

CERTIFICATE OF ACCREDITATION

This is to attest that

UL INTERNATIONAL ITALIA S.R.L.

VIA DELLE INDUSTRIE 5 & 6 CARUGATE (MI) 20061, REPUBLIC OF ITALY

Testing Laboratory TL-553

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 November 6, 2023



President

International Accreditation Service, Inc.

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Accredited to ISO/IEC 17025:2017

Effective Date November 6, 2023

FDA ASCA Program

FDA ASCA Program Scope

Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems and Laboratory Medical Equipment	
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 IEC 60601-1- 2:2014 [incl. AMD1:2021] [19-36]	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION [19-36]	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
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 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION [19-34]	Safety requirements f or electrical equipment f or measurement, control, and laboratory use - Part 1: general requirements (except 10.5.3 [only Vicat Test], 11.6, 12.2.1, 12.5.1, 12.5.2, 12.6)

Regular Scope

Medical and Laboratory Equipment	
ANSI/AAMI ES60601-1	Medical electrical equipment – Part 1: General requirements f or basic safety and essential performance (except 8.5.5, 8.5.5.2, 8.8.4.2, 9.6.2.1, 9.6.3, 10.1.1, 11.2.2.1, 11.6.7, 15.4.3.4)





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ANSI/AAMI/IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-9	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
IEC/EN 60601-1	Medical electrical equipment – Part 1: General requirements f or basic safety and essential performance (except 8.5.5, 8.5.5.2, 8.8.4.2, 9.6.2.1, 9.6.3, 10.1.1, 11.2.2.1, 11.6.7, 15.4.3.4)
IEC/EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC/EN/UL 61010-1	Safety requirements f or electrical equipment f or measurement, control, and laboratory use - Part 1: general requirements (except 10.5.3 [only Vicat Test], 11.6, 12.2.1, 12.5.1, 12.5.2, 12.6)
IEC/EN/UL 61010-2-010	Safety requirements for electrical equipment f or measurement, control and laboratory use - Part 2-010: particular requirements for laboratory equipment for the heating of materials
IEC/EN/UL 61010-2-011	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-011: Particular requirements for refrigerating equipment (except 11.7.102.3, 13.2.3)
IEC/EN/UL 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 (except 13.1, 13.1.101, 13.1.103, 13.1.104, 13.2.102.1, 13.101)
IEC/EN/UL 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
IEC/EN/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
Lighting	
ANSI C62.41.2	IEEE Recommended practice on Characterization of Surges in Low-Voltage (1000 V and Less) AC Power Circuits
CIE 13.3	Method of Measuring and Specifying Color Rendering of Light Sources
CIE 15	Colorimetry
CIE 154	Maintenance of Outdoor Lighting Systems



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EN 13032-1	Light And Lighting – Measurement And Presentation Of Photometric Data Of Lamps And Luminaires – Part 1: Measurement And File Format
EN 13032-4	Light And Lighting – Measurement And Presentation Of Photometric Data Of Lamps And Luminaires – Part 4: Led Lamps, Modules And Luminaires
EN 50171	Central power supply systems
EN IEC 60598-2-23	Luminaires – Part 2-23: Particular requirements - Extra-low-voltage lighting systems for ELV light sources
IEC 62301	Household electrical appliances – Measurement of standby power
IEC 62717*	LED modules for general lighting – Performance requirements
IEC 62722-2-1	Luminaire performance – Part 2-1: Particular requirements for LED luminaires
IEC/EN 60570	Electrical supply track systems for luminaires
IEC/EN 60598-1	Luminaires – Part 1: General requirements and tests
IEC/EN 60598-2-1	Luminaires – Part 2-1: Particular requirements – Fixed general purpose luminaires
IEC/EN 60598-2-2	Luminaires – Part 2-2: Particular requirements – Recessed luminaires
IEC/EN 60598-2-3	Luminaires – Part 2-3: Particular requirements – Luminaires for road and street lighting
IEC/EN 60598-2-4	Luminaires – Part 2-4: Particular requirements. Portable general purpose luminaires
IEC/EN 60598-2-5	Luminaires – Part 2-5: Particular requirements. Floodlights
IEC/EN 60598-2-13	Luminaires - Part 2-13: Particular requirements – Ground recessed luminaires
IEC/EN 60598-2-17	Luminaires – Part 2-17: Particular requirements - Luminaires for stage lighting, television, film and photographic studios (outdoor and indoor)
IEC/EN 60598-2-22	Luminaires – Part 2-22: Particular requirements – Luminaires for emergency lighting
IEC/EN 60598-2-23	Luminaires – Part 2-23: Particular requirements - Extra-low-voltage lighting systems for ELV light sources
IEC/EN 60598-2-24	Luminaires – Part 2-24: Particular requirements – Luminaires with limited surface temperatures
IEC/EN 60598-2-25	Luminaires – Part 2-25: Particular requirements – Luminaires for use in clinical areas of hospitals and health care buildings
IEC/EN 60838-1	Miscellaneous lampholders – General requirements and tests
IEC/EN 60838-2-2	Miscellaneous lampholders – Part 2-2: Particular requirements – Connectors for LED-modules (Except cl. 19)



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IEC/EN 61347-1	Lamp control-gear – Part 1: General and safety requirements
IEC/EN 61347-2-3	Lamp control-gear – Part 2-3: Particular requirements for A.C. and/or D.C. supplied electronic control gear for fluorescent lamps
IEC/EN 61347-2-7	Lamp control-gear – Part 2-7: Particular requirements for battery supplied electronic control-gear for emergency lighting (self-contained)
IEC/EN 61347-2-11	Lamp Control-gear – Part 2-11: Particular Requirements for Miscellaneous Electronic Circuits Used with Luminaries
IEC/EN 61347-2-13	Lamp control-gear – Part 2-13: Particular requirements for D.C. or A.C. supplied electronic control-gear for LED modules
IEC/EN 62031	LED modules for general lighting – Safety specifications
IEC/EN 62034	Automatic test systems for battery powered emergency escape lighting
IEC/EN 62384	DC or AC supplied electronic control gear for LED modules – Performance requirements
IEC/EN 62471	Photo-biological safety of lamps and lamp systems
IEC/EN 62471-2	Photo-biological safety of lamps and lamp systems – Part 2: Guidance on manufacturing requirements relating to non-laser optical radiation safety (Cl. 5.4 Labeling)
IEC/EN 62722-1*	Luminaire performance – Part 1: General requirements
IES LM 58	Spectroradiometric measurements
SASO 2870:2015	Energy efficiency, functionality and labeling requirements for lighting products – part 1
SASO 2902:2018	Energy Efficiency, Functionality and Labeling Requirements for Lighting Products – Part 2
SASO 2927:2019	Energy efficiency functionality and labelling requirements for lighting products – Part 3: Street lighting
SASO EN 13032-4	Light and lighting. Measurement and presentation of photometric data of lamps and luminaires. LED lamps, modules and luminaires
SASO IEC 62471	Photo-biological safety of lamps and lamp systems
SASO IEC 62471-2	Photo-biological safety of lamps and lamp systems – Part 2: Guidance on manufacturing requirements relating to non-laser optical radiation safety
SASO IEC/PAS 62717	LED modules for general lighting – Performance requirements
SASO IEC TR 62778	Application of IEC 62471 for the assessment of blue light hazard to light sources and luminaires
ENERGY STAR	
ANSI C78.377	Specification for the Chromaticity of Solid State Lighting Products
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ANSI C82.77	Harmonic Emission Limits – Related Power Quality Requirements for Lighting Equipment
ANSI/UL 153	Standard for Portable Electric Luminaires, Secs. 124 to 128 A
ANSI/UL 1574	Standard for Track Lighting Systems, Sec. 54
ANSI/UL 1598	Luminaires, Secs. 19.7, 19.10-16
ANSI/UL 1598C	Lighting-Emitting Diode (LED) Retrofit Luminaire Conversion Kits
CIE 18.2	The basis of physical photometry
CIE 84	Measurement of luminous flux.
IEC/EN 62442-3	Energy performance of lamp controlgear – Part 3: Controlgear for tungsten- halogen lamps and LED light sources - Method of measurement to determine the efficiency of controlgear
IEC/TR 61341	Method of measurement of centre beam intensity and beam angle(s) of reflector lamps
IES LM-79	Solid state Lighting Luminaires, v. 2.1
IES LM-82	Characterization of LED Light Engines and LED Lamps for Electrical and Photometric Properties as a Function of Temperature
IES LM-84	Approved Method for Measuring Luminous Flux and Colo Maintenance of LED Lamps, Light Engines, and Luminaires
IES TM-21-11	Projecting Long Term Lumen Maintenance of LED Light Sources
IES TM-21-19	Projecting Long Term Lumen, Photon, and Radiant Flux Maintenance of LED Light Sources
IES TM-28-14	Projecting Long-Term Luminous flux Maintenance of LED Lamps and Luminaires.
Appliances	
ANSI Z83.11-2016/CSA 1.8-2016	Gas food service equipment
AS 4563-2004	Commercial catering gas equipment
AS 5263.0:2013	Gas appliances – Part 0: General requirements
AS/NZS 5263.0	Gas appliances – Part 0: General requirements
AS/NZS 5263.1.1	Gas Appliances – Part 1.1: Domestic gas cooking appliances
AS/NZS 5263.1.7	Gas appliances – Part 1.7: Domestic outdoor gas cooking appliances
AS/NZS 5263.1.8	Gas appliances – Part 1.8: Decorative gas appliances
AS/NZS 5263.1.9	Gas appliances – Part 1.9: Gas laundry dryers



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CSA/ANSI Z21.1- 2018/CSA 1.1-2018	Household cooking gas appliances
EN 30-1-1	Domestic cooking appliances burning gas – Part 1-1: Safety – General
EN 30-1-2	Domestic cooking appliances burning gas – Part 1-2: Safety – Appliances having forced-convection ovens and/or grills
EN 30-1-3	Domestic cooking appliances burning gas – Part 1-3: Safety – Appliances having a glass ceramic hotplate
EN 30-1-4	Domestic cooking appliances burning gas – Part 1-4: Safety – Appliances having one or more burners with an automatic burner control system
EN 30-2-1	Domestic cooking appliances burning gas – Part 2-1: Rational use of energy – General
EN 30-2-2	Domestic cooking appliances burning gas – Part 2-2: Rational use of energy – Appliances having forced-convection ovens and/or grills
EN 203-1	Gas heated catering equipment – Part 1: General safety rules
EN 203-2-1	Gas heated catering equipment – Part 2-1: Specific requirements – Open burners and wok burners
EN 203-2-2	Gas heated catering equipment – Part 2-2: Specific requirements – Ovens
EN 203-2-3	Gas heated catering equipment – Part 2-3: Specific requirements – Boiling pans
EN 203-2-4	Gas heated catering equipment – Part 2-4: Specific requirements – Fryers
EN 203-2-6	Gas heated catering equipment – Part 2-6: Specific requirements – Hot water heaters for beverage
EN 203-2-7	Gas heated catering equipment – Part 2-7: Specific requirements – Salamanders and rotisseries
EN 203-2-8	Gas heated catering equipment – Part 2-8: Specific requirements – Brat pans and paella cooker
EN 203-2-9	Gas heated catering equipment – Part 2-9: Specific requirements – Solid tops, warming plates and griddles
EN 203-2-10	Gas heated catering equipment – Part 2-10: Specific requirements – Chargrills
EN 203-2-11	Gas heated catering equipment – Part 2-11: Specific requirements – Pasta pans
EN 203-3	Gas heated catering equipment – Part 3: Materials and parts in contact with food and other sanitary aspects
EN 298	Automatic burner control systems for burners and appliances burning gaseous or liquid fuels (except cl. 10.2.2 from 7.101.4.1.4 to 7.101.4.3.3)



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EN 484	Specification for dedicated liquefied petroleum gas appliances – Independent hotplates, including those incorporating a grill for outdoor use.
EN 497	Specification for dedicated liquefied petroleum gas appliances – Multi-purpose boiling burners for outdoor use
EN 498	Specification for dedicated liquefied petroleum gas appliances – Barbecues for outdoor use
EN 12067-2	Gas/air ratio controls for gas burners and gas burning appliances – Electronic types (except 6.4, 7.7.2.2)
EN 13611	Safety and control devices for gas burners and gas burning appliances - General requirements (except 6.2, 6.3, 6.4, 7.2, 7.3, 7.4, 7.5.1, 7.5.3, 7.5.4, 7.5.5, 7.7.2.2)
EN 15181	Measuring method of the energy consumption of gas fired ovens
GSO 1049	Method of test for domestic cookers for use with liquefied petroleum gases
GSO 1050	Domestic cookers for use with liquefied petroleum gases
GSO EN 203-1:2009	Gas heated catering equipment – Part 1: General safety rules
SASO-167	Methods of test for domestic cookers for use with liquefied petroleum gases
SASO-168	Domestic cookers for use with liquefied petroleum gases
UAE.S GSO 1049	Method of test for domestic cookers for use with liquefied petroleum gases
UAE.S 1050	Domestic cookers for use with liquefied petroleum gases
Controls	
EN IEC 60730-2-12	Automatic electrical controls – Part 2-12: Particular requirements for electrically operated door locks
EN IEC 60730-2-14	Automatic electrical controls – Part 2-14: Particular requirements for electric actuators
EN IEC 61058-1	Switches for appliances – Part 1: General requirements
IEC 61058-1	Switches for appliances – Part 1: General requirements
IEC/EN 60204-1	Safety of machinery – Part 1: General requirements
IEC/EN 60730-1	Automatic electrical controls for household and similar use – Part 1: General requirements
IEC/EN 60730-2-6	Automatic electrical controls – Part 2-6: Particular requirements for automatic electrical pressure sensing controls including mechanical requirements
IEC/EN 60730-2-9	Automatic electrical controls – Part 2-9: Particular requirements for temperature sensing control



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IEC/EN 60730-2-12	Automatic electrical controls – Part 2-12: Particular requirements for electrically operated door locks
IEC/EN 60730-2-14	Automatic electrical controls – Part 2-14: Particular requirements for electric actuators
IEC/EN 61058-1-1	Switches for appliances – Part 1-1: Requirements for mechanical switches
IEC/EN 61058-1-2	Switches for appliances – Part 1-2: Requirements for electronic switches
IEC/EN 61810-1	Electromechanical elementary relays – Part 1: General and safety requirements (Exclusion: Cl. 15 and Annex O)

