SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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ELECTRICAL

Valid To: January 31, 2026 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 [1] requirements), accreditation is granted to this laboratory at the location listed above, to perform the following tests on the following types of products: Environmental, Medical, Consumer, Industrial, Automotive, Commercial, Telecommunications, Military, Marine, Test & Measurement, Outdoor, Aerospace:

Test Description:	**Test Method [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); CSA 60601-1 (Ed. 3.2); 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)

Test Description:	**Test Method [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 60601-2-36 (Equipment for extra-corporeally induced lithotripsy); 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); IEC 60601-2-65 Dental Intra-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)

Test Description:	**Test Method [2]:**
Product Safety (cont.) *Medical (cont.)*	IEC 80601-2-60 Performance of Dental Equipment; ISO 80601-2-61 Pulse Oximeter Equipment; ISO 80601-2-69 Oxygen Concentrator Equipment; ISO 80601-2-70 Sleep Apnoea Equipment; IEC 80601-2-77 robotically assisted surgical equipment; EN/IEC 62366; EN/IEC 62304
Office (*excluding clauses detailed in Table #3 below*) [3]	EN 60950-1; IEC 60950-1; CSA 60950-1; UL 60950-1; EN 60950-21; IEC 60950-21; CSA 60950-21; UL 60950-21; EN 60950-22; IEC 60950-22; CSA 60950-22; UL 60950-22; IEC 62368-1; EN 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); EN/IEC/CSA 61010-2-081 (Automatic and Semi-automatic Laboratory Equipment for Analysis and other Purposes); 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)
Electronics	EN/IEC/CSA/UL 60065
Household	EN/IEC/CSA/UL 60335-1; EN/IEC/CSA 60335-2-2 (Vacuum Cleaners); EN/IEC/CSA 60335-2-6 (Stationary Ranges, Hobs, Ovens); EN/IEC/CSA 60335-2-9 (Grills, Toasters); IEC/EN/CSA 60335-2-10 (Floor treatment machines); EN/IEC/CSA 60335-2-14 (Kitchen Machines); EN/IEC/CSA 60335-2-29 (Battery Chargers); IEC/EN 60335-2-38 (commercial griddles and electric grills); IEC/EN/CSA 60335-2-41 (Pumps); EN/IEC/CSA 60335-2-59 (Insect Killers); EN/IEC/CSA 60335-2-64 (Commercial Electric Kitchen Machines); IEC/EN 60335-2-75 (commercial dispensing appliances and vending 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)

The below tests are performed using the above Product Safety standards:

- Input current / Power Input - Durability of Markings - Access to Live Parts - Energy Hazards - Capacitance Discharge - TNV Circuits, Limits, Connections Voltages Generated Externally - SELV Circuits - Torque - Telecommunication Network Separation and Protection - Limited Current Circuits, Values - Limited Power Sources - Resistances of Earthing Conductors - GND Continuity Test - Humidity Conditioning - Creepage Distances, Clearances - Working Voltage - Stability - Thermal Cycling and Thermal Aging - Mechanical Strength / Impact - Enclosed and Sealed Parts	- Steady Force Test - Drop Test - Stress Relief - Wall or Ceiling Mounted Equipment - Handles and Manual Controls - Battery Overcharge/Discharge and Reverse Current Measurements - Spillage Tests - Protection against Hazardous Moving Parts - Thermal Requirements / Ball Pressure Test - Temperature Rise - Resistance to Abnormal Heat - Touch Current and Protective Conductor Current / Leakage - Dielectric Strength / Hipot - Component Failure and Abnormal Operation - Power Supply Output/transformer/accessible Connector Overload - Voltage Surge / Impulse - Sound Pressure Level - Resistance to Fire

EPA ENERGY STAR Testing

Product Family Guidelines:	**Test Method [2]:**
Computers	ENERGY STAR Program Requirements for Computers, Version 8.0; IEC 62301; EPRI Generalized Test Protocol for Calculating the Energy Efficiency of Internal A.C.-D.C. and D.C.-D.C. Power Supplies
Imaging Equipment	ENERGY STAR Program Requirements for Imaging Equipment, Version 3.2; IEC 62301
Uninterruptable Power Supplies	ENERGY STAR Program Requirements for Uninterruptable Power Supplies, Version 2.0
Displays	ENERGY STAR Program Requirements for Displays, Version 8.0
Audio/Video Equipment	ENERGY STAR Program Requirements for Audio/Video Equipment, Version 3.0

Test Description:	**Test Method [2]:**
Electromagnetic Compatibility	
Commercial Emissions Radiated and Conducted (10m Semi-Anechoic Chamber, up to 40 GHz)	47 CFR, FCC Part 15 B (using ANSI C63.4:2014); 47 CFR, FCC Part 18 (using FCC MP-5:1986); CISPR 11; AS/NZS CISPR 11 (2004); EN 55011; CISPR 12; EN 55012; CISPR 13; EN 55013; CISPR 14; EN 55014; KS C 9814-2; AS/NZS CISPR 14.1; CISPR 22; EN 55022; AS/NZS CISPR 22; KS C 9814-1; SANS 214-1; CISPR 32; AS/NZS CISPR 32; EN 55032; KS C 9832; VCCI-CISPR 32 (up to 6GHz); SANS 2332; CNS 13803; CNS 13783-1; CNS 15936:2016 (up to 6 GHz); EN 12015 VCCI V-3 ICES-001; ICES-002; ICES-003; ICES-005; JIS C 1806-1; SANS 222; SANS 211; KS C 9811; TCVN 7189:2009 QCVN 118:2018/BTTTT
Current Harmonics	IEC 61000-3-2; EN 61000-3-2; IEC 61000-3-12; EN 61000-3-12; SANS 61000-3-2; JIS C 61000-3-2
Flicker and Fluctuations	IEC 61000-3-3; EN 61000-3-3; IEC 61000-3-11; EN 61000-3-11; SANS 61000-3-3
Electrostatic Discharge	IEC 61000-4-2; EN 61000-4-2; SANS 61000-4-2
Radiated Immunity	IEC 61000-4-3; EN 61000-4-3; SANS 61000-4-3
Electrical Fast Transient/Burst	IEC 61000-4-4; EN 61000-4-4; SANS 61000-4-4
Surge	IEC 61000-4-5; EN 61000-4-5; SANS 61000-4-5
Conducted Immunity	IEC 61000-4-6; EN 61000-4-6; SANS 61000-4-6
Power Frequency Magnetic Field Immunity	IEC 61000-4-8; EN 61000-4-8; SANS 61000-4-8
Voltage Dips, Short Interrupts, and Line Voltage Variations	IEC 61000-4-11; EN 61000-4-11; SANS 61000-4-11; IEC 61000-4-34; EN 61000-4-34
Ring Wave	IEC 61000-4-12; EN 61000-4-12
Automotive (Generic)	UNECE REG 10; EU 2015/208:2018
AUTOMOTIVE Electrostatic Discharge (ESD)	ISO 10605; SAE J1113-13
Conducted Emissions	CISPR 25 (2002, 2008) Sections 6.2 and 6.3; CISPR 25 (2016, 2021) Sections 6.3 and 6.4; CISPR 25

Test Description:	**Test Method [2]:**
Radiated Emissions Anechoic	CISPR 25 (2002,2008) Section 6.4; CISPR 25 (2016, 2021) Section 6.5; CISPR 25
Radiated Immunity Anechoic	ISO 11452-2; SAE J1113-21
Radiated Immunity Anechoic (Radar Pulse Only)	ISO 11452-2
Radiated Immunity (Portable Transmitters)	ISO 11452-9
Vehicle Radiated Immunity (ALSE)	ISO 11451-2
Generic / Product Specific EMC Standards	ANSI C12.20:2010; CISPR 14-2; CISPR 24; CISPR 35: EN 12015; EN 12016; EN 13766; ISO 13766; EN 13766-1; ISO 13766-1; EN 13766-2; ISO 13766-2; EN 50361; EN 50364; EN 50371; EN 55024 (excluding Acoustic Telecommunication Terminal Equipment); EN 55035 (except IEC 61000-4-20, and 21); EN 55103-2; ETSI EN 301 489-1; ETSI EN 301 489-3; ETSI EN 301 489-4; ETSI EN 301 489-5; ETSI EN 301 489-6; ETSI EN 301 489-7; ETSI EN 301 489-8; ETSI EN 301 489-9; ETSI EN 301 489-10; ETSI EN 301 489-12; ETSI EN 301 489-15; ETSI EN 301 489-16; ETSI EN 301 489-17; ETSI EN 301 489-18; ETSI EN 301 489-19; ETSI EN 301 489-20; ETSI EN 301 489-23; ETSI EN 301 489-24; ETSI EN 301 489-25; ETSI EN 301 489-26; ETSI EN 300 386 v1.5.1; ETSI EN 300 386 v1.6.1; IEC 12895; EN 12895; IEC 13309; EN 13309; IEC 14982; ISO 14982; EN 14982; IEC 50121-1; EN 50121-1; IEC 50121-2; EN 50121-2; IEC 50121-3; EN 50121-3; IEC 50121-3-1; EN 50121-3-1; IEC 50121-3-2; EN 50121-3-2; IEC 50121-4; EN 50121-4; IEC 50130-4; EN 50130-4: IEC 50155; EN 50155; IEC 50270; EN 50270; IEC 50293; EN 50293

Test Description:	**Test Method [2]:**
Generic / Product Specific EMC Standards (cont.)	IEC 50370-1; EN 50370-1; IEC 50370-2; EN 50370-2; IEC 55014-2; EN 55014-2; IEC 55024 (excluding Acoustic Telecommunication Terminal Equipment); IEC 60533; EN 60533; IEC 60601-1-2; EN 60601-1-2; JIS T0601-1-2; KS C IEC 60601-1-2:2007; SANS 60601-1-2; IEC 60945; EN 60945; IEC 60974-10; EN 60974-10 IEC 61000-6-1; IEC 61000-6-2; KS C 9610-6-1; KS C 9610-6-2; EN 61000-6-1; EN 61000-6-2; IEC 61000-6-3; IEC 61000-6-4; KS C 9610-6-3; KS C 9610-6-4 EN 61000-6-3; EN 61000-6-4; IEC 61000-6-7; EN 61000-6-7 IEC 61000-6-8; EN 61000-6-7 IEC 61204-3; EN 61204-3; IEC 61326-1; EN 61326-1; SANS 61326-1; IEC 61326-2-1; EN 61326-2-1; IEC 61326-2-2; EN 61326-2-2; IEC 61326-2-3; EN 61326-2-3; IEC 61326-2-4; EN 61326-2-4; IEC 61326-2-5; EN 61326-2-5; IEC 61326-2-6; EN 61326-2-6; IEC 61326-3-1; EN 61326-3-1; IEC 61326-3-2; EN 61326-3-2; IEC 61547; EN 61547; IEC 61800-3; (test methods only, excluding supply influences -magnetic fields); EN 61800-3 (test methods only, excluding supply influences -magnetic fields); IEC 61851-21-2 (excluding annex “B”); EN 61851-21-2 (excluding annex “B”); IEC 62233; EN 62233; IEC 62920; EN 62920; ISO 11451-4; JIS C 1806-1; SANS 214-2; SANS 2335; KN 51; KS B 6945; KS B 6955; KS C IEC 60947-1; KS C 9040-2; KS C 9547:2020; KS C 9815:2019; KS C 9800-3:2017 Annex 18; KS C 9814-2; KS C 9835; KS C 9835: 2019; KS C 9974-10; KS C 9990

Test Description:	**Test Method [2]:**
Generic / Product Specific EMC Standards (cont.)	KS X 3124:2020; KS X 3125:2020; KS X 3126:2020; KS X 3127; KS X 3128; KS X 3123; KS X 3130; KS X 3131; KS X 3132; KS X 3134; KS X 3136; KS X 3137; KS X 3138; KS X 3139; QCVN 96:2015/BTTTT
Radio/Wireless Communications	
Unintentional Radiators / Unlicensed Radio FCC	ANSI C63.4; ANSI C63.10; 47 CFR Part 15.207 (ANSI C63.10: 2020 Section 6.6.4); 47 CFR, FCC Part 15.247; 47 CFR, FCC Part 15.407
Intentional Radiators	47 CFR, FCC Part 15, Subpart C (using ANSI C63.10: 2020)
Industrial; Scientific; and Medical Equipment	47 CFR, FCC Part 18 (using FCC MP-5:1986)
Canada	Radio Scope 1 – RSS-Gen; RSS-210 (Up to 40 GHz); RSS-215; RSS-216 (Up to 40 GHz); RSS-220 (Up to 40 GHz); RSS-243; RSS-247 (Up to 40 GHz); RSS-248
Europe (EU)	ETSI EN 300 220-1; ETSI EN 300 220-2; ETSI EN 300 330-1; ETSI EN 300 330-2; ETSI EN 300 440-1; ETSI EN 300 440-2; ETSI EN 301 511; ETSI EN 301 908-1; ETSI EN 301 908-2; ETSI EN 301 908-13
Taiwan	DGT LP0002 (2024)
Vietnam	QVCN 55:2023/BTTT
Australia / New Zealand	AS/NZS 4268
Hong Kong	HKCA 1039; HKCA 1042; HKCA 1049
Korea	*Regulations on Radio Equipment (Ordinance of MSIT No. 86, Jan 4, 2022);* *Unlicensed Radio Equipment Established Without Notice (MSIT Public Notification 2024-10, July 5, 2024);* Conformity Assessment Procedure of Radio Equipment (RRA Announce 2015-135 KS X 3123)

Testing Activities Performed in Support of FCC Certification in Accordance with 47 Code of Federal Regulations and FCC KDB 974614; Appendix A; Table A.1		
Rule Subpart/Technology:	**Test Method(s):**	**Maximum Frequency (MHz)**
Unintentional Radiators		
Part 15B	ANSI C63.4:2014	40000
Industrial; Scientific; and Medical Equipment		
Part 18	FCC MP-5:1986	40000
Intentional Radiators		
Part 15C	ANSI C63.10: 2020	40000
Note: Accreditation does not imply acceptance to the FCC equipment authorization program. Please see the FCC website (https://apps.fcc.gov/oetcf/eas/) for a listing of FCC approved 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
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
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)
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

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

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)

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* [1]*:*

Standards:	**ASCA Doc Number:**
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	19-46
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) [Incl. AMD2:2021]	19-46
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	19-49
ANSI AAMI/IEC 60601-1-2:2014 [Including AMD 1:2021]	19-36
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	19-36
IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION	12-336
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	5-132
ANSI AAMI/IEC 60601-1-8:2006 and A1:2012	5-131
ANSI AAMI/IEC 60601-1-8:2006 and A1:2012 [Including AMD 2:2021]	5-131
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	5-131
ANSI/AAMI HA60601-1-11:2015	19-47
ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021]	19-47
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	19-38
ANSI AAMI/IEC 60601-1-12:2016 [Including AMD 1:2021]	19-39
IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION	19-39
ANSI AAMI/IEC 60601-2-2:2017	6-389
IEC 60601-2-5 Edition 3.0 2009-07	12-205
IEC 60601-2-8 Edition 2.1 b:2015	12-301
IEC 60601-2-10 Edition 2.1 2016-04	6-423
IEC 60601-2-16 Edition 5.0 2018-4	9-121
IEC 60601-2-17 Edition 3.0 2013-11	12-272
IEC 60601-2-18 Edition 3.0 2009-08	9-114
IEC 60601-2-19 Edition 3.0 2020-09	6-461
IEC 60601-2-20 Edition 3.0 2020-09	6-462
IEC 60601-2-21 Edition 3.0 2020-09	6-463
IEC 60601-2-22 Edition 3.1 2012-10	12-268
IEC 60601-2-23 Edition 3.0 2011-02	1-87
IEC 60601-2-25 Edition 2.0 2011-10	3-105
ANSI AAMI/IEC 60601-2-25:2011/(R)2016	3-105
IEC 60601-2-27 Edition 3.0 2011-03	3-126
ANSI AAMI/IEC 60601-2-27:2011(R)2016	3-126
IEC 60601-2-28 Edition 3.0 2017-06	12-309
IEC 60601-2-34 Edition 3.0 2011-05	3-115
IEC 60601-2-36 Edition 2.0 2014-04	9-119
IEC 60601-2-37 Edition 2.1 2015	12-293
IEC 60601-2-43 Edition 2.2 2019-10 CONSOLIDATED VERSION	12-329
IEC 60601-2-43 Edition 3.0 2022-12	12-351
IEC 60601-2-44 Edition 3.2: 2016	12-302
IEC 60601-2-45 Edition 3.1 2015	12-294
IEC 60601-2-47 Edition 2.0 2012-02	3-155

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* [1]*:*

Standards:	**ASCA Doc Number:**
ANSI AAMI/IEC 60601-2-47:2012/(R)2016	3-155
IEC 60601-2-50 Edition 3.0 2020-09	6-450
IEC 60601-2-52 Edition 1.0 2009-12	6-321
IEC 60601-2-52 Edition 1.1 2015-03 CONSOLIDATED VERSION	6-489
IEC 60601-2-54 Edition 2.0 2022-09	12-348
IEC 60601-2-57 Edition 1.0 2011-01	12-242
IEC 60601-2-63 Edition 1.2 2021-05 CONSOLIDATED VERSION	12-339
IEC 60601-2-64 Edition 1.0 2014-09	12-318
IEC 60601-2-65 Edition 1.2 2021-05 CONSOLIDATED VERSION	12-340
IEC 60601-2-68 Edition 1.0 2014-09	12-319
ANSI AAMI/IEC 80601-2-30:2018	3-123
IEC 80601-2-30 Edition 2.0 2018-03	3-123
ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02)	1-139
ISO 80601-2-69 Second edition 2020-11	1-148
ISO 80601-2-70 First Edition 2015-01-15	1-115
ISO 80601-2-70 Second edition 2020-11	1-151
IEC 80601-2-60 Edition 2.0 2019-06	4-262
ANSI AAMI/IEC 80601-2-77:2020	6-438
IEC 80601-2-77 Edition 1.0 2019-07	6-438
IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION	19-34
ANSI UL 61010-1 3rd Ed, dated May 12, 2012 with revision through July 19, 2019	19-41

[1]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.

Boxborough, 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 18th day of April 2024.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3331.06
Valid to January 31, 2026

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