



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

DEPUY SYNTHES MEDTEST LABS  
700 Orthopaedic Drive  
Warsaw, IN 46582  
Jennifer Tikka Phone: 574 404 8661

MECHANICAL

Valid To: March 31, 2024

Certificate Number: 3543.01

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**

**Biomechanics**

**Test Method**

WI-7862, WI-7864

Testing Parametric Envelope

Axial Load (Electromechanical Testing)	± 288 kN
Axial Load (Servo-hydraulic Testing)	± 100 kN
Horizontal Shear Load	± 5 kN
Axial Torque	± 225N-m

Determination of endurance properties for partial and total hip joint prostheses and performance of stemmed femoral components

ISO 7206-4

Endurance properties testing and performance requirements of neck region of stemmed femoral components

ISO 7206-6

**Tribology**

Testing Parametric Envelope

WI-5976, 103472887,  
103342608, MVI 103497110

Axial Load (Fz)	-3000N to 4480N
Shear Load (Fx, Fy)	± 1000N
Torque (Mz, My)	± 40N-m (axial, abduction)
Torque (Mx)	± 80N-m (flexion)
Flexion/Extension Rotation	± 180°
Adduction/Abduction Rotation	± 25°
Internal/External Rotation	± 40°
Vertical Translation	± 24mm
Anterior/Posterior Translation	± 25mm
Medial/Lateral Translation	± 25mm
Frequency	0.5Hz -2.0Hz
Temperature	20°C - 45°C

Wear of total hip-joint prostheses: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test

ISO 14242-1

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**Test****Tribology (continued)****Test Method**

Wear of total hip joint prostheses: Methods of measurement	ISO 14242-2 (Gravimetric Method Only)
Wear of total hip joint prostheses: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test	ISO 14242-3
Wear of total hip-joint prostheses: Testing hip prostheses under variations in component positioning which results in direct edge loading	ISO 14242-4
Wear of total knee joint prostheses: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test	ISO 14243-1
Wear of total knee joint prostheses: Methods of measurement	ISO 14243-2
Wear of total knee-joint prostheses: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test	ISO 14243-3
Wear of total knee prostheses: Durability performance of the patellofemoral joint	ISO 14243-5
Standard Test Method for Dynamic Impingement Between Femoral and Acetabular Hip Components	ASTM F2582



# Accredited Laboratory

A2LA has accredited

**DEPUY SYNTHES MEDTEST LABS**

*Warsaw, IN*

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 30<sup>th</sup> day of June 2022.

A blue ink signature of Mr. Trace McInturff.

Mr. Trace McInturff, Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 3543.01  
Valid to March 31, 2024  
Revised February 14, 2023

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