SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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MECHANICAL

Valid To: March 31, 2022 Certificate Number: 5702.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on Surgical Implants and Prosthetics:

Test Technology:	**Test Method(s):**
Tribology	
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 14242-1: 2014/Amd 1:2018
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 14243-1: 2009
Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement	ISO 14243-2: 2016
Implants for surgery — Wear of total knee-joint prostheses — Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test	ISO 14243-3: 2014
Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans	ISO 23747: 2015
Mechanical	
Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems	ISO 11608-1: 2014
Standard Test Method for Impingement of Acetabular Prostheses	ASTM F2582-14
Standard Test Method for Seal Strength of Flexible Barrier Materials	ASTM F88-15
Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation	ASTM F2028-17

Test Technology:	**Test Method(s):**
Standard Specification for Metallic Implantable Strands and Cables	ASTM F2180-17
Implants for surgery — Hydroxyapatite — Part 4: Determination of coating adhesion strength	ISO 13779-4: 2018
Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings	ASTM F1147-05(2017)
Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	ASTM F1044-05(2017)
Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings	ASTM F1160-14(2017)*
Implants for surgery — Partial and total hip-joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads	ISO 7206-10: 2018
Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications	ISO 80369-6: 2016

*Equipment for this test is calibrated to ISO 7500-1 with a documented equivalence to ASTM E4, but the dynamic verification of the equipment per ASTM E467 is not performed.

Accredited Laboratory

A2LA has accredited

SPINESERV GMBH & CO.KG

Ulm, Germany

for technical competence in the field of

Mechanical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (*refer to joint ISO-ILAC-IAF Communiqué dated April 2017*).

Presented this 26th day of February 2020.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 5702.01
Valid to March 31, 2022

For the tests to which this accreditation applies, please refer to the laboratory's Mechanical Scope of Accreditation.