



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

DEVICE CONFORMITY AND TESTING, LLC

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ELECTRICAL

Valid To: June 30, 2026

Certificate Number: 6136.01

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:

Test Technology:

Information Technology

Information and Communication Technology
Equipment

Medical Equipment¹

Test Method(s)²:

IEC 60950-1:2005/AMD2:2013

IEC 62368-1:2018³;
IEC 62368-1 Ed. 4 2023-05³

IEC 60601-1:1988/AMD2:1995;
IEC 60601-1:2005+A1:2012;
IEC 60601-1:2005+A1:2012+A2:2020;
ES60601-1:2005/(R)2012 and A1:2012
C1:2009/(R)2012 and A2:2010/(R)2012
(Consolidated Text);
IEC 60601-1-4:1996/AMD1:1999;

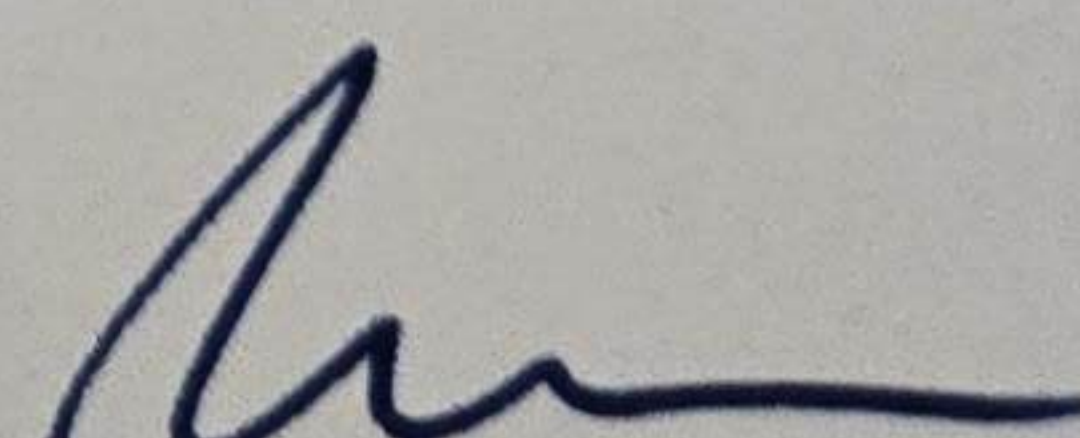
IEC 60601-1-6:2010+A1:2013+A2:2020;
IEC 60601-1-6 Edition 3.1 2013-10;
IEC 60601-1-6 Edition 3.2 2020-07
CONSOLIDATED VERSION;

IEC 60601-1-8:2006+A1:2012+A2:2020;
IEC 60601-1-8 Edition 2.1 2012-11;
IEC 60601-1-8 Edition 2.2 2020-07
CONSOLIDATED VERSION;

IEC 60601-1-11:2015+A1:2020;
IEC 60601-1-11 Edition 2.0 2015-01;
IEC 60601-1-11 Edition 2.1 2020-07
CONSOLIDATED VERSION;

IEC 60601-2-2 Edition 6.0 2017-03;
IEC 60601-2-2 Edition 6.1 2023-02;
IEC 60601-2-18:2009-08

(A2LA Cert. No. 6136.01) 06/26/2024

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Test Technology:Medical Equipment¹ (Cont'd)**Test Method(s) ²:**

IEC 60601-2-64:2014-09;

IEC 60601-2-68 Edition 1.0 2014-09

Electrical Equipment for Measurement, Control,
and Laboratory Use

IEC 61010-1:2010+A1:2016;

IEC 61010-1 Edition 3.1 2017-01

CONSOLIDATED VERSION;

IEC 61010-2-010:2019;

IEC 61010-2-051:2018;

IEC 61010-2-101:2018

Testing Activities performed under the scope of the U.S FDA ASCA Pilot 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) Pilot Program* published on September 25th, 2020, and in accordance with all requirements of A2LA R256 *Specific Requirements- FDA ASCA Program*.⁴

Standards	Document ID
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	5-132
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	5-131
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	19-38
IEC 60601-2-2 Edition 6.0 2017-03	6-389
IEC 60601-2-64:2014-09	12-318
IEC 60601-2-68 Edition 1.0 2014-09	12-319
IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION	19-34

¹ 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.

² For any test method requiring an IP rating, the CAB is limited to IPx0, where x = 0, 1, 2, 3 or 4.

³ Excluding:

Annex B – Excluding equipment that connects to the wired telephone network.

Annex B – Excluding equipment intended for building-in or rack mounting.

Annex E – Any equipment with audio amplifiers.

Annex G – Components.

Annex J – Insulated winding wires.

Annex L – Disconnect devices.

Annex S – Tests for resistance to heat and fire.

⁴ 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 FDA.gov.



Accredited Laboratory

A2LA has accredited

DEVICE CONFORMITY AND TESTING, LLC

Devens, MA

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 27th day of July 2026.

A handwritten signature in blue ink, appearing to read "Trace McInturff".

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 6136.01
Valid to June 30, 2028

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