SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Acertara Acoustic Laboratories, LLC

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TESTING

ISO/IEC 17025 Accreditation Granted: **02 June 2025**

Certificate Number: **ACT-1394.01** Certificate Expiry Date: **02 June 2027**

Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Ultrasonic Medical Therapeutic Equipment	Acoustic Pressure Intensity & Power Thermal; Air & Simulated Use Temperature	12-205, IEC 60601-2-5 Edition 3.0 2009-07	Clauses 201.10.102 201.11.1.2.2 201.11.1.3 201.12.1.101 201.12.1.105 201.12.4.4.104 201.12.4.4.105 201.12.4.4.106 Values per definitions summarized in table 201.101
Ultrasonic Medical Diagnostic & Monitoring Equipment	Acoustic Pressure, Intensity & Power, Thermal & Mechanical Indices	12-293, IEC 60601-2-37 Edition 2.1 2015	Clauses 201.11.1.2.2 201.11.1.3 201.12.1 201.12.4.2 Values per definitions summarized in table 201.101 and 201.103

Note:

1. Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, FDA Accreditation Scheme for Conformity Assessment (ASCA) Program – Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment. Laboratories

meeting these requirements are eligible to apply to participate in the FDA ASCA program. Participation in the FDA ASCA program can be confirmed by visiting their website https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-accredited-testing-laboratories.

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