

# CERTIFICATE OF ACCREDITATION

This is to attest that

#### **UNDERWRITERS LABORATORIES TAIWAN CO., LTD.**

NO.260, DA-YEH ROAD, BEITOU DISTRICT TAIPEI CITY, 112, TAIWAN

#### **Testing Laboratory TL-1013**

has met the requirements of AC89, *IAS Accreditation Criteria for Testing Laboratories as well as the FDA ASCA Program 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 12, 2025



International Accreditation Service
Issued under the authority of IAS management

International Accreditation Service, Inc.

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# UNDERWRITERS LABORATORIES TAIWAN CO., LTD.

www.ul.com

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Satellite	Beitou Dist., Taipei City 112,			
Laboratory	TAIWAN			
TL-1250	No.60, Ln.12, Sec.2, Nanshan	Eric Hu	+886.2.7737.3527	14
	Road, Luzhu Dist., Taoyuan City			
	338, TAIWAN			

Accredited to ISO/IEC 17025:2017 FDA ASCA Program

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# FDA ASCA Pilot Program Scope TL-1013 Main and Satellite Locations

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 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- 2-2:2017 [6-389]	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	
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	

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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 60601-1-2 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 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 equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION [19-39]	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
IEC 60601-2-2 Edition 6.0 2017-03 [6-389]	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 60601-2-10 Edition 2.1 2016-04 [17-16]	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
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 60601-2-34 Edition 3.0 2011-05 [3-115]	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment

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IEC 60601-2-37 Edition 2.1 2015 [12-293]	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-47 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 60601-2-52 Edition 1.0 2009-12 [6-321]	Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds [Including: Technical Corrigendum 1 (2010)]
IEC 60601-2-57 Edition 1.0 2011-01 [12-242]	Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
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
IEC 80601-2-60 Edition 2.0 2019-06 [4-262]	Medical electrical equipment - part 2-60: particular requirements for the basic safety and essential performance of dental equipment
ISO 80601-2-55 Second edition 2018-02 [1-140]	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-56 Second edition 2017-03 [6-421]	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)].
ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02) [1-139]	Medical electrical equipment - Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment
ISO 80601-2-70 First Edition 2015-01-15 [1-115]	Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment
ISO 80601-2-70 Second Edition 2020-11 [1-151]	Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment
ISO 80601-2-74 First edition 2017-05 [1-138]	Medical electrical equipment Part 2-74: Particular requirements for the basic safety and essential performance of respiratory humidifying equipment





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### Regular Scope TL-1013 Main and Satellite Locations

ELECTRICAL	
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 and medical electrical systems used in the home healthcare environment
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
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- 1-12	Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
ANSI/AAMI/IEC 60601- 2-2	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
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 80601- 2-30	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
ANSI/AAMI MP80601-2- 49	Medical electrical equipment—Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors
ANSI/UL 61010-031	Safety Requirements for Electrical Equipment for Measurement, Control And Laboratory Use - Part 031: Safety Requirements For Hand-Held Probe Assemblies For Electrical Measurement And Test
ANSI/UL 61010-1	Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements
ANSI/UL 61010-2-010	Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-010: Particular Requirements for Laboratory Equipment for the Heating of Materials
ANSI/UL 61010-2-020	Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-020: Particular Requirements for Laboratory Equipment for Laboratory Centrifuges

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ANSI/UL 61010-2-030	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-030: Particular Requirements for Equipment Having Testing or Measuring Circuits
ANSI/UL 61010-2-032	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 2-032: Particular Requirements for Hand-Held and Hand-Manipulated Current Sensors for Electrical Test and Measurement
ANSI/UL 61010-2-033	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-033: Particular Requirements for Hand-Held Multimeters and Other Meters, for Domestic and Professional Use, Capable of Measuring Mains Voltage
ANSI/UL 61010-2-040	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-040: Particular Requirements for Laboratory Equipment for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials
ANSI/UL 61010-2-051	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-051: Particular Requirements for Laboratory Equipment for Laboratory Equipment for Mixing and Stirring
ANSI/UL 61010-2-081	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-081: Particular Requirements for Laboratory Equipment for Automatic and Semi-Automatic Laboratory Equipment for Analysis and Other Purposes
ANSI/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
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. 60601-1-1	Medical electrical equipment - Part 1-1: General requirements for safety collateral standard: safety requirements for medical electrical systems
CAN/CSA C22.2 No. 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
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. 60601-1-11	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. 60601-1-12	Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
CAN/CSA C22.2 No. 60601-2-2	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

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CAN/CSA C22.2 No. 60601-2-10	Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
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. 60601-2-24	Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers
CAN/CSA C22.2 No. 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
CAN/CSA C22.2 No. 60601-2-26	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
CAN/CSA C22.2 No. 60601-2-27	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
CAN/CSA C22.2 No. 60601-2-30	Medical electrical equipment Part 2-30: particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
CAN/CSA C22.2 No 60601-2-34	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
CAN/CSA C22.2 No 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
CAN/CSA C22.2 No. 60601-2-40	Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
CAN/CSA C22.2 No. 60601-2-41	Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
CAN/CSA C22.2 No. 60601-2-46	Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables
CAN/CSA C22.2 No. 60601-2-47	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
CAN/CSA C22.2 No. 60601-2-49	Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring 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. 60601-2-57	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
CAN/CSA C22.2 No. 61010-031	Safety requirements for electrical equipment for measurement, control and laboratory use — Part 031: Safety requirements for hand-held and hand-manipulated probe assemblies for electrical test and measurement
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

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Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-020: Particular requirements for laboratory centrifuges
Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-030: Particular requirements for equipment having testing or measuring circuits
Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-032: Particular requirements for hand-held and hand manipulated current sensors for electrical test and measurement
Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-033: Particular requirements for hand-held multimeters for domestic and professional use, capable of measuring mains voltage
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
Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-051: Particular requirements for laboratory equipment for mixing and stirring
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
Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
Medical electrical equipment — Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
Medical electrical equipment - Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
Medical electrical equipment Part 1: General requirements for basic safety and essential performance
Medical Electrical Equipment Part 1-1: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

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EN 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN 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 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 60601-1-12	Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
EN 60601-2-2	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
EN 60601-2-10	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
EN 60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
EN 60601-2-24	Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers
EN 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
EN 60601-2-26	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
EN 60601-2-27	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
EN 60601-2-30	Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
EN 60601-2-34	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
EN 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 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 60601-2-41	Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
EN 60601-2-46	Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables

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EN 60601-2-47	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
EN 60601-2-49	Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
EN 60601-2-52	Medical electrical equipment – Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
EN 60601-2-57	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
EN 61010-031	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 031: Safety requirements for hand-held probe assemblies for electrical measurement and test
EN 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements
EN 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 61010-2-020	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-020: Particular requirements for laboratory centrifuges
EN 61010-2-030	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-030: Particular requirements for equipment having testing or measuring circuits
EN 61010-2-032	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-032: Particular requirements for HAND-HELD and hand-manipulated current sensors for electrical test and measurement
EN 61010-2-033	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-033: Particular requirements for hand-held multimeters and other meters, for domestic and professional use, capable of measuring mains voltage
EN 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 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 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 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
EN 80601-2-30	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN 80601-2-60	Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

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EN 80601-2-61	Medical electrical equipment – Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment
EN IEC 80601-2-26	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
EN IEC 80601-2-49	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors
EN ISO 80601-2-55	Medical Electrical Equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN ISO 80601-2-56	Medical electrical equipment - Part 2-56: Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement
EN ISO 80601-2-61	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
EN ISO 80601-2-70	Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment
EN ISO 80601-2-74	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
IEC 60601-1	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
IEC 60601-1-1	Medical Electrical Equipment Part 1-1: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems
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
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
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
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 60601-1-12	Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
IEC 60601-2-2	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 60601-2-10	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
IEC 60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 60601-2-24	Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers

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IEC 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-2-26	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
IEC 60601-2-27	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 60601-2-30	Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
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 60601-2-40	Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
IEC 60601-2-41	Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
IEC 60601-2-46	Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables
IEC 60601-2-47	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
IEC 60601-2-49	Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
IEC 60601-2-52	Medical electrical equipment – Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
IEC 60601-2-57	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
IEC 61010-031	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 031: Safety requirements for hand-held probe assemblies for electrical measurement and test
IEC 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements
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
IEC 61010-2-020	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-020: Particular requirements for laboratory centrifuges
IEC 61010-2-030	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-030: Particular requirements for equipment having testing or measuring circuits
IEC 61010-2-032	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-032: Particular requirements for HAND-HELD and hand-manipulated current sensors for electrical test and measurement
IEC 61010-2-033	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-033: Particular requirements for hand-held multimeters

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	and other meters, for domestic and professional use, capable of measuring mains voltage
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
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
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
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 80601-2-26	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
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 80601-2-61	Medical electrical equipment – Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment
ISO 80601-2-55	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-56	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
ISO 80601-2-60	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 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 80601-2-70	Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnea breathing therapy equipment
ISO 80601-2-74	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
UL 60601-1	Medical Electrical Equipment, Part 1: General Requirements for Safety

#### **TL-1013 Main Location**

EN IEC 61051-1	Varistors for use in electronic equipment – Part 1: Generic specification
EN IEC 61051-2	Varistors for use in electronic equipment – Part 2: Sectional specification for
	surge suppression varistors



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#### **TL-1013 Satellite Location**

IEC 62680-1-2,	Universal Serial Bus Interfaces for Data and Power – Common Components.
EN IEC 62680-1-2	USB Power Delivery Specification
SASO-IEC-62680-1-2	Universal serial bus interfaces for data and power- Part 1-2: Common components - USB Power Delivery specification
IEC 62680-1-3,	Universal serial bus interfaces for data and power – Part 1-3: Common
EN IEC 62680-1-3	components – USB Type-C® Cable and Connector Specification
SASO-IEC-62680-1-3	Universal serial bus interfaces for data and power - Part 1-3: Universal Serial Bus interfaces - Common components - USB Type-CTM cable and connector specification

#### TL-1250 Location

ENERGY STAR	ENERGY STAR Program Requirements Product Specification for Electric Vehicle
Electric Vehicle Supply	Supply Equipment version 1.2
Equipment (AC)	ENERGY STAR Level 1 and Level 2 Electric Vehicle Supply Equipment Test Method (Rev. Apr-2017)
	ENERGY STAR Test Method for Determining Display Energy – Rev. Sep-2015
	Section 6.7.5.2 of Consumer Electronics Association (CEA) 2037 A,
	Determination of Television Set Power Consumption
ENERGY STAR	ENERGY STAR Program Requirements Product Specification for Electric Vehicle
Electric Vehicle Supply	Supply Equipment version 1.2
Equipment (DC)	ENERGY STAR DC-Output Electric Vehicle Supply Equipment Test Method
	(Rev. Mar-2021)
	ENERGY STAR Test Method for Determining Display Energy – Rev. May-2019
	Section 6.7.5.2 of Consumer Electronics Association (CEA) 2037 A,
	Determination of Television Set Power Consumption

