



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

SIGMA SCIENTIFIC SERVICES LLC

7737 N University Drive, Suite 101

Tamarac, FL 33321

Mr. Jorge Millan

E-Mail: [jmillan@sigmabiomedical.com](mailto:jmillan@sigmabiomedical.com)

ELECTRICAL

Valid To: December 31, 2023

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<sup>2</sup> requirements), accreditation is granted to this laboratory to perform the following tests:

<b><u>Test Technology:</u></b>	<b><u>Test Method(s)<sup>1</sup>:</u></b>
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 ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
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
Medical Electrical Equipment- Part 1-11: General Requirements for the Basic Safety and Essential Performance- Collateral Standard: Requirements for Medical Electrical Equipment and Medical	IEC 60601-1-11 Edition 2.1 2020-07

Electrical Systems Used in the Home Healthcare Environment	
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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

*<sup>1</sup>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:  <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 published on September 25th, 2020, and in accordance with all requirements of A2LA R256 Specific Requirements- FDA ASCA Program<sup>2</sup></i>  <i>Note the following exclusions for all FDA ASCA testing: LED test per IEC 62471, Lithium battery test, Oxygen bomb test, UV Radiation, Flammable Liquids, and flammable anesthetic mixtures test, Cathode ray tubes test</i>
<b>Standards</b>
IEC 60601-2-37 Edition 2.1 2015
IEC 60601-2-5 Edition 3.0 2009-07
IEC 60601-2-62 Edition 1.0 2013-07
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION OR IEC60601-1-11 Edition 2.0 2015-01
ANSI/AAMI HA60601-1-11:2015
IEC 60601-1 Edition 3.2 2020-08
ANSI AAMI ES60601- 1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012

*<sup>2</sup>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

### SIGMA SCIENTIFIC SERVICES LLC

Tamarac, 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 14<sup>th</sup> day of April 2022.

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

Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 4896.01  
Valid to December 31, 2023

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