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 28th day of March 2022.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 6568.01
Valid to April 30, 2024

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

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

DEKRA TESTING AND CERTIFICATION (SHANGHAI) LTD., GUANGZHOU BRANCH
Block 5, No.3, Qiyun Road, Huangpu District,
Guangzhou, People's Republic of China
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ELECTRICAL

Valid To: April 30, 2024 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

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

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

Test Technology:	**Test Method(s) [2]:**
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
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
Respiratory therapy equipment – Part 1: Nebulizing systems and their components	EN 13544-1

Test Technology:	**Test Method(s) [2]:**
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
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

Test Technology:	**Test Method(s) [2]:**
Unintentional Radiators	
Emissions	
Radiated and Conducted	CFR 47, FCC Part 15 Subpart B (using ANSI C63.4:2014 and ANSI C63.4a:2017); 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
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
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

Test Technology:	**Test Method(s) [2]:**
Immunity	
ESD	IEC 61000-4-2; EN 61000-4-2; BS EN 61000-4-2; GB/T 17626.2
Fast Transients	IEC 61000-4-4; EN 61000-4-4; BS EN 61000-4-4; GB/T 17626.4
Surge	IEC 61000-4-5; EN 61000-4-5; BS EN 61000-4-5; GB/T 17626.5
Conducted Immunity	IEC 61000-4-6; EN 61000-4-6; BS EN 61000-4-6; GB/T 17626.6
Voltage Dips, Interrupts	IEC 61000-4-11; EN 61000-4-11; BS EN IEC 61000-4-11; GB/T 17626.11
Product Standards	EC 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; IEC 60601-1-2; EN 60601-1-2; BS EN 60601-1-2; 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; IEC 61326-1; EN IEC 61326-1; BS EN IEC 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; ISO 7176-21; IEC 60118-13

Test Technology:	**Test Method(s) [2]:**
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
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
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
Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)	EN 62479
Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz)	EN 62311
Generic standard for assessment of low power electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (10 MHz to 300 GHz)	EN 50663
Generic standard for assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz)	EN 50665

Test Technology:	**Test Method(s) [2]:**
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
Radio Frequency (RF) Exposure Compliance of Radiocommunication Apparatus (All Frequency Bands)	RSS-102 Measurement (RF Exp.)
License-Exempt Radio Apparatus: Category I Equipment	RSS-210
Wireless Power Transfer Devices	RSS-216

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

ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)
IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION
IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION
IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION
ANSI AAMI HA60601-1-11:2015
IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION
IEC 60601-2-2 Edition 6.0 2017-03
IEC 60601-2-10 Edition 2.1 2016-04
IEC 60601-2-18 Edition 3.0 2009-08
IEC 60601-2-22 Edition 3.1 2012-10
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 80601-2-30 Edition 2.0 2018-03
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 2.2 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 60601-2-52 Edition 1.0 2009-12
IEC 60601-2-54 Edition 1.2 2018-06 CONSOLIDATED VERSION
ISO 80601-2-55 Second Edition 2018-02
ISO 80601-2-56 Second Edition 2017-03
IEC 60601-2-57 Edition 1.0 2011-01
IEC 80601-2-59 Edition 2.0 2017-09
IEC 80601-2-60 Edition 2.0 2019-06
ISO 80601-2-61 Second Edition 2017-12 (Corrected Version 2018-02)
IEC 60601-2-62 Edition 1.0 2013-07
IEC 60601-2-63 Edition 1.2 2021-05 CONSOLIDATED VERSION
IEC 60601-2-65 Edition 1.2 2021-05 CONSOLIDATED VERSION
ISO 80601-2-69 Second Edition 2020-11
IEC 80601-2-77 Edition 1.0 2019-07

[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] 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*.

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.

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 28th day of March 2022.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 6568.01
Valid to April 30, 2024

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