

 Test TS EN ISO/IEC 17025 AB-1535-T	LABİOTEK BİYOTEKNOLOJİ LAB.PROTEZ S.VE T.L.Ş. Accreditation Nr: AB-1535-T Revision Nr: 02 Date: 23.05.2025 Testing Laboratory <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> Address : BEŞTEPE MAH. SÖĞÜTÖZÜ CAD. No:43/ YENİMAHALLE/ANKARA Ankara / Türkiye </td><td style="width: 50%; vertical-align: top;"> Phone : +90 312 292 4506 Fax : - Email : fkerbay@labiotech.com.tr Website : </td></tr> </table>	Address : BEŞTEPE MAH. SÖĞÜTÖZÜ CAD. No:43/ YENİMAHALLE/ANKARA Ankara / Türkiye	Phone : +90 312 292 4506 Fax : - Email : fkerbay@labiotech.com.tr Website :
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Medical Devices		
Tested Materials / Products	Name of Test	Testing Method (National, International Standards, In-house Methods)
Intramedullary Fixation Devices	Static Torsional Test	ASTM F1264 - ANNEX A2
Intramedullary Fixation Devices	Bending Fatigue Test	ASTM F1264 - ANNEX A3
Intramedullary Fixation Devices	Bending Fatigue Test Method for IMFD Locking Screws	ASTM F1264 - ANNEX A4
Metalic Bone Plates	Single Cycle Bending Test	ASTM F382 - ANNEX A1
Metallic Bone Plates	Bending Fatigue Test	ASTM F382 - ANNEX A2
Metallic Medical Bone Screws	Static Torsional Test	ASTM F543 - ANNEX A1
Metallic Medical Bone Screws	Axial Pullout Load Test	ASTM F543 - ANNEX A3
Spinal Arthrodesis Implants	Flexion/Extension Moment Test Axial Gripping Capacity Test Axial Torque Gripping Capacity Test	ASTM F1798
Intervertebral Body Fusion Devices	Static Axial Compression Test Dynamic Axial Compression Test Static Torsion Test	ASTM F2077
Spinal Artificial Discs	Static Axial Compression Test Dynamic Axial Compression Test Static Torsion Test	ASTM F2346
Intervertebral Body Fusion Devices	Subsidence Test	ASTM F2267
Metal Tibial Trays Components of Total Knee Joint Replacements	Cyclic Fatigue Test	ASTM F1800
Modular Prostheses	Axial Disassembly Test of Taper Connections	ASTM F2009
Metallic Implantable Strands and Cables	Tensile Test	ASTM F2180
Implant Body/Connecting Part Joints of Endosseous Dental Implant Systems	Static Torsion Test	ISO/TS 13498
Orthodontic Anchor Screws	Fracture Torque Test	ISO 19023
Stainless Steel Needle Tubing	Stiffness Test	ISO 9626 - ANNEX B



Accreditation Scope

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Stainless Steel Needle Tubing	Breakage Resistance Test	ISO 9626 - ANNEX C
Stainless Steel Needle Tubing	Corrosion Resistance Test	ISO 9626 - ANNEX D
Absorbable Bone Screws	Axial Pullout Load Test	ASTM F2502 - ANNEX A3
Absorbable Bone Plates	Static Bending Test	ASTM F2502 - ANNEX A4
Absorbable Bone Screws	Static Torsional Test	ASTM F2502 - ANNEX A1
Modular Acetabular Devices	Axial Dissassembly Test	ASTM F1820
Modular Acetabular Devices	Offset Pullout or Lever Out Dissassembly Test	ASTM F1820
Modular Acetabular Devices	Torque Out Disassembly Test	ASTM F1820
External Skeletal Fixation Devices	Compression Test of Circular Ring or Ring Segment Bridge Elements	ASTM F1541 - ANNEX A3
Stemmed Femoral Components	Static Compression Test Static Tensile Test	ISO 7206-10
External Skeletal Fixation Devices	Static Four-Point Bending Test Static Torsion Test	ASTM F1541 - ANNEX A5
External Skeletal Fixation Devices	Static Axial Load Test Static Torsion Test Dynamic Test	ASTM F1541 - ANNEX A7
Stemmed Femoral Components	Fatigue Test Of Head And Neck Region	ISO 7206-6
Metallic Angled Orthopedic Fracture Devices	Single Cycle Compression Bending Test	ASTM F384 - ANNEX A1
Metallic Angled Orthopedic Fracture Devices	Bending Fatigue Test	ASTM F384 - ANNEX A2
Spinal Implant Constructs	Static Tension Bending Test	ASTM F1717
Spinal Implant Constructs	Static Torsion Test	ASTM F1717
Spinal Implant Constructs	Dynamic Compression Bending Test	ASTM F1717
Spinal Implant Constructs	Static Compression Bending Test	ASTM F1717
Disposable Sterile Hypodermic Syringes	Evaluation of Tolerance on Graduated Capacity	ISO 7886-1



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Disposable Sterile Hypodermic Syringes	Evaluation of Graduated Scale	ISO 7886-1
Disposable Sterile Hypodermic Syringes	Evaluation of Barrel	ISO 7886-1
Disposable Sterile Hypodermic Syringes	Evaluation of Plunger Stopper/Plunger Assembly	ISO 7886-1
Disposable Sterile Hypodermic Syringes	Evaluation of Nozzle	ISO 7886-1
Disposable Sterile Hypodermic Syringes	Dead Space Determination Test	ISO 7886-1 - ANNEX C
Occipital-Cervical-Thoracic Spinal Implant Constructs	Static Compression Bending Test	ASTM F2706
Occipital-Cervical-Thoracic Spinal Implant Constructs	Static Tension Bending Test	ASTM F2706
Occipital-Cervical-Thoracic Spinal Implant Constructs	Static Torsion Test	ASTM F2706
Occipital-Cervical-Thoracic Spinal Implant Constructs	Dynamic Compression Bending Test (Fatigue Test)	ASTM F2706
Stemmed Femoral Components	Torque Resistance Test of Femoral Head	ISO 7206-13
Metalic Spinal Screws	Static Bending Test	ASTM F2193 - ANNEX A4
Metalic Spinal Plates	Static Bending Test Fatigue Bending Test	ASTM F2193 - ANNEX A2
Metalic Spinal Rods	Static Bending Test Fatigue Bending Test	ASTM F2193 - ANNEX A3
Metalic Spinal Screws	Fatigue Bending Test	ASTM F2193 - ANNEX A4
Intramedullary Fixation Devices	Static Four-Point Bending Test	ASTM F1264 - ANNEX A1
Endosseous Dental Implants	Dynamic Loading Test	TS EN ISO 14801
Disposable Sterile Hypodermic Needles	Determination of Needle Penetration and Drag Force	TS EN ISO 7864 Ek D
Disposable Sterile Hypodermic Needles	Determination of Needle Clamping Force	TS EN ISO 7864 Ek E
Stemmed Femoral Components	Fatigue Test	ISO 7206-4

