SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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ELECTRICAL

Valid To: April 30, 2026 Certificate Number: 6568.01

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 organization to perform the following tests:

Test Technology:	**Test Method(s)[2]:**
Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	IEC 60601-1, EN 60601-1; ANSI/AAMI ES60601-1; CAN/CSA-C22.2 No. 60601-1
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment	IEC 60601-1-3, EN 60601-1-3; CAN/CSA-C22.2 No. 60601-1-3
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance – Collateral standard: Usability	IEC 60601-1-6, EN 60601-1-6; CAN/CSA-C22.2 No. 60601-1-6
Medical devices - Application of usability engineering to medical devices	IEC 62366; EN 62366; IEC 62366-1; EN 62366-1; CSA IEC 62366-1; ANSI/AAMI/IEC 62366-1
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	IEC 60601-1-8; EN 60601-1-8; ANSI/AAMI/IEC 60601-1-8; CAN/CSA-C22.2 No. 60601-1-8
Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for environmentally conscious design	IEC 60601-1-9; EN 60601-1-9; CAN/CSA C22.2 No. 60601-1-9

Test Technology:	**Test Method(s)[2]:**
Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance – Collateral standard: Requirements for the development of physiologic closed-loop controllers	IEC 60601-1-10; EN 60601-1-10; CSA C22.2 NO. 60601-1-10
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	IEC 60601-1-11; EN 60601-1-11; ANSI/AAMI HA60601-1-11; CAN/CSA-C22.2 No. 60601-1-11
Medical electrical Equipment -- Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment	IEC 60601-1-12; EN 60601-1-12; ANSI/AAMI/IEC 60601-1-12; CAN/CSA-C22.2 No. 60601-1-12
Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	IEC 60601-2-2, EN IEC 60601-2-2; ANSI/AAMI/IEC 60601-2-2; CSA C22.2 NO. 60601-2-2
Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	IEC 60601-2-10; EN 60601-2-10; CAN/CSA-C22.2 No.60601-2-10A
Medical electrical equipment – Part 2-18: Particular requirements for basic safety and essential performance of endoscopic equipment	IEC 60601-2-18; EN 60601-2-18; CAN/CSA-C22.2 No. 60601-2-18
Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	IEC 60601-2-22; EN IEC 60601-2-22; CAN/CSA-C22.2 No. 60601-2-22
Safety of laser products - Part 1: Equipment classification and requirements	IEC 60825-1; EN 60825-1; CSA E60825-1
Medical electrical equipment – Part 2-24: Particular requirements for basic safety and essential performance of infusion pumps and controllers	IEC 60601-2-24; EN 60601-2-24; CAN/CSA-C22.2 No. 60601-2-24

Test Technology:	**Test Method(s)[2]:**
Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	IEC 60601-2-25; EN 60601-2-25; ANSI/AAMI/IEC 60601-2-25; CAN/CSA C22.2 No. 60601-2-25
Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs	IEC 80601-2-26; EN 80601-2-26; CAN/CSA-C22.2 No. 60601-2-26
Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	IEC 60601-2-27; EN 60601-2-27; ANSI/AAMI/IEC 60601-2-27; CAN/CSA C22.2 No. 60601-2-27
Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	IEC 60601-2-28; EN 60601-2-28; CSA C22.2 No. 60601-2-28
Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers	IEC 80601-2-30; EN IEC 80601-2-30; AAMI/IEC 80601-2-30; CSA C22.2 NO. 80601-2-30
Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment	IEC 60601-2-34; EN 60601-2-34; CAN/CSA C22.2 No. 60601-2-34
Medical electrical equipment – Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy	IEC 60601-2-36; EN 60601-2-36; CAN/CSA-C22.2 No. 60601-2-36
Medical electrical equipment – Part 2-37: Particular requirements for basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	IEC 60601-2-37; EN 60601-2-37; CAN/CSA-C22.2 No. 60601-2-37
Medical electrical equipment – Part 2-40: Particular requirements for basic safety and essential performance of electromyographs and evoked response equipment	IEC 60601-2-40; EN 60601-2-40; CAN/CSA-C22.2 No. 60601-2-40
Medical electrical equipment – Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis	IEC 60601-2-41; EN 60601-2-41; CAN/CSA-C22.2 No. 60601-2-41

Test Technology:	**Test Method(s)[2]:**
Medical electrical equipment – Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures	IEC 60601-2-43; EN 60601-2-43; CAN/CSA C22.2 No. 60601-2-43
Medical electrical equipment – Part 2-44: Particular requirements for basic safety and essential performance of X-ray equipment for computed tomography	IEC 60601-2-44; EN 60601-2-44; CAN/CSA-C22.2 No. 60601-2-44
Medical electrical equipment - Part 2-45: Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices	IEC 60601-2-45; EN 60601-2-45; CAN/CSA-C22.2 No. 60601-2-45
Medical electrical equipment - Part 2-46: Particular requirements for basic safety and essential performance of operating tables	IEC 60601-2-46; EN IEC 60601-2-46; CSA C22.2 No. 60601-2-46
Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	IEC 60601-2-47; EN 60601-2-47; ANSI/AAMI/IEC 60601-2-47; CAN/CSA C22.2 No. 60601-2-47
Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment	IEC 80601-2-49; EN 80601-2-49; ANSI/AAMI/ MP80601-2-49; CAN/CSA-C22.2 No. 60601-2-49
Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds	IEC 60601-2-52; EN 60601-2-52; CAN/CSA-C22.2 No. 60601-2-52
Medical electrical equipment – Part 2-54: Particular requirements for basic safety and essential performance of X-ray equipment for radiography and radioscopy	IEC 60601-2-54; EN 60601-2-54; CAN/CSA-C22.2 No. 60601-2-54
Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors	ISO 80601-2-55; EN ISO 80601-2-55; CAN/CSA-C22.2 No. 80601-2-55
Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	ISO 80601-2-56; EN ISO 80601-2-56

Test Technology:	**Test Method(s)[2]:**
Medical electrical equipment – Part 2-57: Particular requirements for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring, and cosmetic/aesthetic use	IEC 60601-2-57; EN 60601-2-57; CAN/CSA-C22.2 No. 60601-2-57
Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening	IEC 80601-2-59; EN IEC 80601-2-59; CAN/CSA-C22.2 No. 80601-2-59
Medical electrical equipment – Part 2-60: Particular requirements for basic safety and essential performance of dental equipment	IEC 80601-2-60; EN IEC 80601-2-60; CAN/CSA-C22.2 No. 80601-2-60
Dentistry - Patient Chair	ISO 6875; EN ISO 6875
Dentistry - Dental units – Part 1: General requirements and test methods	ISO 7494-1; EN ISO 7494-1
Dentistry - Dental units – Part 2: Air, water, suction, and wastewater systems	ISO 7494-2; EN ISO 7494-2
Dentistry - Operating lights	ISO 9680; EN ISO 9680
Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	ISO 80601-2-61; EN ISO 80601-2-61; CAN/CSA-C22.2 No. 80601-2-61
Medical electrical equipment – Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment	IEC 60601-2-62; EN 60601-2-62; CAN/CSA-C22.2 No. 60601-2-62
Medical electrical equipment – Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment	IEC 60601-2-63; EN 60601-2-63; CAN/CSA-C22.2 No. 60601-2-63
Medical electrical equipment – Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment	IEC 60601-2-65; EN 60601-2-65; CAN/CSA-C22.2 No. 60601-2-65
Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems	IEC 60601-2-66; EN IEC 60601-2-66; CAN/CSA-C22.2 No. 60601-2-66

Test Technology:	**Test Method(s)[2]:**
Medical Electrical Equipment – Part 2-67: Particular Requirements for basic safety and Essential Performance of oxygen conserving equipment	ISO 80601-2-67; EN ISO 80601-2-67
Medical electrical equipment – Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment	ISO 80601-2-69; EN ISO 80601-2-69; CAN/CSA-C22.2 No.80601-2-69
Medical electrical equipment – Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment	IEC 80601-2-77; EN IEC 80601-2-77; ANSI/AAMI 80601-2-77; CSA C22.2 No. 80601-2-77
Medical electrical equipment – Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation, or alleviation	IEC 80601-2-78; EN IEC 80601-2-78; ANSI/AAMI/IEC 80601-2-78; CSA C22.2 No. 80601-2-78
Medical electrical equipment – Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment	IEC 60601-2-83; EN IEC 60601-2-83
Medical suction equipment – Part 1: Electrically powered suction equipment	ISO 10079-1; EN ISO 10079-1; CAN/CSA-ISO 10079-1
Medical Suction Equipment – Part 3: Suction equipment powered from a vacuum or positive pressure gas source	ISO 10079-3; EN ISO 10079-3; CSA ISO 10079-3
Hoists for the transfer of disabled persons – Requirements and test methods	ISO 10535; EN ISO 10535; CSA Z10535.1
Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type	ISO 81060-1; EN ISO 81060-1; AAMI / ANSI / ISO 81060-1
Anaesthetic and respiratory equipment – Nebulizing systems and components	ISO 27427; EN ISO 27427; CSA ISO 27427
Standard specification for infrared thermometers for intermittent determination of patient temperature	ASTM E 1965-1998
Medical vehicles and their equipment – Road ambulances	EN 1789

Test Technology:	**Test Method(s)[2]:**
Medical vehicles and their equipment – Air ambulances – Part 1: Requirements for medical devices used in air ambulances	EN 13718-1
Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements	IEC 61010-1; EN 61010-1; CAN/CSA-C22.2 No. 61010-1; UL61010-1
Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials	IEC 61010-2-010; EN IEC 61010-2-010; CSA C22.2 No. 61010-2-010; UL 61010-2-010
Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-011: Particular requirements for refrigerating equipment	IEC 61010-2-011; EN IEC 61010-2-011; CSA C22.2 No. 61010-2-011; UL 61010-2-011
Safety Requirements for electrical equipment for measurement, control, and laboratory use – Part 2-020: Particular requirements for laboratory centrifuges	IEC 61010-2-020; EN 61010-2-020; CAN/CSA-C22.2 No. 61010-2-020; UL 61010-2-020
Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials	IEC 61010-2-040; EN IEC 61010-2-040; CSA C22.2 No. 61010-2-040; UL 61010-2-040
Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-051: Particular requirements for laboratory equipment for mixing and stirring	IEC 61010-2-051; EN IEC 61010-2-051; CSA C22.2 No. 61010-2-051; UL 61010-2-051
Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes	IEC 61010-2-081; EN IEC 61010-2-081; CSA C22.2 No. 61010-2-081; UL 61010-2-081
Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV	IEC 60601-2-1; EN IEC 60601-2-1
Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators	IEC 60601-2-4; EN 60601-2-4; ANSI/AAMI/IEC 60601-2-4; CAN/CSA-C22.2 NO. 60601-2-4

Test Technology:	**Test Method(s)[2]:**
Medical electrical equipment - Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV	EN 60601-2-8; IEC 60601-2-8; CAN/CSA-C22.2 NO. 60601-2-8
Medical electrical equipment Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators	CAN/CSA-C22.2 No. 80601-2-12; ISO 80601-2-12; EN ISO 80601-2-12
Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation	ISO 80601-2-13; EN ISO 80601-2-13; CAN/CSA-C22.2 NO. 80601-2-13; ISO 80601-2-13; EN ISO 80601-2-13
Medical electrical equipment – Part 2-19: Particular requirements for basic safety and essential performance of infant incubators	CAN/CSA-C22.2 No.60601-2-19; ANSI/AAMI/IEC 60601-2-19; IEC 60601-2-19; EN IEC 60601-2-19
Medical electrical equipment – Part 2-20: Particular requirements for basic safety and essential performance of infant transport incubators	ANSI/AAMI/IEC 60601-2-20; CSA C22.2 NO. 60601-2-20; IEC 60601-2-20; EN IEC 60601-2-20
Medical electrical equipment – Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers	ANSI/AAMI/IEC 60601-2-21; CAN/CSA-C22.2 No.60601-2-21; IEC 60601-2-21; EN IEC 60601-2-21
Electrical medical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment	IEC 60601-2-68; EN 60601-2-68; CAN/CSA-C22.2 No. 60601-2-68
Medical electrical equipment – Part 2-70: Particular requirements for basic safety and essential performance of sleep apneoa breathing therapy equipment	ISO 80601-2-70; EN ISO 80601-2-70; CAN/CSA C22.2 No. 80601-2-70
Medical electrical equipment - Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients	ISO 80601-2-72; EN ISO 80601-2-72; CAN/CSA-C22.2 No.80601-2-72

Test Technology:	**Test Method(s)[2]:**
Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment	ISO 80601-2-74; EN ISO 80601-2-74; CSA C22.2 No.80601-2-74
Medical electrical equipment - Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment	ISO 80601-2-79 EN ISO 80601-2-79 CSA C22.2 No. 80601-2-79
Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency	ISO 80601-2-80; EN ISO 80601-2-80; CSA C22.2 No. 80601-2-80
Medical Electrical Equipment - Part 2-84: Particular Requirements For Basic Safety And Essential Performance Of Emergency And Transport Ventilators	ISO 80601-2-84; CSA C22.2 No. 80601-2-84
Medical Electrical Equipment - Part 2-87: Particular Requirements For Basic Safety And Essential Performance Of High-frequency Ventilators	ISO 80601-2-87; EN ISO 80601-2-87
Medical electrical equipment —Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment	ISO 80601-2-90; EN ISO 80601-2-90
Dentistry - Mobile dental units and dental patient chairs - Part 1: General requirements	ISO 5467-1; EN ISO 5467-1
Dentistry - Mobile dental units and dental patient chairs - Part 2: Air, water, suction and wastewater systems	ISO 5467-2; EN ISO 5467-2
Medical Suction Equipment - Part 4: General Requirements	ISO 10079-4; EN ISO 10079-4
Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer	ISO 14708-1; EN ISO 14708-1
Respiratory equipment - Particular requirements for basic safety and essential performance of infant cardiorespiratory monitors	ISO 18778; EN ISO 18778

Test Technology:	**Test Method(s)[2]:**
Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods	EN 12184
Wheelchairs-Part 1 : Determination of static stability	ISO 7176-1
Wheelchairs-Part 2: Determination of dynamic stability of electrically powered wheelchairs	ISO 7176-2
Wheelchairs-Part 3: Determination of effectiveness of brakes	ISO 7176-3
Wheelchairs-Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range	ISO 7176-4
Wheelchairs-Part 5: Determination of dimensions, mass and manoeuvring space	ISO 7176-5
Wheelchairs-Part 6: Determination of maximum speed of electrically powered wheelchairs	ISO 7176-6
Wheelchairs-Part 7: Measurement of seating and wheel dimensions	ISO 7176-7
Wheelchairs-Part 8: Requirements and test methods for static, impact and fatigue strengths	ISO 7176-8
Wheelchairs-Part 9: Climatic tests for electric wheelchairs	ISO 7176-9
Wheelchairs-Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs	ISO 7176-10
Wheelchairs-Part 13 Determination of coefficient of friction of test surfaces	ISO 7176-13
Wheelchairs-Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods	ISO 7176-14
Wheelchairs-Part 15: Requirements for information disclosure, documentation and labelling	ISO 7176-15
Wheelchairs-Part 25: Batteries and chargers for powered wheelchairs	ISO 7176-25

Test Technology:	**Test Method(s)[2]:**
Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for laboratory equipment for in vitro diagnostic (IVD) medical equipment	IEC 61010-2-101; EN IEC 61010-2-101; CSA C22.2 No. 61010-2-101; UL 61010-2-101
Dentistry—Powered polymerization activators	ISO 10650; EN ISO 10650
Wheelchair seating Part 10: Resistance to ignition of postural support devices Requirements and test method	ISO 16840-10
Unintentional Radiators ***Emissions*** Radiated and Conducted	CFR 47, FCC Part 15 Subpart B (using ANSI C63.4:2014); CFR 47, FCC Part 18 (using MP-5:1986); ICES-GEN; ICES-001; ICES-005; ICES-003; IEC 61000-6-3; EN 61000-6-3; BS EN 61000-6-3; GB 17799.3; IEC 61000-6-4; EN 61000-6-4; BS EN IEC 61000-6-4; GB 17799.4; CISPR 11; EN 55011; BS EN 55011; GB 4824; CISPR 14-1; EN 55014-1; BS EN 55014-1; GB 4343.1; GB/T 9254; CISPR 32; AS/NZS CISPR 32; EN 55032; VCCI-CISPR 32; BS EN 55032 CISPR 15; EN 55015; AS/NZS CISPR 15; BS EN IEC 55015; GB/T 17743; IEC 60601-1-2; EN 60601-1-2; BS EN 60601-1-2; YY 0505; YY 9706.102 IEC 61326-1; EN 61326-1; BS EN 61326-1; GB/T 18268.1; IEC 61326-2-6; EN IEC 61326-2-6; BS EN IEC 61326-2-6; GB/T 18268.26-2010; ETSI EN 300 386
Harmonic Current Emissions	GB 17625.1; IEC 61000-3-2; EN 61000-3-2; EN IEC 61000-3-2; BS EN IEC 61000-3-2; SANS 61000-3-2; SASO-IEC-GSO-61000-3-2
Voltage Fluctuations and Flicker	GB/T 17625.2; IEC 61000-3-3; EN 61000-3-3; BS EN 61000-3-3; GB/T 17625.7; IEC 61000-3-11; EN 61000-3-11; BS EN 61000-3-11;

Test Technology:	**Test Method(s)[2]:**
Voltage Fluctuations and Flicker *(continued)*	SANS 61000-3-3; SASO-IEC-61000-3-11
Click	GB 4824; CISPR 11; EN 55011; BS EN 55011; GB 4343.1; CISPR 14-1; EN 55014-1; BS EN 55014-1
Disturbance Power	GB 4343.1; CISPR 14-1; EN 55014-1; BS EN 55014-1
Immunity	
ESD	IEC 61000-4-2; EN 61000-4-2; BS EN 61000-4-2; GB/T 17626.2; SANS 61000-4-2; SASO-IEC-61000-4-2
Fast Transients	IEC 61000-4-4; EN 61000-4-4; BS EN 61000-4-4; GB/T 17626.4; SANS 61000-4-4; SASO-IEC-61000-4-4
Surge	IEC 61000-4-5; EN 61000-4-5; BS EN 61000-4-5; GB/T 17626.5; SANS 61000-4-5; SASO-GSO-IEC-61000-4-5
Conducted Immunity	IEC 61000-4-6; EN 61000-4-6; BS EN 61000-4-6; GB/T 17626.6; SANS 61000-4-6; SASO-IEC-61000-4-6
Voltage Dips, Interrupts	IEC 61000-4-11; EN 61000-4-11; BS EN IEC 61000-4-11; GB/T 17626.11; SANS 61000-4-11; SASO-GSO-IEC-61000-4-11
Power Magnetic Fields	IEC 61000-4-8; EN 61000-4-8; BS EN 61000-4-8; SANS 61000-4-8; SASO-IEC-61000-4-8
Radiated Field Immunity (9kHz~30MHz)	IEC 61000-4-39; EN 61000-4-39; BS EN 61000-4-39; SASO-IEC-61000-4-39
Radiated Immunity (80MHz~6GHz, 10V/m@3m, 30V/m@1m)	IEC 61000-4-3; EN IEC 61000-4-3;

Test Technology:	**Test Method(s)[2]:**
Radiated Immunity (80MHz~6GHz, 10V/m@3m, 30V/m@1m) *(continued)*	EN 61000-4-3; BS EN 61000-4-3; SANS 61000-4-3; SASO-GSO-IEC-61000-4-3
Harmonics and interharmonics including mains signalling at a.c. power port, low frequency immunity tests	IEC 61000-4-13; EN 61000-4-13; BS EN 61000-4-13; SANS 61000-4-13; SASO-IEC-61000-4-13
EMC Medical	IEC 60601-1-2; IEC 60118-13; IEC TR 60601-4-2; EN 60601-1-2; BS EN 60601-1-2; ISO 7176-21; ANSI RESNA WC-2:2019 Section 21; ANSI/AAMI/IEC 60601-1-2; CAN/CSA-C22.2 No. 60601-1-2
Generic / Product Family / Specific Standards	IEC 61000-6-1; EN 61000-6-1; BS EN IEC 61000-6-1; GB/T 17799.1; IEC 61000-6-2; EN 61000-6-2; BS EN IEC 61000-6-2; GB/T 17799.2; IEC 61000-6-3; EN 61000-6-3; BS EN 61000-6-3; GB 17799.3; IEC 61000-6-4; EN 61000-6-4; BS EN IEC 61000-6-4; GB 17799.4; CISPR 11; EN 55011; BS EN 55011; GB 4824; YY 0505; CISPR 14-1; EN 55014-1; BS EN 55014-1; GB 4343.1; CISPR 14-2; EN 55014-2; BS EN 55014-2; GB/T 4343.2; GB/T 9254; CISPR 24; EN 55024; BS EN 55024; GB/T 17618; IEC 61326-1; EN 61326-1; BS EN 61326-1; GB/T 18268.1; ETSI EN 300 386; CISPR 15; EN 55015; AS/NZS CISPR 15; BS EN IEC 55015; GB/T 17743; IEC 61547; EN 61547; BS EN 61547; GB/T 18595; CISPR 32; EN 55032; AS/NZS CISPR 32; VCCI-CISPR 32; BS EN 55032; CISPR 35; EN 55035; BS EN 55035; YY 9706.102; EN IEC 61326-1; BS EN IEC 61326-1; IEC 61326-2-6; EN IEC 61326-2-6; BS EN IEC 61326-2-6; GB/T 18268.26; SANS 211; SANS 214-1; SANS 214-2;

Test Technology:	**Test Method(s)[2]:**
Generic / Product Family / Specific Standards *(continued)*	SANS 2332; SANS 60601-1-2; SANS 61326-1; SANS 61000-6 -1; SANS 61000-6-2; SANS 61000-6-3; SANS 61000-6-4; SANS 2335; SANS 215; SANS 61547; SASO-IEC-61326-1; SASO-IEC-61326-2-1; SASO-IEC-61326-2-2; SASO-IEC-61326-2-3; SASO-IEC-61326-2-4; SASO-IEC-61326-2-5; SASO-IEC-61326-2-6; SASO-CISPR-14 -1; SASO-CISPR-14-2; SASO-GSO-CISPR-15; SASO-IEC-61547; SASO-IEC-TR-61547-1; SASO-IEC-61547-1; SASO-IEC-CISPR-32; SASO-CISPR-24; SASO-CISPR-11; SASO-GSO-IEC-61000-6-3; SASO-IEC-61204-3
Intentional Radiators ***Unlicensed***	CFR 47, FCC Part 15 Subpart C, CFR 47, FCC Part 15 Subpart E, CFR 47, FCC Part 15 Subpart F (all using ANSI C63.10:2013) (*up to 40 GHz*); FCC KDB Publication: 905462 D02 UNII DFS Compliance Procedure New Rules v02; ANSI C63.10:2020
Wideband transmission systems; Data transmission equipment operatingin the 2,4 GHz ISM band andusing wide band modulation techniques; Harmonized Standard covering the essential requirementsof article 3.2 of Directive 2014/53/EU	ETSI EN 300 328
5 GHz RLAN; Harmonized Standard covering the essential requirements Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU	ETSI EN 301 893

Test Technology:	**Test Method(s)[2]:**
Short Range Devices (SRD); Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU	ETSI EN 300 440
Wireless Access Systems (WAS); 5,8 GHz fixed broadband data transmitting systems; Harmonized Standard for access to radio spectrum	ETSI EN 302 502
Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU	ETSI EN 300 330
Product Specific EMC	ETSI EN 301 489-1; ETSI EN 301 489-3; ETSI EN 301 489-17; ETSI EN 301 489-33; ETSI EN 301 489-34
General Requirements for Compliance of Radio Apparatus (ISED)	RSS-GEN
Digital Transmission Systems (DTSs), Frequency Hopping Systems (FHSs) and License-Exempt Local Area Network (LE-LAN) Devices	RSS-247
License-Exempt Radio Apparatus: Category I Equipment	RSS-210
Wireless Power Transfer Devices	RSS-216
Japan	ARIB STD-T66; Article 2 Paragraph 1 item 19; Article 2 Paragraph 1 item 19-2-2; ARIB STD-33; Article 2 Paragraph 1 item 19-2; Article 2 Paragraph 1 item 19-2-3; ARIB STD-T71; Article 2 Paragraph 1 item 19-3; Article 2 Paragraph 1 item 19-3-2; Article 2 Paragraph 1 item 19-3-3; MIC Notice No.88
Australia	AS/NZS 4268

Test Technology:	**Test Method(s)[2]:**
RF Exposure Assessment (up to 40 GHz)	
EU	EN 62479; EN 62311; EN 50663; EN 50665
Canada	RSS-102; RSS-102 Measurement (RF Exp.)
Australia	AS/NZS 2772.1; AS/NZS 2772.2
Bluetooth Radio and Protocol Conformance Testing - BT SIG	
Primary Scope Options	RF:1; RF-PHY:1; RF-PHY:2; LE Protocols:1; LE Protocols:2
Supplemental Scope Options	Host Layers; Traditional Profiles and Protocols; GATT-Based Profile & Service

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 DocNumber**
ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	19-46
IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION	19-34
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
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	5-131
IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION	19-37
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	19-38
ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021]	19-47
IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION	19-39
ANSI AAMI IEC 60601-1-12:2016 [Including AMD 1:2021]	19-39
IEC 60601-2-2 Edition 6.0 2017-03	6-389
ANSI AAMI IEC 60601-2-2:2017	6-389
IEC 60601-2-10 Edition 2.1 2016-04	17-16
IEC 60601-2-18 Edition 3.0 2009-08	9-114
IEC 60601-2-22 Edition 3.1 2012-10	12-268
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 80601-2-30 Edition 2.0 2018-03	3-123
ANSI AAMI IEC 80601-2-30:2018	3-123
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
ANSI AAMI IEC 60601-2-47:2012/(R)2016	3-155
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
ISO 80601-2-55 Second Edition 2018-02	1-140
ISO 80601-2-56 Second Edition 2017-03	6-421
IEC 60601-2-57 Edition 1.0 2011-01	12-242
IEC 80601-2-59 Edition 2.0 2017-09	6-405
IEC 80601-2-60 Edition 2.0 2019-06	4-262
ISO 80601-2-61 Second Edition 2017-12 (Corrected Version 2018-02)	1-139
IEC 60601-2-62 Edition 1.0 2013-07	12-281
IEC 60601-2-63 Edition 1.2 2021-05 CONSOLIDATED VERSION	12-339
IEC 60601-2-65 Edition 1.2 2021-05 CONSOLIDATED VERSION	12-340
ISO 80601-2-69 Second Edition 2020-11	1-148
IEC 80601-2-77 Edition 1.0 2019-07	6-438
ANSI AAMI IEC 80601-2-77:2020	6-438
IEC/TR 60601-4-2 Edition 1.0 2016-05	19-19
IEC 60601-2-1 Edition 4.0 2020-10	12-338
IEC 60601-2-8 Edition 2.1 b:2015	12-301
80601-2-12 Second edition 2020-02	1-146
ISO 80601-2-13 Second edition 2022-04	1-165
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 60601-2-68 Edition 1.0 2014-09	12-319
ISO 80601-2-70 Second edition 2020-11	1-151
ISO 80601-2-72 Second edition 2023-06	1-163
ISO 80601-2-74 First edition 2017-05	1-138
ISO 80601-2-79 First edition 2018-07	1-143
ISO 80601-2-80 First edition 2018-07	1-144
ISO 80601-2-84 First edition 2020-07	1-160
ISO 80601-2-87 First edition 2021-04	1-152

[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.

[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.

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 [3]:

Rule Subpart/Technology	**Test Method**	**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 C63.10:2013	40000
U-NII without DFS Intentional Radiators Part 15E	ANSI C63.10:2013	40000
U-NII with DFS Intentional Radiators Part 15E	FCC KDB 905462 D02 (v02)	40000
Ultra-Wideband Operation Part 15F	ANSI C63.10:2013	40000

[3] 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.

[4] Exclusions Table

Standard	**Exclusion item**
IEC 60601-1, EN 60601-1; ANSI/AAMI ES60601-1; CAN/CSA-C22.2 No. 60601-1	11.4 ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics；
	11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS
ASTM E 1965-1998	5.5 Special Requirements about clinical Accuracy
	6.2 Clinical Accuracy Tests
ISO 80601-2-56; EN ISO 80601-2-56	201.102 Clinical accuracy validation
ISO 7494-1; EN ISO 7494-1	5.1.7 Biocompatibility
	5.1.10.2 Flammability
ISO 80601-2-61; EN ISO 80601-2-61; CAN/CSA-C22.2 No. 80601-2-61	201.12.1.101 SpO2 accuracy of pulse oximeter equipment

Standard	Exclusion item
ISO 80601-2-67; EN ISO 80601-2-67	201.11.7 Biocompatibility of ME equipment and ME systems
ISO 10079-1; EN ISO 10079-1; CAN/CSA-ISO 10079-1	4.3 Clinical investigation
	4.4 Biophysical or modelling research
ISO 10079-3; EN ISO 10079-3; CSA ISO 10079-3	4.3 Clinical investigation
	4.4 Biophysical or modelling research
ISO 81060-1; EN ISO 81060-1; AAMI / ANSI / ISO 81060-1	11 Biocompatibility
ISO 27427; EN ISO 27427; CSA ISO 27427	8 Biocompatibility
IEC 60601-2-36; EN 60601-2-36; CAN/CSA-C22.2 No. 60601-2-36	201.11.7 Biocompatibility
ISO 80601-2-72; EN ISO 80601-2-72; CAN/CSA-C22.2 No.80601-2-72	201.11.7 Biocompatibility of ME equipment and ME systems
ISO 80601-2-74; EN ISO 80601-2-74; CSA C22.2 No.80601-2-74	201.11.7 Biocompatibility of ME equipment and ME systems
ISO 80601-2-79 EN ISO 80601-2-79 CSA C22.2 No. 80601-2-79	201.11.7 Biocompatibility Test
ISO 80601-2-80; EN ISO 80601-2-80; CSA C22.2 No. 80601-2-80	201.11.7 Biocompatibility Test
ISO 80601-2-84; CSA C22.2 No. 80601-2-84	201.11.7 Biocompatibility Test
ISO 80601-2-87; EN ISO 80601-2-87	201.11.7 18562-1:2017 Biocompatibility Test
ISO 80601-2-90; EN ISO 80601-2-90	201.11.7 18562-1:2017 Biocompatibility Test

Accredited Laboratory

A2LA has accredited

DEKRA TESTING AND CERTIFICATION (SHANGHAI) LTD., GUANGZHOU BRANCH

Guangzhou, People's Republic of China

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 26th day of April 2024.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 6568.01
Valid to April 30, 2026

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