



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

EXPONENT, INC.<sup>1</sup>  
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Philadelphia, PA 19104  
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MECHANICAL

Valid To: June 30, 2019

Certificate Number: 2561.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory at the location listed above, *as well as the three satellite laboratory locations listed below*, to perform the following tests on the following materials: medical grade plastics, metals and biomaterials, medical consumables, tissue and medical devices in conformance with the U.S. FDA Good Laboratory Practice (GLP) Regulations per 21 CFR 58<sup>2</sup>:

<u>Test</u>	<u>Test Method(s)</u>
<b><i>Electrochemical Tests:</i></b>	
Corrosion Susceptibility	ASTM F2129
Evaluation of Galvanic Corrosion	ASTM F3044
Potentiostatic and Potentiodynamic Anodic Polarization Measurements	ASTM G5
<b><i>Biotribology:</i></b>	
Spinal Implant Wear Rate	ASTM F2423; ISO 18192-1
Knee Implant Wear Rate	ISO 14243-1, -2, -3
Material Wear Rate	ASTM F732
Particle Analysis	ASTM F1877
<b><i>Tissue Characterization:</i></b>	
Mechanical Characterization of Cadaveric and Animal Tissue	SOP.160 <sup>3</sup> , 053 <sup>3</sup> , 116 <sup>3</sup>
MicroCT Imaging and Analysis	SOP.286 <sup>3</sup>
Tissue Ball Burst Testing	SOP.287 <sup>3</sup>

<u>Test</u>	<u>Test Method(s)</u>
<b><i>Device Specific Tests:</i></b>	
Bone Screw Testing	ASTM F543
Static and Dynamic Characterization of Spinal Constructs	ASTM F1717
Mechanical Methods for Intervertebral Body Fusion Devices	ASTM F2077
Subsidence Testing	ASTM F2267
Mechanical Characterization of Total Disc Replacements	ASTM F2346
Push-out Testing	ASTM Draft Guide Dated Aug 29, 2000; SOP.357 <sup>3</sup>
Hip Rim Impingement	ASTM F2582
Total Hip Disassembly	ASTM F1820
Breast Implant Fatigue	ISO 14607 Annex E
<b><i>Sample Preparation and Conditioning:</i></b>	
Accelerated Shelf Aging	ASTM F1980
Accelerated Aging	ASTM F2003
<b><i>Implant Characterization:</i></b>	
Characterization of Retrieved Implants	SOP.200 <sup>3</sup> ; ASTM F561; ISO 12891
SEM	SOP.213 <sup>3</sup> ; SOP.166 <sup>3</sup>
Surface Characterization Using a Zygo White Light Interferometer	SOP.011 <sup>3, 5</sup>
Photomicrographs	ASTM E883; SOP.264 <sup>3</sup>
Taper Measurement Using a Talyrond	ASTM F3129; SOP.309 <sup>3</sup>
MicroCT Imaging and Analysis	SOP.286 <sup>3</sup>
<b><i>Cardiovascular Device Characterization:</i></b>	
Peripheral Stent Testing (MAPS)	ASTM F2942, ASTM F2477; SOP.342 <sup>3</sup>
Heart Valve Pulse Duplication	ISO 5840-1, -2, -3
Heart Valve Durability	ISO 5840-1, -2, -3

<u>Test</u>	<u>Test Method(s)</u>
<b><i>Spectroscopy/Chemical Tests:</i></b>	
FTIR	ASTM E1252, E334; SOP.081 <sup>3</sup>
Hydroperoxide Index	SOP.064 <sup>3, 4</sup> ; SOP.347 <sup>3</sup>
Oxidation Index	ASTM F2102; SOP.347 <sup>3</sup>
Trans-Vinylene Index	ASTM F2381; SOP.347 <sup>3</sup>
UHMWPE Crystallinity Index	ASTM F2102; SOP.347 <sup>3</sup>
PEEK Crystallinity Index	ASTM F2778; SOP.256 <sup>3</sup>
<b><i>Biomaterials Testing:</i></b>	
Tensile	ASTM D638, E8
Compression	ASTM D695, F451
IZOD Impact	ASTM F648 (Annex A1), D256
Poisson's Ratio Testing	SOP.006 <sup>3</sup>
Small Punch	ASTM F2183; ASTM F2977
Fatigue Crack Propagation	ASTM E647
Nitinol Tensile Testing	ASTM F2516
Bending of Bone Cement	ISO 5833
Fatigue Life of Bone Cement	ASTM F2118
Coefficient of Friction	ASTM D1894
<b><i>Hydroxyapatite Testing:</i></b>	
Dissolution Testing	SOP.188 <sup>3, 6</sup> ; ASTM F1926
Solubility	SOP.188 <sup>3, 6</sup>
<b><i>Textiles:</i></b>	
Ball Burst Testing	ASTM D6797
Water Impact Penetration Testing	AATCC Test Method 42
Water Hydrostatic Pressure Testing	AATCC Test Method 127

<u>Test</u>	<u>Test Method(s)</u>
<b><i>Syringes, Needles and Related Equipment-Conical Fittings:</i></b>	
Gauging	ISO 594/1, 4.1, 5.1
Liquid Leakage	ISO 80369-7; ISO 594/1, 4.2, 5.2
Air Leakage	ISO 80369-7; ISO 594/1, 4.3, 5.3
Separation Force	ISO 80369-7; ISO 594/1, 4.4, 5.4
Stress Cracking	ISO 80369-7; ISO 594/1, 4.5, 5.5
<b><i>Syringes, Needles and Related Equipment-Lock Fittings:</i></b>	
Gauging	ISO 594/2, 4.1, 5.1
Leakage	ISO 80369-7; ISO 594/2, 4.2, 5.2, 5.3
Separation Force	ISO 80369-7; ISO 594/2, 4.3, 5.4
Unscrewing Torque	ISO 80369-7; ISO 594/2, 4.4, 5.5
Ease of Assembly	ISO 594/2, 4.5, 5.6
Resistance to Overriding	ISO 80369-7; ISO 594/2, 4.6, 5.7
Stress Cracking	ISO 80369-7; ISO 594/2, 4.7, 5.8
<b><i>Catheters:</i></b>	
Tensile Testing	ISO 10555-1 Annex B
Leak Testing	ISO 10555-1 Annex C
Gravity Flow	ISO 10555-1 Annex E
Burst Testing	ISO 10555-1 Annex F
<b><i>Consumer Product Testing:</i></b>	
Football Glove Testing	SFIA Specification FBG - V.001 - 2015

<sup>1</sup>This accreditation covers testing performed at the main laboratory listed above, and the satellite laboratories listed below.

EXPONENT  
MRI  
Philip Chao  
1 Centurian Dr. Newark, DE 19713

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<u>Test</u>	<u>Test Method(s)</u>
<b><i>MRI Related Testing:</i></b>	
MRI Artifacts	ASTM F2119
MRI Induced Force and Displacement	ASTM F2052
MRI Induced Heating	ASTM F2182
MRI Induced Torque	ASTM F2213
MRI Safety Labeling	ASTM F2503

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EXPONENT  
Liz Smith  
Department of Radiology  
111 S. 11<sup>th</sup> St., Philadelphia, PA 19107

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<u>Test</u>	<u>Test Method(s)</u>
<b><i>Device Imaging</i></b>	
Radiopacity	ASTM F640

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EXPONENT  
Steve Kurtz  
3401 Market St, Suite 345, Philadelphia, PA 19104

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<u>Test</u>	<u>Test Method(s)</u>
<b><i>Spectroscopy/Chemical Tests:</i></b>	
FTIR	ASTM E1252, E334; SOP.081 <sup>3</sup>
Hydroperoxide Index	SOP.064 <sup>3, 4</sup> ; SOP.347 <sup>3</sup>
Oxidation Index	ASTM F2102; SOP.347 <sup>3</sup>
Trans-Vinylene Index	ASTM F2381; SOP.347 <sup>3</sup>
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PEEK Crystallinity Index	ASTM F2778; SOP.256 <sup>3</sup>

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<u>Test</u>	<u>Test Method(s)</u>
<b><i>Biomaterials Testing:</i></b>	
Small Punch	ASTM F2183, F2977
<b><i>Implant Characterization:</i></b>	
Characterization of Retrieved Implants	SOP.200 <sup>3</sup> ; ASTM F561; ISO 12891
MicroCT Imaging and Analysis	SOP.286 <sup>3</sup>

<sup>2</sup>The materials testing standards listed on this scope of accreditation may be used for both medical and non-medical plastics and metals.

<sup>3</sup>In-House method

Literature References:

<sup>4</sup>D. C. Mazzucco, J. Dumbleton, and S. M. Kurtz, "Can accelerate aqueous aging simulate in vivo oxidation of gamma-sterilized UHMWPE?," J. Biomed Water Res B Appl Biomater, vol. 79, pp 79-85, 2006.

<sup>5</sup>S. M. Kurtz, J. Pelozo, R. Siskey, and M. L. Villarraga, "Analysis of a retrieved polyethylene total disc replacement component," Spine J, vol. 5, pp 344-50, 2005

<sup>6</sup>FDA Guidance: 510(K) Information Needed for Hydroxyapatite Coated Orthopedic Implants (February 27, 1997)



## *Accredited Laboratory*

A2LA has accredited

**EXPONENT, INC.**

*Philadelphia, PA*

for technical competence in the field of

**Mechanical Testing**

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *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 8 January 2009).



Presented this 21<sup>st</sup> day of June 2017.

A handwritten signature in black ink, written over a horizontal line.

President and CEO  
For the Accreditation Council  
Certificate Number 2561.01  
Valid to June 30, 2019

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