SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

TUV RHEINLAND OF NORTH AMERICA, INC.
295 Foster Street
Suite 100
Littleton, MA 01460
Mr. David Spencer Phone: (925) 249-9123 ext. 2116
Email: dspencer@us.tuv.com

ELECTRICAL

Valid To: January 31, 2024 Certificate Number: 3331.06

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 [4] requirements), accreditation is granted to this laboratory at the location listed above, to perform the following product safety tests:

Test Description:	**Test Method [1,2]:**
Product Safety	
Medical (excluding clauses detailed in Table #1and #2 below) [3]	UL 60601-1 (Ed. 2); ANSI/AAMI ES 60601-1 (Ed. 3); ANSI/AAMI ES 60601-1 (Ed. 3.1); ANSI/AAMI ES 60601-1 (Ed. 3.2); CSA 60601-1 (Ed. 2); CSA 60601-1 (Ed. 3); CSA 60601-1 (Ed. 3.1); 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 (Ed 3.1), IEC 60601-1 (Ed. 3.1); EN/IEC 60601-1 (Ed 3.2), IEC 60601-1 (Ed. 3.2); EN/IEC 60601-1-1 (Medical Electrical Systems); EN/IEC 60601-1-3 (Radiation Protection in Diagnostic X-ray equipment); EN/IEC 60601-1-6 (Usability); EN/IEC 60601-1-8 (Alarms); EN/IEC 60601-1-11 (Home Healthcare); EN/IEC 60601-1-12 (Equipment for EMS use Environments); 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 60601-2-8 (Therapeutic X-ray Equipment, range 10 kV to 1 MV); 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);

5202 Presidents Court, Suite 220 | Frederick, MD 21703-8515 | Phone: 301 644 3248 | Fax: 240 454 9449 | www.A2LA.org

Test Description:	**Test Method [1,2]:**
Product Safety (cont.) *Medical (cont.)*	EN/IEC 60601-2-16 (Haemodialysis, Haemodiafiltration, and Haemofiltration Equipment); EN/IEC 60601-2-17 (Automatically Controlled Brachytherapy After-loading 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); 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); EN/IEC 60601-2-28 (X-ray Tube Assembly for Medical Diagnostics); 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 60601-2-43 (X-ray Equipment for Interventional Procedures); EN/IEC 60601-2-44 (X-ray Equipment for Computed Tomography); EN/IEC 60601-2-45 (Mammographic X-ray Equipment and Mammographic Stereotactic Devices); 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); EN/IEC 60601-2-54 (X-ray Equipment or Radiography and Radioscopy); IEC 60601-2-57 (Non-Laser Light Source Equipment); EN/IEC 60601-2-63 (Dental Extra-oral X-ray Equipment); EN/IEC 60601-2-68 (X-ray-based Image-guided Radiotherapy Equipment for use with Electron Accelerators, Light Ion Beam Therapy Equipment and Radionuclide Beam Therapy Equipment); EN/IEC 60601-2-83 (Home Light Therapy Equipment); EN/IEC 80601-2-30 (Automated Non-Invasive BP); EN/IEC 62366; EN/IEC 62304

Test Description:	**Test Method [1,2]:**
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 (Electrical Equipment for Measurement, Control, and Laboratory use); IEC/EN/UL/CSA 61010-2-010 (Laboratory Equipment for the Heating of Materials); IEC/EN/UL/CSA 61010-2-020 (Laboratory Centrifuges); IEC/EN/UL/CSA 61010-2-030 (Equipment Having Testing or Measuring Circuits); IEC/EN/UL/CSA 61010-2-040 (Sterilizers and Washer-disinfectors used to Treat Medical Materials); IEC/EN/UL/CSA 61010-2-091(Cabinet X-ray systems, [non-medical]); EN/IEC/CSA 61010-2-101 (In vitro diagnostic (IVD) Medical Equipment); EN/IEC/CSA 61010-2-081 (Automatic and Semi-automatic Laboratory Equipment for Analysis and other Purposes)
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); IEC/EN 62040-1; UL 1778; CSA 107.3; IEC 60825-1 (Safety of Laser Products); IEC 60825-2 (Safety of Optical Fibre Communication Systems [OFCS]); IEC 60825-4 (Laser Guards); EN/IEC 62471 (Photobiological Safety of Lamps and Lamp Systems)

[1] When the date, edition, version, etc. is not identified in the scope of accreditation, laboratories may use the version that immediately precedes the current version for a period of one year from the date of publication of the standard measurement method, 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
36	EMC requirements
37	Flammable gases
Appendix F	Flammable mixtures

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

Clause	Measurement/Testing
8.8.4.2	Resistance to environmental stress
8.9.1.7	Material groups classification
9.5.2	Cathode ray tubes
9.6.3	Hand-transmitted vibration
9.7.5	Pressure vessels
11.2	Fire prevention (Spark ignition test apparatus)
15.4.3.4	Primary Lithium batteries
17	EMC Requirements
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)

Table #4: Clauses excluded from IEC 61010-1 Ed.3 (2010)

Clause	Measurement/Testing
8.1.101	Dynamic test of horizontal heating surfaces (IEC 61010-2-010:2019)
11.7.4	Pressure test (IEC 61010-2-040:2015)

Table #5: Clauses excluded from IEC 60601-2-2

Clause	Measurement/Testing
201.15	NE thermal performance
201.15.101.7	NE adhesion
201.17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Table #6: Clauses excluded from IEC 60601-1-11

Clause	Measurement/Testing
10.1.2	Requirements for mechanical strength for non-TRANSIT-OPERABLE ME EQUIPMENT
10.1.3	Requirements for mechanical strength for TRANSIT-OPERABLE ME EQUIPMENT
12	Additional requirements for ELECTROMAGNETIC EMISSIONS of ME EQUIPMENT and ME SYSTEMS

Table #7: Clauses excluded from IEC 60601-2-37

Clause	Measurement/Testing
201.7.9.3.101	(Verification of) Technical data regarding (ultrasound) acoustic output levels
201.11.1.3.1.1	Simulated use (temperatures using flesh mimicking material)
202.6	ELECTROMAGNETIC COMPATIBILITY

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* [4]*:*

Standards:

ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)
ANSI AAMI HA60601-1-11:2015

IEC 60601-1-3 Edition 2.1 2013-04
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION
IEC 60601-2-2 Edition 6.0 2017-03
IEC 60601-2-5 Edition 3.0 2009-07
IEC 60601-2-8 Edition 2.1 b:2015
IEC 60601-2-10 Edition 2.1 2016-04
IEC 60601-2-16 Edition 5.0 2018-4
IEC 60601-2-17 Edition 3.0 2013-11
IEC 60601-2-18 Edition 3.0 2009-08
IEC 60601-2-19 Edition 2.1 2016-04
IEC 60601-2-20 Edition 2.1 2016-04
IEC 60601-2-21 Edition 2.1 2016-04

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* [4]*:*
Standards:
IEC 60601-2-22 Edition 3.1 2012-10 IEC 60601-2-23 Edition 3.0 2011-02 IEC 60601-2-25 Edition 2.0 2011-10 IEC 60601-2-27 Edition 3.0 2011-03 IEC 60601-2-28 Edition 3.0 2017-06 IEC 60601-2-29 Edition 3.0 2008-06 IEC 60601-2-34 Edition 3.0 2011-05 IEC 60601-2-36 Edition 2.0 2014-04 IEC 60601-2-37 Edition 2.1 2015 IEC 60601-2-43 Edition 2.0 2010-03 IEC 60601-2-43 Edition 2.2 2019-10 CONSOLIDATED VERSION IEC 60601-2-44 Edition 3.2: 2016 IEC 60601-2-45 Edition 3.1 2015 IEC 60601-2-47 Edition 2.0 2012-02 IEC 60601-2-50 Edition 2.1 2016-04 IEC 60601-2-52 Edition 1.0 2009-12 IEC 60601-2-54 Edition 1.2 2018-06 CONSOLIDATED VERSION IEC 60601-2-57 Edition 1.0 2011-01 IEC 60601-2-63 Edition 1.1 2017-07 CONSOLIDATED VERSION IEC 60601-2-68 Edition 1.0 2014-09 IEC 80601-2-30 Edition 2.0 2018-03

[4]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

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 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This laboratory also meets *A2LA R256 - Specific Requirements - FDA ASCA Program*. 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 17th day of December 2021.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3331.06
Valid to January 31, 2024

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