



INTERNATIONAL
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CERTIFICATE OF ACCREDITATION

This is to attest that

TECHNICAL UNIVERSAL VERIFICATION BELGELENDİRME LABORATUVAR EĞİTİM VE SAĞLIK HIZM. SAN. TIC. LTD. ŞTİ.

MACUN MAHALLESİ ATB İŞ MERKEZİ A BLOK NO:3 YENİMAHALLE
ANKARA 06560, TURKEY

Testing Laboratory TL-1000

has met the requirements of AC89, *IAS Accreditation Criteria for Testing Laboratories*, and has demonstrated compliance with ISO/IEC Standard 17025:2017, *General requirements for the competence of testing and calibration laboratories*. This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date February 1, 2024



President

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SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

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Accredited to ISO/IEC 17025:2017

Effective Date February 1, 2024

Biocompatibility Testing	
European Pharmacopoeia 10.0 - 2.6.8 Pyrogens	Pyrogen Test Method (The test consists of measuring the rise in body temperatures evoked in rabbits by intravenous injection of a sterile solution of the substance to be examined).
ISO 10993-1	Biological Evaluation Of Medical Devices. Evaluation And Testing Within A Risk Management Process
ISO 10993-3	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-4	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2016	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 10993-11	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity, Annex F (informative), Information on material-mediated pyrogens
ISO 10993-12	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation
OECD (2020), Test No. 471	Bacterial Reverse Mutation Test
OECD 487	In Vitro Mammalian Cell Micronucleus Test
Biomechanical Testing	
ASTM F382-17	Standard Specification and Test Method for Metallic Bone Plates

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ASTM F384-17	Standard Specifications and Test Methods for Metallic Angled Orthopaedic Fracture Fixation Devices
ASTM F543-17	Standard Specification and Test Methods Metallic Medical Bone Screws
ASTM F897	Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws
ASTM F1223	Standard Test Method for Determination of Total Knee Replacement Constraint
ASTM F1264-16	Standard Specification and Test Methods for Intramedullary Fixation Devices
ASTM F1541-17	Standard Specification and Test Methods for External Skeletal Fixation Devices
ASTM F1672	Standard Specification for Resurfacing Patellar Prosthesis
ASTM F1717-18	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
ASTM F1798-13	Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
ASTM F1800	Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements
ASTM F1814-15	Standard Guide for Evaluating Modular Hip and Knee Joint Components
ASTM F1820-13	Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices
ASTM F1829-17	Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear
ASTM F1875	Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface
ASTM F2009	Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses
ASTM F2077-18	Test Methods for Intervertebral Body Fusion Devices
ASTM F2083-12	Standard Specification for Knee Replacement Prosthesis
ASTM F2096	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F2193-18	Standard Specifications and Test Methods for Components used in the Surgical Fixation of the Spinal Skeletal System
ASTM F2267	Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
ASTM F2346-18	Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs

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ASTM F2423	Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses
ASTM F2502	Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants
ASTM F2502-17	Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants
ASTM F2580	Standard Test Method for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis
ASTM F2580-18	Standard Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis
ASTM F2582	Standard Test Method for Dynamic Impingement Between Femoral and Acetabular Hip Components
ASTM F2665	Standard Specification for Total Ankle Replacement Prosthesis
ASTM F2706	Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model
ASTM F2723	Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation
ASTM F2724	Standard Test Method for Evaluating Mobile Bearing Knee Dislocation
ASTM F2777-16	Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion Standard Practice for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops
ISO 6872	Dentistry - Ceramic Materials
ISO 7206-2	Implants for surgery – Partial and total hip joint prostheses – Part 2: Articulating surfaces made of metallic, ceramic and plastics materials
ISO 7206-4	Implant for Surgery – Partial and Total Hip joint prostheses – Part 4: Determination of endurance properties testing and performance of stemmed femoral components
ISO 7206-6	Implants for surgery – Partial and total hip joint prostheses – Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components
ISO 7206-10	Implants for surgery – Partial and total hip-joint prostheses – Part 10: Determination of resistance to static load of modular femoral heads
ISO 7206-13	Implants for surgery – Partial and total hip joint prostheses – Part 13: Determination of resistance to torque of head fixation of stemmed femoral components
ISO 7207-1	Implants for surgery – Components for partial and total knee joint prostheses – Part 1: Classification, definitions and designation of dimensions

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ISO 7207-2	Implants for surgery – Components for partial and total knee joint prostheses – Part 2: Articulating surfaces made of metal, ceramic and plastics materials
ISO 12189	Implants for surgery — Mechanical testing of implantable spinal devices — Fatigue test method for spinal implant assemblies using an anterior support
ISO 13498	Dentistry – Torsion test of implant body/connecting part joints endosseous dental implant systems
ISO 14242-1	Implants for surgery – Wear of total hip-joint prostheses – Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test
ISO 14242-2	Implants for surgery – Wear of total hip-joint prostheses – Part 2: Methods of measurement
ISO 14243-1	Implants for surgery – Wear of total knee-joint prostheses – Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test
ISO 14243-2	Implants for surgery – Wear of total knee-joint prostheses – Part 2: Methods of measurement
ISO 14801	Dentistry – Implants – Dynamic loading test for endosseous dental implants
ISO 14879	Implants for surgery – Total knee-joint prostheses – Part 1: Determination of endurance properties of knee tibial trays
ISO 18192-1	Implants for Surgery – Wear of Total Intervertebral Spinal Disc Prostheses – Part 1: Loading And Displacement Parameters For Wear Testing And Corresponding Environmental Conditions For Test
ISO 21534	Non-active surgical implants – Joint replacement implants – Particular requirements
ISO 21536	Non-active surgical implants – Joint replacement implants – Specific requirements for knee-joint replacement implants
Microbiological Testing	
ISO 11737-1	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
ISO 11737-2	Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
Physical and Chemical Tests	
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

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ASTM F2459-18	Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis
ISO 2271	Surface active agents – Detergents – Determination of anionic-active matter by manual or mechanical direct two-phase titration procedure
SM 5520-B	Determination of Oil-Grease Residue