



# CERTIFICATE OF ACCREDITATION

*This is to attest that*

**UL JAPAN, INC.**  
4383-326 ASAMA-CHO  
ISE-SHI MIE-KEN 516-0021, JAPAN

**Testing Laboratory TL-449**

has met the requirements of AC89, *IAS Accreditation Criteria for Testing Laboratories* as well as the *FDA ASCA specifications* and has demonstrated compliance with ISO/IEC Standard 17025:2017, *General requirements for the competence of testing and calibration laboratories*. This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date February 14, 2024



A handwritten signature in black ink that reads "Raj Nathan".

**President**

Visit [www.iasonline.org](http://www.iasonline.org) for current accreditation information.

# SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

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## UL JAPAN, INC.

[www.ul.com](http://www.ul.com)

**Contact Name** Mamoru Murabayashi

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*Accredited to ISO/IEC 17025:2017*

*Effective Date February 14, 2024*

*FDA ASCA Program*

### FDA ASCA Program Scope

<b>Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems and Laboratory Medical Equipment</b>	
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] [19-46]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021] [19-47]	Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD) [Including Amendment1 (2021)]
ANSI AAMI IEC 60601-1-8:2006 and A1:2012 [Including AMD 2:2021] [5-131]	Medical Electrical Equipment - Part 1-8: 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 [Including Amendment 2 (2021)]
ANSI AAMI IEC 60601-2-25:2011/(R)2016 [3-105]	Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
ANSI AAMI IEC 60601-2-27:2011(R)2016 [3-126]	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
ANSI AAMI IEC 60601-2-47: 2012/(R)2016 [3-155]	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
ANSI AAMI IEC 80601-2-30:2018 [3-123]	Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non- invasive sphygmomanometers
IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION [12-336]	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

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IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION [5-132]	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION 5-131]	Medical electrical equipment -- part 1-8: 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 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION [19-38]	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 60601-2-18: Edition 3.0 2009-08 [9-114]	Medical electrical equipment - part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 60601-2-25 Edition 2.0 2011-10 [3-105]	Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-2-27 Edition 3.0 2011-03 [3-126]	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment [Including: Corrigendum 1 (2012)]
IEC 60601-2-28 Edition 3.0 2017-06 [12-309]	Medical electrical equipment - part 2-28: particular requirements for the basic safety and essential performance of x-ray tube assemblies for medical diagnosis
IEC 60601-2-34 Edition 3.0 2011-05 [3-115]	Medical electrical equipment - part 2-34: particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
IEC 60601-2-47 Edition 2.0 2012-02 [3-155]	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
IEC 60601-2-63 Edition 1.2 2021-05 CONSOLIDATED VERSION [12-339]	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
IEC 60601-2-65 Edition 1.2 2021-05 CONSOLIDATED VERSION [12-340]	Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral-X-ray equipment
IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION [19-34]	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
IEC 80601-2-30: Edition 2.0 2018-03 [3-123]	Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non- invasive sphygmomanometers

Regular Scope

TL-449  
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<b>Electronic Energy Star</b>	
ENERGY STAR program requirements product specification for audio/video	
ENERGY STAR program requirements product specification for computers	
ENERGY STAR program requirements product specification for displays	
ENERGY STAR program requirements, product specification for imaging equipment	
ENERGY STAR program requirements product specification for televisions	
ANIS/AAMI ES60601-1	Medical electrical equipment - part 1: general requirements for basic safety and essential performance
ANSI/AAMI HA60601-1-11	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
ANSI/AAMI/IEC 60601-1-8	Medical electrical equipment - Part 1-8: 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
ANSI/AAMI/IEC 60601-2-25	Medical electrical equipment – part 2-25: particular requirements for the basic safety and essential performance of electrocardiographs
ANSI/AAMI/IEC 60601-2-27	Medical electrical equipment – part 2-27: particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
ANSI/AAMI/IEC 60601-2-47	Medical electrical equipment – part 2-47: particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
ANSI/AAMI/IEC 62304	Medical device software – Software life cycle processes
ANSI AAMI IEC 80601-2-30	Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non- invasive sphygmomanometers
EN 50563	External a.c.. d.c. and a.c.. a.c. power supplies. Determination of no-load power and average efficiency of active modes
EN 50564	Electrical and electronic household and office equipment – measurement of low power consumption
EN 50564 2011	Electrical and electronic household and office equipment – measurement of low power consumption
EN 60034-5	Rotating electrical machines – Part 5: Degrees of protection provided by the integral design of rotating electrical machines (IP code) – Classification (IPX1, IPX2, IPX3, IPX4, IPX5, IPX6, IPX7, IPX8, IP1X, IP2X, IP3X, IP4X, IP5X, IP6X)
EN 62087-1 2016	Audio, video, and related equipment – Determination of power consumption – Part 1: General
EN 62087-2 2016	Audio, video, and related equipment – Determination of power consumption – Part 2: Signals and media
EN 62087-3 2016	Audio, video, and related equipment – Determination of power consumption – Part 3: Television sets
EN 62087-6 2016	Audio, video and related equipment – Determination of power consumption – Part 6: Audio equipment
ES 7993	Energy Efficiency Label for Television and Displays
IEC 60034-5	Rotating electrical machines – Part 5: Degrees of protection provided by the integral design of rotating electrical machines (IP code) – Classification (IPX1, IPX2, IPX3, IPX4, IPX5, IPX6, IPX7, IPX8, IP1X, IP2X, IP3X, IP4X, IP5X, IP6X)
IEC 60068-2-1	Environmental testing – Part 2-1: Tests – Test A: Cold
IEC 60068-2-2	Environmental testing – Part 2-2: Tests – Test B: Dry heat



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IEC 60068-2-6	Environmental testing – Part 2-6: Tests – Test Fc: Vibration (sinusoidal)
IEC 60068-2-11	Environmental testing – Part 2: Tests – Test Ka: Salt Mist
IEC 60068-2-13	Basic environmental Testing procedures – Part 2-13: Tests - Test M: Low air pressure
IEC 60068-2-14	Environmental testing – Part 2-14: Tests – Test N: Change of temperature – Edition 6.0 (Exception: Clause 9)
IEC 60068-2-27	Environmental testing – Part 2-27: Tests – Test Ea and guidance: Shock
IEC 60068-2-30	Environmental testing – Part 2-30: Tests – Test Db: Damp heat, cyclic (12 h + 12 h cycle)
IEC 60068-2-31	Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment-type specimens
IEC 60068-2-38	Environmental testing – Part 2-38: Tests – Test Z/AD: Composite temperature/humidity cyclic test
IEC 60068-2-52	Environmental testing – Part 2-52: Tests – Test Kb: Salt mist, cyclic (sodium chloride solution) - Edition 3.0
IEC 60068-2-64	Environmental testing – Part 2-64: Test methods – Test Fh – Vibration, broad-band random (digital control) and guidance
IEC 60068-2-78	Environmental testing – Part 2-78: Tests – Test Cab: Damp heat, steady state
IEC 60335-1	Household and similar electrical appliances – Safety – Part 1: General requirements
IEC 60335-2-84	Household and similar electrical appliances – Safety – Part 2-84: Particular requirements for toilet appliances
IEC 60601-1	Medical electrical equipment – part 1: general requirements for basic safety and essential performance
IEC 60601-1-11	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 60601-1-3	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-2-18	Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 60601-2-28	Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-2-34	Medical electrical equipment – part 2-34: particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
IEC 60601-2-37	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-51	Medical electrical equipment – part 2-51: particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs
IEC 60601-2-63	Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
IEC 60601-2-65	Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

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IEC 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
IEC 62087-1 2015 Ed 1.0	Audio, video, and related equipment – Determination of power consumption – Part 1: General
IEC 62087-2 2015 Ed 1.0	Audio, video, and related equipment – Determination of power consumption – Part 2: Signals and media
IEC 62087-3 2015 Ed 1.0	Audio, video, and related equipment – Determination of power consumption – Part 3: Television sets
IEC 62087-6 2015 Ed 1.0	Audio, video and related equipment – Determination of power consumption – Part 6: Audio equipment
IEC 62301	Household electrical appliances – measurement of standby power
IEC 62301 2011 Ed 2.0	Household electrical appliances – measurement of standby power
IEC 62304	Medical device software – Software life cycle processes
IEC 80601-2-30	Medical electrical equipment – part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 80601-2-49	Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors
IEC 80601-2-60	Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
IEC/EN 60065	Audio, video and similar electronic apparatus – safety requirements
IEC/EN 60086-1	Primary batteries – general
IEC/EN 60086-2	Primary batteries – physical and electrical specifications
IEC/EN 60086-4	Primary batteries – part 4: safety of lithium batteries
IEC/EN 60086-5	Primary batteries – part 5: safety of batteries with aqueous electrolyte
IEC/EN 60204-1	Safety of machinery – Part 1: General requirements
IEC/EN 60529	Degrees of protection provided by enclosures (IP code) (IPX1, IPX2, IPX3, IPX4, IPX5, IPX6, IPX7, IPX8, IP1X, IP2X, IP3X, IP4X, IP5X, IP6X)
IEC/EN 60950-1	Information technology equipment – safety – part 1: general requirements
IEC/EN 60950-22	Information technology equipment – Safety – Part 22: Equipment to be installed outdoors
IEC/EN 61960	Secondary cells and batteries containing alkaline or other non-acid electrolytes - secondary lithium cells and batteries for portable applications
IEC/EN 62087	Methods of measurement for the power consumption of audio, video and related equipment
IEC/EN 62368-1	Audio/video, information and communication technology equipment – part 1: safety requirements
IEC/EN 62368-3	Audio/video, information and communication technology equipment – Part 3: Safety aspects for DC power transfer through communication cables and ports
IEC/EN 62133	Secondary cells and batteries containing alkaline or other non-acid electrolytes – safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
IEC/EN 62133-1	Secondary cells and batteries containing alkaline or other non-acid electrolytes – safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 1: Nickel systems
IEC/EN 62133-2	Secondary cells and batteries containing alkaline or other non-acid electrolytes – safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems
IEC/EN 62281	Safety of primary and secondary lithium cells and batteries during transport

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ISO 16750-1	Road vehicles - Environmental conditions and testing for electrical and electronic equipment – Part 1: General
ISO 16750-3	Road vehicles – Environmental conditions and testing for electrical and electronic equipment – Part 3: Mechanical loads – Third Edition
ISO 16750-4	Road vehicles – Environmental conditions and testing for electrical and electronic equipment – Part 4: Climatic loads – Third Edition (Exception: Clause 5.8)
ISO 16750-5	Road vehicles - Environmental conditions and testing for electrical and electronic equipment - Part 5: Chemical loads - Second Edition
ISO 20653	Road vehicles – Degrees of protection (IP code) – Protection of electrical equipment against foreign objects, water and access – Second Edition
MS 2576	Minimum energy performance standards (MEPS) for television
PNS 378: 2000	Television Receivers and Video Monitors - Viewing Screen Dimensions - Method of Measurement