SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

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ELECTRICAL

Valid To: January 31, 2020 Certificate Number: 3331.06

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following product safety tests:

Test Description:	**Test Method [1,2]:**
Product Safety	
Medical (excluding clauses detailed in Table #1 and #2 below)[3]	UL 60601-1 (Ed. 2); ANSI/AMI 60601-1 (Ed. 3); CSA 60601-1 (Ed. 2 and 3); EN/IEC 60601-1 (Ed. 2), IEC 60601-1 (Ed. 2); EN/IEC 60601-1 (Ed. 3), IEC 60601-1 (Ed. 3); EN/IEC 60601-1-1 (Medical Electrical Systems); EN/IEC 60601-1-4 (PEMS); EN/IEC 60601-1-6 (Usability); EN/IEC 60601-1-8 (Alarms); EN/IEC 60601-1-11 (Home Healthcare); EN/IEC 60601-2-2 (High Frequency Surgical Equipment); EN/IEC 60601-2-4 (Cardiac Defibrillators); EN/IEC 60601-2-5 (Ultrasonic Physiotherapy Equipment); EN/IEC 60601-2-10 (Nerve and Muscle Stimulators); EN/IEC 60601-2-12 (Lung Ventilators; Critical Care Ventilators); EN/IEC 60601-2-13 (Anaesthetic Systems); EN/IEC 60601-2-16 (Haemodialysis, Haemodiafiltration, and Haemofiltration Equipment); EN/IEC 60601-2-17 (Automatically-Controlled Brachytherapy Afterloading Equipment); EN/IEC 60601-2-18 (Endoscopic Equipment); EN/IEC 60601-2-19 (Baby Incubators); EN/IEC 60601-2-20 (Transport Incubators); EN/IEC 60601-2-21 (Infant Radiant Warmers); EN/IEC 60601-2-22 (Diagnostic and Therapeutic Laser Equipment); EN/IEC 60601-2-23 (Transcutaneous Partial Pressure Monitoring Equipment);

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Test Description:	**Test Method[1,2]:**
Product Safety (cont.)	
Medical (cont.)	EN/IEC 60601-2-24 (Infusion Pumps and Controllers); EN/IEC 60601-2-25 (Electrocardiographs); EN/IEC 60601-2-26 (Electroencephalographs); EN/IEC 60601-2-27 (Electrocardiographic Monitoring Equipment); IEC 60601-2-30 (Automatic Cycling Non-Invasive Blood Pressure Monitoring Equipment); EN/IEC 60601-2-34 (Direct Blood Pressure Monitoring Equipment); EN/IEC 60601-2-35 (Blankets, Pads, and Mattresses Intended for Heating); EN/IEC 60601-2-37 (Ultrasonic Medical Diagnostic and Monitoring Equipment); EN/IEC 60601-2-38 (Electrically Operated Hospital Beds); EN/IEC 60601-2-39 (Peritoneal Dialysis Equipment); EN/IEC 60601-2-40 (Electromyographs and Evoked Response Equipment); EN/IEC 60601-2-41 (Surgical Luminaires and Luminaires for Diagnosis); EN/IEC 60601-2-46 (Operating Tables); EN/IEC 60601-2-47 (Ambulatory Electrocardiographic Systems); EN/IEC 60601-2-49 (Multifunction Patient Monitoring Equipment); EN/IEC 60601-2-50 (Infant Phototherapy Equipment); EN/IEC 60601-2-51 (Recording and Analyzing Single Channel and Multichannel Electrocardiographs); EN/IEC 60601-2-52 (Medical Beds); IEC 60601-2-57 (Non-Laser Light Source Equipment); EN/IEC 80601-2-30 (Automated Non-Invasive BP); EN/IEC 62366; EN/IEC 62304
Office (excluding clauses detailed in Table #3 below) [3]	EN/IEC/CSA/UL 60950-1; EN/IEC/CSA/UL 60950-21; IEC 62368-1
Measurement	EN/IEC/CSA/UL 61010-1; EN/IEC/CSA 61010-2-101; EN/IEC/CSA 61010-81
Electronics	EN/IEC/CSA/UL 60065
Household	EN/IEC/CSA/UL 60335-1; EN/IEC/CSA 60335-2-6 (Stationary Ranges, Hobs, Ovens); EN/IEC/CSA 60335-2-9 (Grills, Toasters); EN/IEC/CSA 60335-2-14 (Kitchen Machines); EN/IEC/CSA 60335-2-29 (Battery Chargers); EN/IEC/CSA 60335-2-59 (Insect Killers); EN/IEC/CSA 60335-2-64 (Commercial Electric Kitchen Machines); EN/IEC/CSA 60335-2-78 (Outdoor Barbecues)

[1] When the date, revision or edition of a test method standard is not identified on the scope of accreditation, the laboratory is expected to be competent in the use of the current version within one year of the date of publication, per part C., Section 1 of A2LA *R101 - General Requirements - Accreditation of ISO-IEC 17025 Laboratories*.

[2] 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.

[3] **Exclusion Tables**

Table #1: Clauses excluded from IEC 60601-1 Ed. 2 (1988)

Clause	Measurement/Testing
29	X-radiation
36	EMC requirements
37	Flammable gases
59	Construction and layout
Appendix F	Flammable mixtures

Table #2: Clauses excluded from IEC 60601-1 Ed. 3.0

Clause	Measurement/Testing
8.9.1.7	Material groups classification
9.5.2	Cathode ray tubes
9.6.2.1	Audible acoustic energy
9.6.3	Hand-transmitted vibration
9.7.5	Pressure vessels
10.1	X-radiation
11.2	Fire prevention (Spark ignition test apparatus)
11.3	Constructional requirements for fire enclosures
15.4.3.4	Primary Lithium batteries
G	Protection against hazards of ignition of flammable anesthetic mixtures
G.4.3	Prevention of electrostatic charges
L	Insulated winding wires for use without interleaved insulation

Table #3: Clauses excluded from IEC/EN 60950-1

Clause	Measurement/Testing
4.3.6	Direct plug-in equipment
4.3.13	Radiation - Ionizing radiation
6.2	Protection of equipment users from over-voltages on telecom. networks
6.3	Protection of the telecommunication wiring system from overheating
7.3	Protection of equipment users from over-voltages on cable distribution system
7.4.2	Voltage surge test
7.4.3	Impulse test
Annex A.1	Flammability test for fire enclosures of movable equipment having a total mass exceeding 18kg, and of stationary equipment
Annex H	Ionizing radiation
Annex M	Telephone ringing signals
Annex Q	Voltage dependent resistors (VDRs)

Accredited Laboratory

A2LA has accredited

TUV RHEINLAND OF NORTH AMERICA, INC.

Littleton, MA

for technical competence in the field of

Electrical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *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 8 January 2009*).

Presented this 4th day of December 2017.

President and CEO
For the Accreditation Council
Certificate Number 3331.06
Valid to January 31, 2020

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