SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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ELECTRICAL

Valid To: December 31, 2025 Certificate Number: 4896.01

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[1] requirements), accreditation is granted to this laboratory to perform the following electrical tests:

| **Test Technology:** | **Test Method(s):** |
|---|---|
| Measurement and Characterization of Medical Ultrasonic Fields | IEC 62127-1 Edition 1.1 2013, IEC 62359 Edition 2.1 2017 |
| Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment | AIUM NEMA UD2 |
| Medical Electrical Equipment – Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment | IEC 60601-2-37 Edition 2.1 2015, Clauses 201.1-201.16 |
| Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance | IEC 60601-1 Edition 3.2 2020-08-Clauses 4-9, 11-16;<br>ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012[3] |
| Medical Electrical Equipment- Part 2-5: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Physiotherapy Equipment | IEC 60601-2-5 Edition 3.0 2009-07 |
| Medical Electrical Equipment- Part 2-62: Particular Requirements for the Basic Safety and Essential Performance of High Intensity Therapeutic Ultrasound (HITU) Equipment | IEC 60601-2-62 Edition 1.0 2013-07 |



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| **Test Technology:** | **Test Method(s):** |
|---|---|
| Medical Electrical Equipment- Part 1-11: General Requirements for the Basic Safety and Essential Performance- Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment | IEC 60601-1-11 Edition 2.1 2020-07 |
| General requirements for basic safety and essential performance- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems | IEC/EN 60601-1-8 (Ed. 2 + Am 1 + Am 2);<br>ANSI AAMI IEC 60601-1-8:2006 and A1:2012 |
| General methods of measuring the performance of ultrasonic pulsed-echo diagnostic equipment | JIS T 1501: 2005 |
| Ultrasonics –Characteristic of Fields | IEC 61846 Edition 1998-04;<br>IEC 63045 Edition 2020-05;<br>IEC 61689 Edition 3.0 2013-02 |
| Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability | IEC 60601-1-6 Edition 3.2 2020-07 |
| **Infant Incubators** | |
| Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators | IEC 60601-2-19 Edition 3.0 2020-09 |
| Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators | IEC 60601-2-20 Edition 3.0 2020-09 |
| **Medical Endoscopes** | |
| Optics and photonics — Medical endoscopes and Endotherapy devices —Part 1: General requirements | ISO 8600-1 2nd Edition (2005-05-1) |
| Determination of field of view and direction of view of endoscopes with optics | ISO 8600-3 2nd Edition (2019-8) |
| Determination of maximum width of insertion portion | ISO 8600-4 3rd Edition (2023-01) |
| Determination of optical resolution of rigid endoscopes with optics | ISO 8600-5 2nd Edition (2020-10) |

| **Test Technology:** | **Test Method(s):** |
|---|---|
| **Medical Endoscopes (continued)** | |
| Photography — Electronic still-picture imaging — Noise measurements | ISO 15739 3rd Edition (2017-05) |
| Photography — Electronic still picture imaging — Resolution and spatial frequency responses | ISO 12233 4th Edition (2023-02) |
| Medical electrical equipment –<br>Part 2-18: Particular requirements for the basic safety and essential performance<br>of endoscopic equipment | IEC 60601-2-18 Edition 3.0 2009-08 |
| Photobiological safety of lamps and lamp systems | IEC 62471 Edition 1.0 b:2006<br>Exclusion: Wavelength range 1100nm - 3000nm |
| **Ophthalmic Instruments** | |
| Ophthalmic instruments – Fundamental Requirements and Test Methods-Part 1: General Requirements Applicable to All Ophthalmic Instruments | ISO 15004-1:2020<br>Exclusion: Wavelength range 1150nm - 2500nm |
| Ophthalmic instruments – Fundamental requirements and Test Methods-Part 2: Light Hazard Protection | ISO 15004-2:2007<br>Exclusion: Wavelength range 1150nm - 2500nm |

**On the following products and materials:**

Diagnostic Ultrasound Systems and Transducers
Ultrasonics – Physiotherapy Systems
Medical Equipment and Medical Devices
High Intensity Therapeutic Ultrasound (HITU) Equipment

*[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.*

*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** | **FDA Recognition Number** |
|---|---|
| IEC 60601-2-37 Edition 2.1 2015 | 12-293 |
| IEC 60601-2-5 Edition 3.0 2009-07 | 12-205 |
| IEC 60601-2-62 Edition 1.0 2013-07 | 12-281 |

| *Testing Activities performed under the scope of the U.S FDA ASCA Pilot Program Specifications:*<br><br>*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** | **FDA Recognition Number** |
| IEC 60601-1-11 Edition 2.0 2015-01<br>IEC 60601-1-11 Edition 2.1 2020 | 19-14<br>19-38 |
| IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION<br>ANSI AAMI IEC 60601-1-8:2006 and A1:2012 [Including AMD 2:2021] | 5-131<br><br>5-131 |
| 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 |
| IEC 60601-2-18 Edition 3.0 2009-08 | 9-114 |
| IEC 60601-1-6 Edition 3.2 2020-07 | 5-132 |
| IEC 60601-2-19 Edition 3.0 2020-09 | 6-461 |
| IEC 60601-2-20 Edition 3.0 2020-09 | 6-462 |

[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 following exclusions apply to the ANSI/AAMI ES60601: Clauses 10.1-10.7.*

*Note: Exclusions listed for ANSI AAMI ES60601-1 also apply to other collaterals and particulars in the 60601/80601 family of standards except where otherwise stated.*

# Accredited Laboratory

A2LA has accredited

## SIGMA SCIENTIFIC SERVICES LLC

*Sunrise, FL*

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 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 6th day of February 2024.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 4896.01
Valid to December 31, 2025

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