CERTIFICATE OF ACCREDITATION

ANSI-ASQ National Accreditation Board
500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

Acertara Acoustic Laboratories, LLC
1900 South Sunset Street, Unit F
Longmont CO 80501

has been assessed by ANAB
and meets the requirements of international standard

ISO/IEC 17025:2005

while demonstrating technical competence in the fields of

CALIBRATION AND TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of calibrations and/or tests to which this accreditation applies.

ACT-1394
Certificate Number

ANAB Approval

Certificate Valid: 07/07/2017-06/02/2019
Version No. 003 Issued: 07/07/2017

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. 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).

ANSI-ASQ National Accreditation Board

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

Acertara Acoustic Laboratories, LLC

1900 South Sunset Street, Unit F
Longmont, CO 80501
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CALIBRATION AND TESTING

Valid to: **June 2, 2019** Certificate Number: **ACT-1394**

TESTING

Electrical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ultrasonic medical therapeutic equipment Acoustic pressures, intensity, and power Thermal and mechanical indices	IEC 60601-2-5 and IEC 61689, NEMA Standard Publication UD-2, Part 1050.10 of the Title 21 US CFR	Medical Electrical Equipment	10 kPa to 19.6 MPa Oscilloscope Hydrophone
Ultrasonic medical diagnostic and monitoring equipment Acoustic pressures, intensity, and power Thermal and mechanical indices	IEC 60601-2-37 and IEC 62359, NEMA Standard Publication UD-2 and UD-3	Medical Electrical Equipment	10 kPa to 19.6 MPa Oscilloscope Hydrophone
Implantable medical devices Implantable devices are exposed to ultrasonic energy	IEC 14708-1, -2, -3 and EN45502-1	Medical Electrical Equipment	10 kPa to 19.6 MPa Source Transducer Oscilloscope Hydrophone

CALIBRATION

Electrical – DC/Low Frequency

Parameter / Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method and/or Equipment
DC Voltage-Measure[2]	(0.1 to 0.5999) V (0.6 to 5.999) V (6 to 60) V (60 to 600) V	0.1% + 0.1 mV 0.05% + 1 mV 0.05% + 10 mV 0.05% + 0.1 V	Fluke 87 V Direct Measurement; FirstCall Calibration Procedure

Electrical – DC/Low Frequency

Parameter / Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method and/or Equipment
AC Voltage-Measure[2]	(0.020 to 0.079) V (0.080 to 0.159) V (0.160 to 0.399) V (0.400 to 0.799) V (0.800 to 1.599) V (1.600 to 3.99) V (4.00 to 7.99) V	2% + 0.5 mV 2% + 1 mV 2% + 2.5 mV 2% + 5 mV 2% + 10 mV 2% + 25 mV 2% + 50 mV	Tektronix TDS3012B TDS3014C Direct Measurement; FirstCall Calibration Procedure
Capacitance[2]	(200.1 to 2 000) pF @100 Hz, 120 Hz, 1 kHz, 10 kHz, 100 kHz	0.5% + 0.3 pF	Agilent U1733C and Capacitors Substitution Measurement; FirstCall Calibration Procedure
RF Gain	(0.3 to 3.5) Vrms (0 to 60) dB	0.38 dB	Tektronix TDS3012B TDS3014C PE7008-1 Attenuators Direct Measurement; PGAT/ATLAS, ARTIS Calibration Procedures
RF Source	10 mV/Div to 1 V/Div DC (-20 to +20) dBm	0.36 dB	Tektronix TDS3012B TDS3014C Direct Measurement; ARTIS Calibration Procedure

Calibration and Measurement Capability (CMC) is expressed in terms of the measurement parameter, measurement range, expanded uncertainty of measurement and reference standard, method, and/or equipment. The expanded uncertainty of measurement is expressed as the standard uncertainty of the measurement multiplied by a coverage factor of 2 (k=2), corresponding to a confidence level of approximately 95%.

Notes:

1. % = percent of reading
2. This scope is formatted as part of a single document including Certificate of Accreditation No. ACT-1394.

Vice President