



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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MECHANICAL

Valid To: March 31, 2028

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 types of tests on Surgical Implants and Prosthetics:

Test Technology:

Test Method(s):

Tribology

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

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

Implants for surgery — Wear of total knee prostheses — Part 5: Durability performance of the patellofemoral joint ISO 14243-5

Elbow wear testing S14
(Test procedure developed by SpineServ based on the findings described by Kincaid, Mimnaugh et al. 2012 - Development of a Laboratory Wear Test Methodology for the Evaluation of Total Elbow Prostheses)

Shoulder wear testing S10
(Test developed by SpineServ based on the findings described by Kohut, Georges; Dallmann, Frank; Irlenbusch, Ulrich (2012): Wear-induced loss of mass in reversed total shoulder arthroplasty with conventional and inverted bearing materials)

Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants ISO 21535

Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants ISO 21536

Test Technology:

Sphericity Implants for surgery Partial and total hip joint prostheses
— Part 2: Articulating surfaces made of metallic, ceramic and
plastics materials

Standard Specification for Total Hip Joint Prosthesis and Hip
Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and
Polymeric Materials

Mechanical

Stainless steel needle tubing for the manufacture of medical
devices — Requirements and test methods

Infusion equipment for medical use — Part 4: Infusion sets for
single use, gravity feed and flow rate

Packaging

Method for Detecting Seal Leaks in Medical Packaging by Dye
Penetration

Accelerated Aging of Sterile Barrier Systems and devices

Test Method(s):

ISO 7206-2

ASTM F2033

ISO 9626 Annex B, C & D

ISO 8536-4
Annex A.3, A.4

ASTM F1929

ASTM F1980

Test Technology:**Parameters:****Test Method(s):****Static Testing:**

Static Load	(± 0.4 to ± 20,000) N
Static Torsion	(± 0.02 to ± 50) Nm
Stroke	(0 to 550) mm
Angular Displacement	(0 to ±1,800) deg

pTI- Static Testing

Dynamic Testing:

Dynamic Load	(± 0.01 to ± 25) kN
Dynamic Torsion	(± 0.25 to ± 25) Nm
Linear Displacement	(0 to ± 50) mm
Angular Displacement	(0 to ± 360) deg
Dynamic	

pTI- Fatigue Testing

Environmental:

Humidity	(10 to 98) % at (10 to 90) °C
Temperature	(-40 to 300) °C

pTI- Aging Pre-Conditioning

Wear Testing:

Rotation	X-(0 to ±25) °; Y-(-60 to +120) °; Z- (0 to ±30) °
Translation	X-(0 to ±20) mm; Z-(0 to ±11) mm
Force	X & Y-(0 to ±600) N; Z-(0 to ±3500) N
Torque	X-(0 to ±6) Nm; Y-(0 to ±50) Nm;

pTI- Wear Testing

Test Technology:

Parameters:

Test Method(s):

Weighing:

Weight

Z-(0 to ±100) Nm

(0.0 to 220,000.00) mg

(0.0 to 10.0) kg

pTI-Weighing

Pressure Testing:

Pressure

(0 to +500 and 0 to -900) kPa

pTI-Pressure Testing



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 27th day of February 2026.

A blue ink signature of Mr. Trace McInturff, written in a cursive style.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 5702.01
Valid to March 31, 2028

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