



# 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 Pilot specifications* and has demonstrated compliance with ISO/IEC Standard 17025:2017, *General requirements for the competence of testing and calibration laboratories*. IAS Integrated Accreditation Policy has been applied. This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date March 1, 2024



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

**President**

# SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

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## UNDERWRITERS LABORATORIES TAIWAN CO., LTD.

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

| Location                           | Address  | Contact Name | Contact Phone        | Scope Pages |
|------------------------------------|--|--------------|----------------------|-------------|
| TL-1013<br>Main                    | No.260 Daye Road, Beitou Dist.,<br>Taipei City 112, TAIWAN                     | Phil Pan     | +886.2.7737.35<br>23 | 2-13        |
| TL-1013<br>Satellite<br>Laboratory | No.35, Sec.2, Zhongyang S. Road,<br>Beitou Dist., Taipei City 112,<br>TAIWAN   | Phil Pan     | +886.2.7737.35<br>23 | 2-13        |
| TL-1250                            | No.60, Ln.12, Sec.2, Nanshan Road,<br>Luzhu Dist., Taoyuan City 338,<br>TAIWAN | Eric Hu      | +886.2.7737.35<br>27 | 13          |

*Accredited to ISO/IEC 17025:2017  
FDA ASCA Pilot Program*

*Effective Date March 1, 2024*

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

| <b>Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems and Laboratory Medical Equipment</b> |  |
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| 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  |
| ANSI/AAMI/IEC 80601-2-30:2018  | Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers   |

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| [3-123]   |  |
| IEC 60601-1-2 Edition<br>4.1 2020-09<br>CONSOLIDATED<br>VERSION<br>[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<br>3.2 2020-07<br>CONSOLIDATED<br>VERSION<br>[5-132]  | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability  |
| IEC 60601-1-8 Edition<br>2.2 2020-07<br>CONSOLIDATED<br>VERSION<br>[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<br>2.1 2020-07<br>CONSOLIDATED<br>VERSION<br>[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<br>1.1 2020-07<br>CONSOLIDATED<br>VERSION<br>[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<br>6.0 2017-03<br>[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<br>2.1 2016-04<br>[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<br>3.0 2009-08<br>[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<br>2.0 2011-10<br>[3-105]                            | Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs  |
| IEC 60601-2-27 Edition<br>3.0 2011-03<br>[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<br>3.0 2011-05<br>[3-115]                            | Medical electrical equipment - Part 2-34: Particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment   |
| IEC 60601-2-37 Edition<br>2.1 2015<br>[12-293]                              | Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment   |

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| 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   |

## 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 |

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| 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  |
| 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                              |

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| 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   |
| 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   |

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| 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   |
| 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 equipment having testing or measuring circuits   |
| CAN/CSA C22.2 No. 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            |
| CAN/CSA C22.2 No. 61010-2-033 | 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   |

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| CAN/CSA C22.2 No. 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   |
| 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                                     |
| 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 C22.2 No. 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. 80601-2-55  | Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors  |
| CAN/CSA C22.2 No. 80601-2-56  | Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement  |
| CAN/CSA C22.2 No. 80601-2-60  | Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment  |
| CAN/CSA C22.2 No. 80601-2-61  | Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment  |
| CAN/CSA C22.2 No. 80601-2-70  | Medical electrical equipment - Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment  |
| CSA C22.2 No. 80601-2-74      | Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment   |
| EN 60601-1                    | Medical electrical equipment Part 1: General requirements for basic safety and essential performance  |
| EN 60601-1-1                  | Medical Electrical Equipment Part 1-1: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems  |
| 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   |
| 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  |



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|               | 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   |
| 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                                      |

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| 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  |
| 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  |

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| 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   |
| 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   |

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| 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 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  |

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| 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 apnoea 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

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| 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 |

## TL-1250 Location

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