# CERTIFICATE OF ACCREDITATION

*This is to attest that*

## UL LLC

2222 WOODALE DRIVE, SUITE 300
MOUNDS VIEW, MINNESOTA 55112, U.S.A.

**Testing Laboratory TL-602**

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 March 16, 2023

***President***

Visit www.iasonline.org for current accreditation information.

# SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

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

## UL LLC

www.ul.com

**Contact Name** Ben Dahlen **Contact Phone** +1-763-586-3585

*Accredited to ISO/IEC 17025:2017* *Effective Date March 16, 2023*

*FDA ASCA Program*

**FDA ASCA Program Scope**

| **Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems and Laboratory Medical Equipment** | |
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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 60601-2-16:2018 [9-121] | Medical electrical equipment — part 2-16: particular requirements for basic safety and essential performance of hemodialysis, hemodialfiltration, and hemofiltration equipment |
| 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 |
| 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 2.1 2012-11 [5-76] | Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard; General requirements, tests |

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| | and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| IEC 60601-1-8 Edition 2.2 20-2007 CONSOLIDATED VERSION [5-131] | Medical electrical equipment - part 1-8: general requirements for basic safety and essential performance - collateral standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION [19-38] | Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment |
| IEC 60601-1-12 Edition 1.0 2014-06 [19-15] | 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 60601-1-12 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 60601-2-10 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 60601-2-16 Edition 5.0 2018-4 [9-121] | Medical electrical equipment — part 2-16: particular requirements for basic safety and essential performance of hemodialysis, hemodialfiltration, and hemofiltration equipment |
| IEC 60601-2-18: Edition 3.0 2009-08 [9-114] | Medical electrical equipment - part 2-18: particular 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 60601-2-31 Edition 2.1 2011-09 [3-102] | Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source |
| IEC 60601-2-34 Edition 3.0 2011-05 [3-115] | Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment |
| IEC 60601-2-47 Edition 2.0 2012-02 [3-155] | Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems |
| IEC 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 |

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| ISO 80601-2-12 First edition 2011-04-15 [1-98] | Medical electrical equipment – Part 2-12: Particular requirements for the safety of lung ventilators – Critical care ventilators [Including: Technical Corrigendum 1 (2011)] |
| ISO 80601-2-12 Second edition 2020-02 [1-146] | Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators |
| ISO 80601-2-55 Second edition 2018-02 [1-140] | Medical electrical equipment -- Part 2-55: Particular requirements for basic safety and essential performance of respiratory gas monitors |
| 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 80601-2-61 Second edition 2017-12 (Corrected version 2018-02) [1-139] | Medical electrical equipment -- Part 2-61: Particular requirements for 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 basic safety and essential performance of sleep apnea 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 80601-2-72 First edition 2015-04-11 [1-105] | Medical electrical equipment – Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients |
| ISO 80601-2-74 First edition 2017-05 [1-138] | Medical electrical equipment -- Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment |

**Regular Scope**

| **Electrical/Electronics** | |
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| **Medical** | |
| ANSI/AAMI ES60601-1 IEC/EN 60601-1 | Medical electrical equipment |
| ANSI/AAMI HA60601-1-11 IEC/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 |
| ANSI/AAMI/IEC/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 |

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| ANSI/AAMI/IEC/EN 60601-2-16 | Medical electrical equipment - Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment |
| ANSI/AAMI/IEC/EN 60601-2-25 | Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs |
| ANSI/AAMI/IEC/EN 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/EN 60601-2-47 | Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems |
| IEC/EN 60601-1-1 | Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems |
| IEC/EN 60601-1-6 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |
| IEC/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 |
| IEC/EN 60601-2-10 | Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators |
| IEC/EN 60601-2-18 | Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment |
| IEC/EN 60601-2-24 | Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers |
| IEC/EN 60601-2-26 | Medical electrical equipment –Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs |
| IEC/EN 60601-2-31 | Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source |
| IEC/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 |
| IEC/EN 60601-2-49 | Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment |
| IEC/EN 60601-2-51 | Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analyzing single channel and multichannel electrocardiographs |
| IEC/EN 80601-2-26 | Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalograph |
| IEC/EN 80601-2-49 | Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors |
| IEC/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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| ISO 80601-2-12 | Medical electrical equipment -- Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators |
| ISO 80601-2-55 | Medical electrical equipment -- Part 2-55: Particular requirements for basic safety and essential performance of respiratory gas monitors |
| 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 basic safety and essential performance of sleep apnea breathing therapy equipment |
| ISO 80601-2-72 | Medical electrical equipment -- Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients |
| ISO 80601-2-74 | Medical electrical equipment -- Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment |
| ISO 80601-2-79 | Medical electrical equipment -- Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment |
| ISO 80601-2-80 | Medical electrical equipment -- Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency |
| ISO 80601-2-84 | Medical electrical equipment -- Part 2-84: Particular requirements for basic safety and essential performance of ventilators for the emergency medical services environment |
| ISO 80601-2-90 | Medical electrical equipment – Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment |
| **Laboratory Equipment** | |
| IEC 61010-1 Edition 3.1 2017-01 | Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements |
| IEC/EN 61010-1 | Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements |
| IEC/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 |
| IEC/EN 61010-2-011 | Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-011: Particular requirements for refrigerating equipment |
| IEC/EN 61010-2-012 | Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-012: Particular requirements for climactic and environmental testing and other temperature conditioning equipment |
| IEC/EN 61010-2-020 | Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements for laboratory centrifuges (excluding Annex AA) |
| IEC/EN 61010-2-030 | Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements for testing and measuring circuits |

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| IEC/EN 61010-2-032 | Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements for hand-held and hand-manipulated current sensors for electrical test and measurement |
| IEC/EN 61010-2-033 | Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements for hand-held multimeters and other meters, for domestic and professional use, capable of measuring mains voltage |
| IEC/EN 61010-2-034 | Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-034: Particular requirements for measurement equipment for insulation resistance and test equipment for electric strength |
| IEC/EN 61010-2-040 | Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements for sterilizers and washer-disinfectors used to treat medical materials |
| IEC/EN 61010-2-051 | Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for laboratory equipment for mixing and stirring |
| IEC/EN 61010-2-081 | Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes |
| IEC/EN 61010-2-101 | Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment |
| IEC/EN 61010-2-120 | Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-120: Particular requirements for machinery aspects of equipment |
| IEC/EN 61010-2-201 | Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-201: Particular requirements for control equipment |
| **Information Technology Equipment (ITE)** | |
| IEC/EN 60950-1 | Information technology equipment. Safety. General requirements (excluding 2.10.4, 4.2.8, 4.3.13.5, 4.7.3, Annex A.3) |
| IEC/EN 60950-21 | Information technology equipment. Safety. Remote power feeding |
| IEC/EN 60950-22 | Information technology equipment. Safety. Equipment installed outdoors (excluding 8.2, 8.3, 9.3, 11, Annex A, Annex C, Annex D) |
| IEC/EN 60950-23 | Information technology equipment. Safety. Large data storage equipment |
| IEC/EN 62368-1 | Audio/video, information and communication technology equipment. Safety requirements |
| IEC/EN 62368-3 | Audio/video, information and communication technology equipment - Part 3: Safety aspects for DC power transfer through communication cables and ports |