SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

COOK RESEARCH INCORPORATED (CRI)
1 Geddes Way
West Lafayette, IN 47906
Ramon Boudreaux Phone: 337 739 4276

ELECTRICAL

Valid To: June 30, 2026 Certificate Number: 2194.02

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 Program[1] and with Good Laboratory Practice (GLP) regulations per 21 CFR 58 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
Medical Electrical Equipment – High Frequency[1,4]	Basic Safety and Essential Performance Testing of Electrosurgical Active Accessories	IEC 60601-2-2[2]; ANSI/AAMI 60601-2-2[2]; BS EN 60601-2-2[2]; CSA C22.2 NO. 60601-2-2[2]; IEC 60601-1; ANSI/AAMI ES60601-1; BS EN 60601-1; CAN/CSA C22.2 NO. 60601-1; BSEP-202 Lab Developed Method
Medical Electrical Equipment – Endoscopic[1,4]	Basic Safety and Essential Performance Testing of Endoscopic Equipment	IEC 60601-2-18[3]; BS EN 60601-2-18[3]; CAN/CSA C22.2 NO .60601-2-18[3]; IEC 60601-1; ANSI/AAMI ES60601-1; BS EN 60601-1; CAN/CSA C22.2 NO. 60601-1; BSEP-218 Lab Developed Method
Medical Electrical Equipment – EMC-ESD [1,4]	Electrostatic Discharge Testing	IEC 60601-1-2; ANSI/AAMI/IEC 60601-1-2; BS EN 60601-1-2; CAN/CSA C22.2 NO. 60601-2 (Section: Electrostatic Discharge Testing); IEC 61000-4-2; ESD-001 Lab Developed Method

5202 Presidents Court, Suite 220 | Frederick, MD 21703-8515 | Phone: 301 644 3248 | Fax: 240 454 9449 | www.A2LA.org

GENERAL TESTS OR PROPERTIES MEASURED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED
Medical Electrical Equipment – EMC-EFT [1,4]	Electrical Fast Transients/Burst and Surge Testing	IEC 60601-1-2; BS EN 60601-1-2; ANSI/AAMI/IEC 60601-1-2; CAN/CSA C22.2 NO. 60601-1-2 (Section: Electrical fast transients/bursts and Surge Testing); IEC 61000-4-4; IEC 61000-4-5; FAST-002 Lab Developed Method
Medical Electrical Equipment – Optical	Optics and Image Quality Testing	BS ISO 8600-1; BS ISO 8600-3; BS ISO 8600-6; OPT-248 Lab Developed Method

[1] These 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 https://www.fda.gov/medical-devices/division-standards-and-conformity-assessment/asca-accredited-testing-laboratories.

[2] Including Sections 201.8.7.3.101 to 201.8.8.3.104, 201.8.10.4.2, and 201.15.101.4

[3] Including Sections 201.4.3, 201.4.6, 201.4.11, 201.5.7, 201.5.9, 201.7.1, 201.7.2, 201.7.4, 201.7.6, 201.7.9, 201.8.4, 201.8.5, 201.8.6, 201.8.7, 201.8.8, 201.8.9, 201.8.10, 201.8.11, 201.9.2, 201.9.3, 201.9.4, 201.11, 201.13.2, 201.15.3

[4] The 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 Program Specifications: *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) Program* published on September 25th, 2020, and in accordance with all requirements of A2LA *R256 Specific Requirements- FDA ASCA Program*[1]

Standards	**ASCA Doc #**
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION;	19-49
ANSI/AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021];	19-46
ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021];	19-36
IEC 60601-2-18: Edition 3.0 2009-08;	9-114
ANSI AAMI/IEC 60601-2-2 Edition 6.0 2017-03;	6-389

Accredited Laboratory

A2LA has accredited

COOK RESEARCH INCORPORATED (CRI)

West Lafayette, IN

for technical competence in the field of

Electrical 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 10th day of June 2024.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2194.02
Valid to June 30, 2026

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