



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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MECHANICAL

Valid To: March 31, 2024

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 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 3: Loading and displacement parameters for wear-testing
machines with displacement control and corresponding
environmental conditions for test

ISO 14243-3: 2014

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

ISO 14243-5: 2019

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

Mechanical

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

ISO 9626: 2016

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

ISO 8536-4: 2019
Annex A.3 and Annex A.4

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Test Technology:

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

Test Method(s):

ASTM F2345-21

ASTM F2582-20



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 7th day of April 2022.

A blue ink signature of the Vice President of Accreditation Services.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 5702.01
Valid to March 31, 2024

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