



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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MECHANICAL

Valid To: March 31, 2026

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
(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)

S14

Shoulder wear testing
(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)

S10

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

Standard Test Methods for Determination of Cyclic Fatigue Strength of Ceramic Modular Femoral Heads

Standard Test Method for Dynamic Impingement Between Femoral and Acetabular Hip Components

Standard Test Methods for Metallic Bone Plates Used in Small Bone Fracture Fixation

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 & A.5

ASTM F2345

ASTM F2582

ASTM F3437

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-Fatigue
Testing

Dynamic Testing:

Dynamic Load

(±0.1 to ±25) kN

Dynamic Torsion

(±0.25 to ±25) Nm

Angular Displacement

(0 to ±360) deg

Dynamic

pTI-Static Testing

Environmental:

Humidity

(10 to 50) % at (10 to 60) °C

Temperature

(-10 to 300) °C

pTI-Aging

Test Technology:

Parameters:

Test Method(s):

Wear Testing:

Rotation

X-(0 to ± 25) °; Y-(-60 to +120) °; Z-(0 to ± 30) °

pTI-Wear Testing

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; Z-(0 to ± 100) Nm

Weighing:

Weight

(4.10 to 220,000.00) mg

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 4th day of April 2024.

A blue ink signature of Mr. Trace McInturff, written over a horizontal line.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 5702.01
Valid to March 31, 2026

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