



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

COOK RESEARCH INCORPORATED (CRI)
 1 Geddes Way
 West Lafayette, IN 47906
 Ramon Boudreaux Phone: 765 463 7537

MECHANICAL

Valid To: June 30, 2024

Certificate Number: 2194.01

In recognition of the successful completion of the A2LA evaluation process (including an assessment of the organization’s compliance with A2LA’s FDA ASCA Accreditation Program¹ requirements), accreditation is granted to this laboratory to perform the following tests on medical devices:

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
Bend and Free Recovery	Bend and Free Recovery	ASTM F2082 BFR-100 Lab Developed Method
Corrosion	Immersion Corrosion Testing	ASTM G31 ISO 9626 ISO 16428 ISO 11070 ISO 10555-1 ISO 20695 ISO 20696 ISO 20697 ISO 25539-1 ISO 25539-2 JIS T 3214 JIS T 3215 JIS T 3216 JIS T 3260 ACOR-716 Lab Developed Method
	Electrochemical Corrosion Testing	ASTM F2129 ASTM F3044 ASTM G5 ASTM G59 ASTM G71 ISO 16428 ISO 25539-1 ISO 25539-2 ECOR-001 Lab Developed Method

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
Deployment ²	Bench Simulated Use and Deployment Testing	ISO 25539-1 ISO 25539-2 ISO 25539-3 DPLY-04 Lab Developed Method
Differential Scanning Calorimetry	Differential Scanning Calorimetry	ASTM E1356 ASTM F2004 DSC-438 Lab Developed Method
Echogenicity	Ultrasound Visibility Testing	ECHO-01 Lab Developed Method
Examination and Measurement	Examination	ISO 7198 ISO 25539-1 ISO 25539-2 ISO 25539-3 EXAM-100 Lab Developed Method
	Thickness Measurement	ISO 5084 ISO 7198 ISO 25539-1 MEAS-825 Lab Developed Method
	Kink Radius Measurement	BS EN 13868 ISO 7198 ISO 25539-1 ISO 25539-2 ASTM F3505 MEAS-829 Lab Developed Method
	Force Measurement	ISO 25539-1 ISO 25539-2 ISO 25539-3 MEAS-900 Lab Developed Method
Fatigue	Pulsatile Fatigue Testing	ASTM F3211 ASTM F2477 ISO 7198 ISO 25539-1 ISO 25539-2 FATG-320 Lab Developed Method
	Flat Plate Fatigue Testing	ASTM F3211 ASTM F2942 ISO 25539-2 ISO 25539-3 FATG-401 Lab Developed Method
	Sling Radial Fatigue Testing	ASTM F3211 ASTM F2942 ISO 25539-1 ISO 25539-2 ISO 25539-3 FATG-500 Lab Developed Method

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
Fatigue <i>(continued)</i>	Low Cycle Longitudinal Fatigue Testing	ASTM F3211 ASTM F2942 ISO 25539-1 ISO 25539-2 ISO 25539-3 FATG-600 Lab Developed Method
	Low Cycle Longitudinal Fatigue Testing of External Sutures	ASTM F3211 ASTM F2942 ISO 25539-1 ISO 25539-2 ISO 25539-3 FATG-610 Lab Developed Method
	Bending Fatigue Testing	ASTM F3211 ASTM F2942 ISO 25539-1 ISO 25539-2 ISO 25539-3 FATG-700 Lab Developed Method
	Longitudinal Fatigue Testing	ASTM F3211 ASTM F2942 ISO 25539-1 ISO 25539-2 ISO 25539-3 FATG-800 Lab Developed Method
	Torsional Fatigue Testing	ASTM F3211 ASTM F2942 ISO 25539-1 ISO 25539-2 ISO 25539-3 FATG-900 Lab Developed Method
Flow	Flow Testing	ISO 10555-1 BS EN 13868 ISO 7198 ISO 25539-1 ISO 25539-2 ISO 20695 ISO 20696 ISO 20697 FLOW-225 Lab Developed Method
	Pressurized Flow and Water Permeability	ANSI/AAMI VP20 ISO 10555-1 ISO 10555-2 ISO 20695 ISO 20696 ISO 20697 ISO 7198 ISO 25539-1 ISO 25539-2 ASTM F1828

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
Flow (<i>continued</i>)	Pressurized Flow and Water Permeability (<i>continued</i>)	FLOW-302 Lab Developed Method
Medical Electrical Equipment ^{1,4}	Basic Safety and Essential Performance Testing of Endoscopic Equipment and Electrosurgical Accessories	IEC/ANSI/AAMI/BS EN/CAN CSA 60601-1 Ed. 3.2; IEC/BS EN 60601-2-18; IEC/ANSI/AAMI/BS EN 60601-2-2 (Sections 201.8.7.3.101 - 201.8.8.3.104, 201.8.10.4.2) ECT-491 Lab Developed Method
MRI Safety Evaluations ³	Magnetically Induced Displacement Force; Magnetically Induced Torque; MR Image Artifacts; Radio Frequency Induced Heating	ASTM F2052 ASTM F2213 ASTM F2182 ASTM F2119 MRI-400 Lab Developed Method
Particulate Counting	Particulate Counts of Endovascular Devices Using the Hiac Royco Liquid Particle Counter	USP 788 AAMI TIR42 ISO 25539-2 PART-02 Lab Developed Method
	Simulated Use Particulate Testing	USP 788 AAMI TIR42 ASTM F2743 ISO 25539-2 PART-03 Lab Developed Method
	Particulate Counts of Endovascular Devices during Pulsatile Fatigue	PART-04 Lab Developed Method
Power Injection	Power Injection Testing	ISO 10555-1 JIS T 3268 ISO 25539-3 POWR-864 Lab Developed Method
Pressure	Pressure Testing: Burst and Leakage	ANSI/AAMI VP20 ISO 7198 ISO 10555-1 ISO 10555-2 ISO 10555-4 ISO 20697 ISO 25539-1 ISO 25539-2 ISO 25539-3 JIS T 3268 JIS T 3247 ISO 11070 PRES-191 Lab Developed Method
	Pressurized Dimensional Measurement	ISO 7198 ISO 10555-4 ISO 25539-1 ISO 25539-2 ASTM F2081 PRES-195 Lab Developed Method

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
Pressure (<i>continued</i>)	Balloon Inflation/Deflation Time and Fatigue Testing	ISO 10555-1 ISO 10555-2 ISO 10555-4 ISO 25539-1 ISO 25539-2 PRES-197 Lab Developed Method
Tension and Compression	Automated Axial Force and Strain Measurement	ASTM E8 / E8M ASTM F1828 ISO 20695 ASTM F2516 ASTM F2606 ISO 7198 ISO 11070 ISO 10555-1 ISO 25539-1 ISO 25539-2 ISO 25539-3 JIS T 3215 JIS T 3216 JIS T 3229 JIS T 3242 JIS T 3245 JIS T 3246 JIS T 3247 JIS T 3260 JIS T 3268 JIS T 3270 PULT-210 Lab Developed Method
Radiopacity ²	Radiopacity Testing	ASTM F640 ISO 25539-1 ISO 25539-2 ISO 25539-3 RAD-01 Lab Developed Method
Radial Force	Automated Radial Force	ASTM F3067 ISO 25539-1 ISO 25539-2 ISO 25539-3 RF-300 Lab Developed Method
Torque	Automated Torque Testing	ASTM A938 ISO 25539-1 ISO 25539-2 ISO 25539-3 TORQ-553 Lab Developed Method

¹These methods have been assessed by A2LA according to A2LA's FDA ASCA Program requirements. Accreditation by A2LA does not imply FDA ASCA-Accreditation. All ASCA-accreditation decisions for testing laboratory applications are made solely by the FDA, a list of approved laboratories can be found at FDA.gov.

²Radiographic activity, when performed as part of these tests, is performed at Cook Research Inc (CRI) or the following:

Purdue University Martin Jischke Hall

³MRI testing, when performed as part of these tests, is performed at the following locations:

Purdue Engineering MRI Facility
IU Health Arnett West Side Urgent Care

⁴The laboratory is only accredited for testing activities outlined within the test methods listed above. Reference to any other activity within these standards, such as risk management or risk assessment, does not fall within the laboratory's accredited capabilities

Testing Activities performed under the scope of the U.S FDA ASCA Pilot Program Specifications: <i>Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program</i> published on September 25th, 2020, and in accordance with all requirements of A2LA R256 <i>Specific Requirements- FDA ASCA Program</i> ¹

Standards

ANSI/AAMI ES60601-1:2005 (R2012) with amendments (includes ANSI/AAMI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012), ANSI/AAMI ES60601-1:2005/A2:2021; IEC 60601-2-18: Edition 3.0 2009; ANSI/AAMI/IEC 60601-2-2:2017



Accredited Laboratory

A2LA has accredited

COOK RESEARCH INCORPORATED (CRI)

West Lafayette, 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 laboratory also meets A2LA R256 - Specific Requirements FDA ASCA Program. 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 26th day of May 2022.

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

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2194.01
Valid to June 30, 2024

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