SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

INTERTEK JAPAN K.K.
Yasuda Shibaura No.2 Bldg. 4F
3-2-12, Kaigan, Minato-ku
Tokyo, Japan 108-0022
Ms. Masako Oyamada Phone: +81 465 89 2316
masako.oyamada@intertek.com

ELECTRICAL

Valid To: September 30, 2024 Certificate Number: 4046.01

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[3] requirements), accreditation is granted to this laboratory to perform the following product safety tests:

Test Technology:	**Test Method(s)** [1, 2]**:**
Product Safety *MEAS, Measurement (excluding Ionizing Measurement, Laser Testing)*	IEC 61010-1; ANSI UL 61010-1 3rd Ed dated May 12 2012 with revision through July 19 2019; IEC 61010-2-081; IEC 61010-2-101
MED, Medical (excluding Resistance to Environment Stress, Cathode Ray Tubes, Lasers and Light Emitting Diods, Primary Lithium Batteries, Protection against Hazards of Ignition of Flammable Anesthetics Mixtures, Simulated Use)	ANSI AAMI ES60601-1:2005/®2012 and A1:2012, C1:2009/®2012 and A2:2010/®2012 (Consolidated Text); ANSI AAMI ES60601-1:2005/®2012 & A1:2012 C1:2009/®2012 & A2:2010/®2012 (Cons. Text) [Incl. AMD2:2021]; EN 60601; IEC 60601-1 [3]; IEC 60601-1-1 ; IEC 60601-1-3 [3]; IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION; IEC 60601-1-4 ; IEC 60601-1-6; IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION; IEC 60601-2-5; IEC 60601-2-18; IEC 60601-2-28 (Ed 2, Ed 3); IEC 60601-2-33; IEC 60601-2-33 Edition 4.0 2022-08; IEC 60601-2-37; IEC 60601-2-38; IEC 60601-2-41; IEC 60601-2-43 (Ed 2, Ed 2.1)

Test Technology:	**Test Method(s) [1, 2]:**
MED, Medical (excluding Resistance to Environment Stress, Cathode Ray Tubes, Lasers and Light Emitting Diods, Primary Lithium Batteries, Protection against Hazards of Ignition of Flammable Anesthetics Mixtures, Simulated Use) (continued)	IEC 60601-2-43 Edition 3.0 2022-12; IEC 60601-2-44; IEC 60601-2-46; IEC 60601-2-52; IEC 60601-2-52 Edition 1.1 2015-03 CONSOLIDATED VERSION; IEC 60601-2-54 (Ed 1.1, Ed 1.2); IEC 60601-2-54 Edition 2.0 2022-09; IEC 60601-2-63; IEC 60601-2-63 Edition 1.2 2021-05 CONSOLIDATED VERSION IEC 62304; IEC 62366; IEC 62366-1; IEC 80601-2-60 Edition 2.0 2019-06; AAMI/CSA 60601-1 ED 3.2; CAN/CSA-C22.2 No. 60601-1:14; JIS T 0601-1
OFF, Office (*excluding Ionizing Measurement, Laser Testing*)	IEC 60950-1
ITAV, IT and AV equipment (*excluding Ionizing Measurement, Laser Testing*)	IEC 62368-1
Electrical equipment of machines	IEC 60204-1; EN 60204-1

On the following products or types of products:
Medical Electrical Equipment, Laboratory Equipment, Information Technology Equipment.

[1] When the date, revision or edition of a test method standard is not identified on the scope of accreditation, the laboratory is expected to be using the current version within one year of the date of publication, per part C., Section 1 of A2LA R101 - General Requirements - Accreditation of ISO-IEC 17025 Laboratories.

[2] The laboratory is only accredited for testing activities outlined within the test methods listed above. Reference to any other activity within these standards, such as risk management or risk assessment, does not fall within the laboratory's accredited capabilities.

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.*[3]	
Standards	**Recognition Number:**
IEC 61010-1 Edition 3.1 2017-01[4]	19-34
IEC 60601-2-5: Edition 3.09 2009-07[5]	12-205
IEC 60601-2-18: Edition 3.0 2009-08[5]	9-114
IEC 60601-2-28 Edition 3.0 2017-06[5]	12-309
IEC 60601-2-33 Ed. 3.2 b: 2015[5]	12-295
IEC 60601-2-37 Edition 2.1 2015[5]	12-293
IEC 60601-2-44 Edition 3.2: 2016[5]	12-302
IEC 60601-2-52 Edition 1.0 2009-12[5]	6-321
IEC 80601-2-60 Edition 2.0 2019-06[5]	4-262
ANSI UL 61010-1 3rd Ed dated May 12 2012 with revision through July 19 2019[4]	19-41
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021][5]	19-46
IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION[5]	12-336
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION[5]	5-132
IEC 60601-2-33 Edition 4.0 2022-08 [5]	12-347
IEC 60601-2-43 Edition 3.0 2022-12[5]	12-351
IEC 60601-2-52 Edition 1.1 2015-03 CONSOLIDATED VERSION[5]	6-489
IEC 60601-2-54 Edition 2.0 2022-09[5]	12-348
IEC 60601-2-63 Edition 1.2 2021-05 CONSOLIDATED VERSION[5]	12-339
[4] *excluding Ionizing Measurement, Laser Testing* [5] *excluding Resistance to Environment Stress, Cathode Ray Tubes, Lasers and Light Emitting Diodes, Primary Lithium Batteries, Protection against Hazards of Ignition of Flammable Anesthetics Mixtures, Simulated Use*	

[3] 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

INTERTEK JAPAN K.K.

Tokyo, Japan

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 9th day of December 2022.

Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 4046.01
Valid to September 30, 2024

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