SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

AA ELECTRO MAGNETIC TEST LABORATORY
Plot174, Udyog Vihar, Phase 4
Sector 18, Gurugram
Gurgaon, India 122015
Authorized Representative: Jay Ghandhi Email: info@aaemtlabs.com

ELECTRICAL

Valid To: May 31, 2024 Certificate Number: 5593.01

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 laboratory to perform the following electrical tests:

Test Technology	**Test Method(s)**[1,2,3]
Emissions – Unintentional Radiators	
Radiated & Conducted *(3m semi-anechoic chamber, up to 40 GHz)*	47 CFR FCC Part 15, Subpart B (using ANSI C63.4:2014); 47 CFR FCC Part 18 (using MP-5:1986); ICES-003; VCCI-CISPR 32:2016 (*up to 6 GHz*); CISPR 11; BS EN 55011; AS/NZS CISPR 11; CISPR 13; EN 55013; AS/NZS CISPR 13; CISPR 14-1; BS EN 55014-1; AS/NZS CISPR 14.1; CISPR 15; EN 55015; AS/NZS CISPR 15; CISPR 22; BS EN 55022; AS/NZS CISPR 22; CIPRS 25; CISPR 32; EN 55032; AS/NZS CISPR 32; CNS 13438 *(1-6 GHz)*
Harmonic Current	AS/NZS 61000.3.2; BS EN 61000-3-2; IEC 61000-3-2
Voltage Changes, Voltage Fluctuations, and Flicker	AS/NZS 61000.3.3; BS EN 61000-3-3; IEC 61000-3-3;
Radio	47 CFR FCC Part 15 Subparts C, E, F, G, H (Using ANSI C63.10:2013); 47 CFR FCC Part 15 Subparts D (Using ANSI C63.17:2013); RSS-GEN; RSS-119; RSS-130, RSS-132; RSS-133; RSS-139; RSS-170, RSS-199; RSS-210; RSS-213; RSS-247; RSS-310; ETSI EN 300 328; ETSI EN 301 893; ETSI EN 302 502; ETSI EN 300 220; ETSI EN 300 330; ETSI EN 300 440; 3GPP TS 24.008 for GSM/UMTS/LT 2015; 3GPP TS 36.5.21; ETSI EN 301 908-13;

Test Technology	Test Method(s)[1,2,3]
Radio (Cont.)	3GPP TS 51010-1; EN 301 511; 3GPP TS 34.121-1; EN 301 908-2-2; ETSI EN 301 908-11; ETSI EN 301 908-13; ETSI EN 301 908-14; ETSI EN 301 908-17; ETSI EN 301 908-52; ETSI EN 301 908-50
RF Exposure *MPE (Calculation Method)*	RSS-102 Measurement (RF Exp.); IEC 62311; BS EN 62311; ANSI/IEEE C95.1-1992; KDB Publication 447498 D03; IEC 62232; IEC TR 62269; IEC 62577; IEC 62493
Telecom *(EFT, ESD, Surge, VDI)*	ITU-T K21, 22, 44, 47
Generic Product and Industry Specific Standards (EMC)	IEC 61000-6-1; BS EN 61000-6-1; GB 17799.1; IEC 61000-6-2; BS EN 61000-6-2; GB 17799.2; IEC 61000-6-3; BS EN 61000-6-3; GB 17799.3; IEC 61000-6-4; BS EN 61000-6-4; GB 17799.4; CISPR 24; BS EN 55024; IEC 61547; CISPR 14-2; BS EN 55014-2; CISPR 20; BS EN 55020; EN 50083-2; CISPR 35; BS EN 55035; IEC 62040-2; IEC 60601-1-2; BS EN 61326-1; EN 301 489-1; ETSI EN 301 489-3; ETSI EN 301 489-17; ETSI EN 301 489-52; GR-1089; EN 50155; IEC 60751; IEC 50121; IEC 62236; EN 301 090; ETSI EN 303 203; EN 301 839; EN 5083-2; IEC 60728-2; IEC 60204; EN 60669-2-2; ETSI EN 136.113; ETSI EN 137.113; ETSI EN 138.113.; 3GPP TS 25.141; ETSI EN 125.141; 3GPP 51.021; ETSI EN 151.021; 3GPP 36.141; ETSI EN 136.141; 3GPP 37.141; ETSI EN 137.141; ETSI EN 136.141; 3GPP 37.141; ETSI EN 137.141; ETSI EN 37.145; TS 45.005; ETSI TS 145 005
Immunity	
Electrostatic Discharge (ESD)	IEC 61000-4-2; BS EN 61000-4-2; AS/NZS 61000.4.2
Radiated Immunity (*Up to 6GHz, 10V/m*)	IEC 61000-4-3; BS EN 61000-4-3; AS/NZS 61000.4.3
Electrical Fast Transient	IEC 61000-4-4; BS EN 61000-4-4; AS/NZS 61000.4.4
Surge	IEC 61000-4-5; BS EN 61000-4-5; AS/NZS 61000.4.5
Conducted Immunity	IEC 61000-4-6; BS EN 61000-4-6; AS/NZS 61000.4.6
Magnetic Field Immunity	IEC 61000-4-8; BS EN 61000-4-8; AS/NZS 61000.4.8

Test Technology	**Test Method(s)**[1,2,3]
Pulse Magnetic Field Immunity	IEC 61000-4-9; BS EN 61000-4-9; AS/NZS 61000.4.9
Voltage Dips and Short Interrupts *(Up to 16A – A/C)*	IEC 61000-4-11; BS EN 61000-4-11; AS/NZS 61000.4.11
Voltage Dips and Short Interrupts *(Up to 16A – D/C)*	IEC 61000-4-29; BS EN 61000-4-29; AS/NZS 61000.4.29
Safety	
Information technology equipment – Safety – Part 1: General requirements	IEC 60950-1
Audio/video, information and communication technology equipment Part 1: Safety requirements	BS EN 623681-1; IEC 62368
Uninterruptible Power Systems (UPS) - Part 1	BS EN 62040-1; IEC 62040-1
Audio, video and similar electronic apparatus – Safety requirements	BS EN 60065; IEC 60065
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	BS EN 60601-1; IEC 60601-1
Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	BS EN 61010-1; IEC 61010-1
Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	IEC 60601-2-21/ IS 13450: Part 2: Sec 21: 2018
Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 20 Infant Transport Incubator	IEC 60601-2-20/ IS 13450: Part 2: Sec 20: 2018

Test Technology	Test Method(s)[1,2,3]
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/ IS 13450: Part 2: Sec 2: 2019
Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.	IEC 60601-2-25 / IS 13450: Part 2: Sec 25 : 2018
Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 27 Electrocardiographic Monitoring Equipment	IEC 60601-2-27 / IS 13450: Part 2 : Sec 27: 2018
Medical electrical equipment - Part 2-69: Particular Requirements for the basic safety and essential performance of oxygen concentrator equipment	ISO 80601-2-69
Medical Electrical Equipment – Part 2-26: Particular Requirements for the basic safety and essential performance of Electro Encephalograph	ISO 80601-2-26 / IS 13450: Part 2: SEC 26: 2018
Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment	IEC 60601-2-40 / IS 13450-2-40: 2018
Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

Test Technology	Test Method(s)[1,2,3]
Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors	IEC 80601-2-49 / IS 13450-2-49
Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	ISO 80601-2-61
Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	IEC 60601-2-47
Medical electrical equipment - Part 1-11: 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
Medical device software - Software life cycle processes	IEC 62304:2006

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:
IEC 60601-2-21 Edition 2.1 2016-04	6-388
IEC 60601-2-20 Edition 2.1 2016-04	6-386
IEC 60601-2-2 Edition 6.0 2017-03	6-389
IEC 60601-2-25 Edition 2.0 2011-10	3-105
IEC 60601-2-27 Edition 3.0 2011-03	3-126

[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*.

[3] 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[4]

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
Unlicensed Personal Communications Service Devices Part 15D	ANSI C63.17:2013	40000
U-NII without DFS Intentional Radiators Part 15E	FCC KDB 905462 D02 (v02)	40000
Ultra-Wideband Operation Part 15F	ANSI C63.10:2013	40000
White Space Devices Part 15H	ANSI C63.10:2013	40000
BPL Intentional Radiators Part 15G	ANSI C63.10:2013	40000
Commercial Mobile Services (FCC Licensed Radio Service Equipment) Parts 22 (cellular), 24, 25 (below 3 GHz), and 27	ANSI C63.26:2015	40000

[4] 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.

Accredited Laboratory

A2LA has accredited

AA ELECTRO MAGNETIC TEST LABORATORY

Gurgaon, India

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 21st day of September 2022.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 5593.01
Valid to May 31, 2024
Revised March 20, 2024

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

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