



CERTIFICATE OF ACCREDITATION

This is to attest that

SGS JAPAN, INC.

YOKOHAMA BUSINESS PARK NORTH SQUARE I, 134, GODO-CHO, HODOGAYA-KU
YOKOHAMA, OT, 240-0005, JAPAN

Testing Laboratory TL-761

has met the requirements of AC89, *IAS Accreditation Criteria for Testing Laboratories*, 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 May 2, 2024



A handwritten signature in black ink, reading "Raj Nathan".

President

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

SGS JAPAN, INC.

www.sgsgroup.jp

Contact Name Takayuki Okawara

Contact Phone +81-5017807877

Accredited to ISO/IEC 17025:2017

Effective Date May 2, 2024

ELECTRICAL AND ELECTRONICS	
Medical Equipment	
ANSI/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 & medical electrical systems used in the home healthcare
ANSI/AAMI 80601-2-30	Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
CAN/CSA C22.2 No. 60601-1	Medical electrical equipment - part 1: general requirements for basic safety and essential performance
CAN/CSA C22.2 No. 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
CAN/CSA C22.2 No. 60601-1-6	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
CAN/CSA C22.2 No. 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
CAN/CSA C22.2 No. 60601-1-10	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
CAN/CSA C22.2 No. 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
CAN/CSA C22.2 No. 60601-2-16	Medical electrical equipment - part 2-16: particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

CAN/CSA C22.2 No. 60601-2-18	medical electrical equipment - part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment
CAN/CSA C22.2 No. 60601-2-52	Medical electrical equipment — Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
CAN/CSA C22.2 No. 60601-2-54	Medical electrical equipment - part 2-54: particular requirements for the basic safety and essential performance of x-ray equipment for radiography and radioscopy
CAN/CSA C22.2 No. 80601-2-60	Medical electrical equipment -- part 2-60: particular requirements for basic safety and essential performance of dental equipment
CAN/CSA C22.2 No. 60601-2-66	Medical electrical equipment - part 2-66: particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems
CAN/CSA C22.2 No. 62304	Medical device software - software life cycle processes
EN/IEC 60601-1	Medical electrical equipment - part 1: general requirements for basic safety and essential performance
EN/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
EN/IEC 60601-1-6	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
EN/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
EN/IEC 60601-1-10	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
EN/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
EN/IEC 60601-2-16	Medical electrical equipment - part 2-16: particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment
EN/IEC 60601-2-18	Medical electrical equipment - part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment
EN/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

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

EN/IEC 80601-2-30	Medical electrical equipment - part 2-30: particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
EN/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
EN/IEC 60601-2-40	Medical electrical equipment - part 2-40: particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
EN/IEC 60601-2-52	Medical electrical equipment — Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
EN/IEC 60601-2-54	Medical electrical equipment - part 2-54: particular requirements for the basic safety and essential performance of x-ray equipment for radiography and radioscopy
EN/IEC 80601-2-60	Medical electrical equipment - part 2-60: particular requirements for basic safety and essential performance of dental equipment
EN/ISO 80601-2-61	Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment
EN/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
EN/IEC 60601-2-66	Medical electrical equipment - part 2-66: particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems
EN/IEC 62304	Medical device software - software life cycle processes
EN/ISO 80601-2-13	Medical electrical equipment - part 2-13: particular requirements for basic safety and essential performance of an anaesthetic workstation
IEC/EN/ANSI/AAMI 62366	Medical devices - part 1: application of usability engineering to medical devices
EN/IEC 62366-1	Medical devices - part 1: application of usability engineering to medical devices
JIS T 0601-1	Medical electrical equipment - part 1: general requirements for basic safety and essential performance
JIS T 0601-1-3	Medical electrical equipment - part 1-3: general requirements for basic safety and essential performance - collateral standard: radiation protection in diagnostic X-ray equipment
JIS T 0601-2-16	Medical electrical equipment - part 2-16: particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment
JIS T 0601-2-18	Medical electrical equipment - part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

JIS T 0601-2-37	Medical electrical equipment - part 2-37: particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
JIS T 0601-2-40	Medical electrical equipment - part 2-40: particular requirements for the safety of electromyographs and evoked response equipment
JIS T 0601-2-66	Medical electrical equipment - part 2-66: particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems
JIS T 2304	Medical device software - software life cycle processes
JIS T 80601-2-60	Medical electrical equipment - part 2-60: particular requirements for basic safety and essential performance of dental equipment
JIS T 80601-2-61	Medical electrical equipment-part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment
JIS T 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
JIS Z 4751-2-54	Medical electrical equipment - part 2-54: particular requirements for the basic safety and essential performance of x-ray equipment for radiography and radioscopy
Measurement, Control and Laboratory Equipment	
CAN/CSA C22.2 No. 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 1: general requirements
CAN/CSA C22.2 No. 61010-2-010	Safety requirements for electrical equipment for measurement, control and laboratory use - part 2-010: particular requirements for laboratory equipment for the heating of materials
CAN/CSA C22.2 No. 61010-2-011	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-011: particular requirements for REFRIGERATING EQUIPMENT
CAN/CSA-C22.2 No. 61010-2-020	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-020: particular requirements for laboratory centrifuges
CAN/CSA-C22.2 No. 61010-2-030	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-030: particular requirements for testing and measuring circuits
CAN/CSA C22.2 No. 61010-2-051	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-051: particular requirements for laboratory equipment for mixing and stirring
CAN/CSA C22.2 No. 61010-2-081	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

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

CAN/CSA C22.2 No. 61010-2-091	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-091: particular requirements for cabinet X-ray systems
CAN/CSA C22.2 No. 61010-2-101	Safety requirements for electrical equipment for measurement, control and laboratory use - part 2-101: particular requirements for in vitro diagnostic (IVD) medical equipment
CAN/CSA-IEC 61010-2-201	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-201: particular requirements for control equipment
EN/IEC 60825-1	Safety of laser products – part 1: equipment classification and requirements
EN/IEC 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 1: general requirements
EN/IEC 61010-2-010	Safety requirements for electrical equipment for measurement, control and laboratory use - part 2-010: particular requirements for laboratory equipment for the heating of materials
EN/IEC 61010-2-011	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-011: particular requirements for REFRIGERATING EQUIPMENT
EN/IEC 61010-2-020	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-020: particular requirements for laboratory centrifuges
EN/IEC 61010-2-030	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-030: particular requirements for testing and measuring circuits
EN/IEC 61010-2-040	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
EN/IEC 61010-2-051	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-051: particular requirements for laboratory equipment for mixing and stirring
EN/IEC 61010-2-081	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
EN/IEC61010-2-091	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-091: particular requirements for cabinet X-ray systems
EN/IEC 61010-2-101	Safety requirements for electrical equipment for measurement, control and laboratory use - part 2-101: particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-2-120	Safety requirements for electrical equipment for measurement, control and laboratory use - part 2-120: particular safety requirements for machinery aspects of equipment

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

EN/IEC 61010-2-201	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-201: particular requirements for control equipment
JIS C 1010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
JIS C 1010-2-30	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-30: Particular requirements for equipment having testing or measuring circuits
JIS C 1010-2-101	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
JIS C 6802	Safety of laser products
UL 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 1: general requirements
UL 61010-2-010	Safety requirements for electrical equipment for measurement, control and laboratory use - part 2-10: particular requirements for laboratory equipment for the heating of materials
UL 61010-2-011	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-011: particular requirements for REFRIGERATING EQUIPMENT
UL 61010-2-020	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-020: particular requirements for laboratory centrifuges
UL 61010-2-030	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-030: particular requirements for testing and measuring circuits
UL 61010-2-040	Safety requirements for electrical equipment for measurement, control and laboratory use - part 2-40: particular requirements for sterilizers and washer disinfectors used to treat medical materials
UL 61010-2-051	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-51: particular requirements for laboratory equipment for mixing and stirring
UL 61010-2-081	Safety requirements for electrical equipment for measurement, control and laboratory use - part 2-81: particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
UL 61010-2-091	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-91: particular requirements for cabinet X-ray systems
UL 61010-2-101	Safety requirements for electrical equipment for measurement, control and laboratory use - part 2-101: particular requirements for in vitro diagnostic (IVD) medical equipment

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

UL 61010-2-201	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-201: particular requirements for control equipment
IT and Office Equipment	
CAN/CSA C22.2 No. 60950-1	Information technology equipment - safety - part 1: general requirements
CAN/CSA C22.2 No. 62368-1	Audio/video, information and communication technology equipment - part 1: safety requirements
EN/IEC/UL 60950-1	Information technology equipment - safety - part 1: general requirements
EN/IEC/UL 62368-1	Audio/video, information and communication technology equipment - part 1: safety requirements
Household and Similar Equipment	
CAN/CSA C22.2 No. 60335-1	Household and similar electrical appliances part 1: general requirements
CAN/CSA C22.2 No. 60335-2-24	Household and similar electrical appliances part 2-24: particular requirements for refrigerating appliances, ice-cream appliances and ice makers
CAN/CSA C22.2 E60335-2-29	Household and similar electrical appliances part 2-29: particular requirements for battery chargers
CAN/CSA C22.2 No. 60335-2-32	Household and similar electrical appliances part 2-32: particular requirements for massage appliances
CAN/CSA C22.2 No. 60335-2-34	Household and similar electrical appliances part 2-34: particular requirements for motor-compressors
CAN/CSA C22.2 No. 60335-2-40	Household and similar electrical appliances part 2-40: particular requirements for electrical heat pumps, air-conditioners and dehumidifiers
CAN/CSA C22.2 No. 60335-2-89	Household and similar electrical appliances part 2-89: particular requirements for commercial refrigerating appliances with an incorporated or remote refrigerant unit or compressor
EN/IEC 60335-2-29	Household and similar electrical appliances part 2-29: particular requirements for battery chargers
EN/IEC 60335-2-32	Household and similar electrical appliances part 2-32: particular requirements for massage appliances
EN/IEC/UL 60335-1	Household and similar electrical appliances part 1: general requirements
EN/IEC/UL 60335-2-24	Household and similar electrical appliances part 2-24: particular requirements for refrigerating appliances, ice-cream appliances and ice makers
EN/IEC/UL 60335-2-34	Household and similar electrical appliances part 2-34: particular requirements for motor-compressors

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

EN/IEC/UL 60335-2-40	Household and similar electrical appliances part 2-40: particular requirements for electrical heat pumps, air-conditioners and dehumidifiers
EN/IEC/UL 60335-2-89	Household and similar electrical appliances part 2-89: particular requirements for commercial refrigerating appliances with an incorporated or remote refrigerant unit or compressor
JIS C 9335-1	Household and similar electrical appliances part 1: general requirements
JIS C 9335-2-24	Household and similar electrical appliances part 2-24: particular requirements for refrigerating appliances, ice-cream appliances and ice makers
JIS C 9335-2-29	Household and similar electrical appliances part 2-29: particular requirements for battery chargers
JIS C 9335-2-32	Household and similar electrical appliances part 2-32: particular requirements for massage appliances
JIS C 9335-2-34	Household and similar electrical appliances part 2-34: particular requirements for motor-compressors
JIS C 9335-2-40	Household and similar electrical appliances part 2-40: particular requirements for electrical heat pumps, air-conditioners and dehumidifiers
JIS C 9335-2-89	Household and similar electrical appliances part 2-89: particular requirements for commercial refrigerating appliances with an incorporated or remote refrigerant unit or compressor
Industrial Automation	
CSA C22.2 No. 14-18	Industrial control equipment
CSA C22.2 No. 120-13	Refrigeration equipment
EN/IEC 60204-1	Safety of machinery - electrical equipment of machines - part 1: general requirements
EN/IEC 60204-11	Safety of machinery - electrical equipment of machines - part 11: requirements for HV equipment for voltages above 1 000 V a.c. or 1 500 V d.c. and not exceeding 36 kV
EN/IEC 60204-33	Safety of machinery - electrical equipment of machines - part 33: requirements for semiconductor fabrication equipment
EN/IEC/UL 61800-5-1	Adjustable speed electrical power drive systems - part 5-1: safety requirements - electrical, thermal and energy
IEC/EN 60034-1:2010 (ed.12)	Rotating electrical machines -- Part 1: Rating and performance
ISO 10218-1	Robots and robotic devices – Safety requirements for industrial robots - Part1: Robots
ISO 13482	Robots and robotic devices - Safety requirements for personal care robots

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

JIS B 8445	Robots and robotic devices - Safety requirements for personal care robots
NFPA 79	Electrical standard for industrial machinery
UL 471	Standard for Commercial Refrigerators and Freezers
UL 508	Industrial Control Equipment
UL 508A	Standard for industrial control panels
UL 1004	Standard for Rotating Electrical Machines
UL 1740	Standard for Robots and Robotic Equipment
Safety Transformers and Similar Equipment	
IEC/EN 61558-1	Safety of transformers, reactors, power supply units and combinations thereof - Part 1: General requirements and tests
IEC/EN 61558-2-1	Safety of transformers, reactors, power supply units and combinations thereof - Part 2-1: Particular requirements and tests for separating transformers and power supply units incorporating separating transformers for general applications
IEC/EN 61558-2-2	Safety of transformers, reactors, power supply units and combinations thereof - Part 2-2: Particular requirements and tests for control transformers and power supply units incorporating control transformers
IEC/EN 61558-2-16	Safety of transformers, reactors, power supply units and combinations thereof - Part 2-16: Particular requirements and tests for switch mode power supply units and transformers for switch mode power supply units for general applications
Portable Tools	
EN/IEC 62841-1	Electric Motor-Operated Hand-Held, Transportable Tools and Lawn and Garden Machinery - part 1: General requirements
EN/IEC 62841-2-2	Electric motor-operated hand-held tools, transportable tools and lawn and garden machinery - part 2-2: Particular requirements for hand-held screwdrivers and impact wrenches

AAMI: Association for the Advancement of Medical Instrumentation

ANSI: American National Standards Institute

CAN/CSA: Canadian Standards Association

EN: European Norm

IEC: International Electrotechnical Commission

JIS: Japanese Industrial Standards

NFPA: National Fire Protection Association

UL: Underwriters Laboratories