SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Device Conformity and Testing, LLC
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ELECTRICAL

Valid To: June 30, 2024 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 Program[2] requirements), accreditation is granted to this laboratory to perform the following tests:

| **Test Technology:** | **Test Method(s)[1]:** |
|---|---|
| Information Technology | IEC 60950-1:2005/AMD2:2013 |
| Information and Communication Technology Equipment | IEC 62368-1:2018 |
| Medical Equipment[3] | IEC 60601-1:1988/AMD2:1995;<br>IEC 60601-1:2005+A1:2012;<br>IEC 60601-1:2005+A1:2012+A2:2020;<br>ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text);<br>IEC 60601-1-4:1996/AMD1:1999;<br><br>IEC 60601-1-6:2010+A1:2013+A2:2020;<br>IEC 60601-1-6 Edition 3.1 2013-10;<br>IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION;<br><br>IEC 60601-1-8:2006+A1:2012+A2:2020;<br>IEC 60601-1-8 Edition 2.1 2012-11;<br>IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION;<br><br>IEC 60601-1-11:2015+A1:2020;<br>IEC 60601-1-11 Edition 2.0 2015-01;<br>IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION;<br><br>IEC 60601-2-2 Edition 6.0 2017-03;<br>IEC 60601-2-18:2009-08;<br>IEC 60601-2-64:2014-09; |



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| **Test Technology:** | **Test Method(s)[1]:** |
|---|---|
| Medical Equipment[3] (*Cont'd*) | IEC 60601-2-68 Edition 1.0 2014-09 |
| Electrical Equipment for Measurement, Control, and Laboratory Use | IEC 61010-1:2010+A1:2016;<br>IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION;<br>IEC 61010-2-010:2019;<br>IEC 61010-2-051:2018;<br>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.*[2]

| **Standards** | **Document ID** |
|---|---|
| ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) | 19-4 |
| IEC 60601-1-6 Edition 3.1 2013-10 | 5-89 |
| IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION | 5-132 |
| IEC 60601-1-8 Edition 2.1 2012-11 | 5-76 |
| IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION | 5-131 |
| IEC 60601-1-11 Edition 2.0 2015-01 | 19-14 |
| 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 60601-2-18:2009-08 | 9-224 |
| 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]When the date, edition, version, etc. is not identified in the scope of accreditation, laboratories may use the version that immediately precedes the current version for a period of one year from the date of publication of the standard measurement method, per part C., Section 1 of A2LA *R101 - General Requirements-Accreditation of ISO-IEC 17025 Laboratories*.

[2]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.

[3]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.

# 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 28th day of July 2022.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 6136.01
Valid to June 30, 2024

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