The Penetration Force And Drag Force for Needles	ISO 7864:2016 -ANNEX D
Syringes for Manual Use	Evaluation of Tolerance on Graduated Capacity	ISO 7886-8
Syringes for Manual Use	Evaluation of Graduated Scale	ISO 7886-9
Syringes for Manual Use	Evaluation of Barrel	ISO 7886-10
Syringes for Manual Use	Evaluation of Plunger Stopper/Plunger Assembly	ISO 7886-11
Syringes for Manual Use	Evaluation of Nozzle	ISO 7886-12
Syringes for Manual Use	Method for Determination of Dead Space	ISO 7886- ANNEX C
Occipital-Cervical-Thoracic Spinal Implant Constructs	Static Compression Bending Test	ASTM F2706-18-8.1.1



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Tested Materials / Products	Name of Test	Testing Method (National, International standards, in house methods)
Occipital-Cervical-Thoracic Spinal Implant Constructs	Static Tension Bending Test	ASTM F2706-18-8.1.2
Occipital-Cervical-Thoracic Spinal Implant Constructs	Static Torsional Test	ASTM F2706-18-8.1.3
Occipital-Cervical-Thoracic Spinal Implant Constructs	Dynamic Compression Bending Test (Fatigue Test)	ASTM F2706-18-8.2.1
Stemmed Femoral Components	Determination of Endurance Properties and Performance of Stemmed Femoral Components	ISO 7206-4:2010
Stemmed Femoral Components	Determination of Endurance Properties of Head and Neck Region of Stemmed Femoral Components	ISO 7206-6:2013
Stemmed Femoral Components	Static Compression Test	ISO 7206-10:2018
Stemmed Femoral Components	Determination of Resistance to Torque of Head Fixation of Stemmed Femoral Components	ISO 7206-13:2016
Metallic Spinal Rods, Plates and Screws	Static Bending Strength Test for Metallic Spinal Screws	ASTM F2193-20-A1
Metallic Spinal Rods, Plates and Screws	Static Bending Test for Spinal Plates Fatigue Bending Test for Spinal Plates	ASTM F2193-20-A2
Metallic Spinal Rods, Plates and Screws	Static Bending Test for Spinal Rods Fatigue Bending Test for Spinal Rods	ASTM F2193-20-A3



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Tested Materials / Products	Name of Test	Testing Method (National, International standards, in house methods)
Metalic Spinal Rods,Plates and Screws	Fatigue Bending Strength Test for Metallic Spinal Screws	ASTM F2193-20-A4

End of Scope



G. Banu MÜDERRİSOĞLU
Secretary General

