CERTIFICATE OF ACCREDITATION

This is to attest that

UL INTERNATIONAL POLSKA SP. Z O.O.

RÓWNOLEGŁA 4
WARSZAWA 02-235, POLAND

Testing Laboratory TL-863

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 8, 2024

President

Visit www.iasonline.org for current accreditation information.

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

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UL INTERNATIONAL POLSKA SP. Z O.O.

www.ul.com

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Accredited to ISO/IEC 17025:2017 *Effective Date March 8, 2024*

FDA ASCA Program

FDA ASCA Program Scope

Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems and Laboratory Medical Equipment	
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] [19-46]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)] (exclude clause 10.1, 10.3, 10.4 and 17)
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 60601-1-12:2016 [Including AMD 1:2021] [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 [Including Amendment 1(2021)]
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 UL 61010-1 3rd Ed, dated May 12, 2012 with revision through July 19, 2019 [19-41]	Standard for Safety for Electrical Equipment For Measurement, Control and Laboratory Use; Part 1: General Requirements
IEC 60601-1-6 Edition 3.2 2020-07	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (applicable test standard IEC 60601-1)

CONSOLIDATED VERSION [5-132]	
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 1.1 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 60601-2-25 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 60601-2-47 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)] (exclude clauses 201.10 and 201.17)
IEC 60601-2-52 Edition 1.1 2015-03 CONSOLIDATED VERSION [6-489]	Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
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 [Including: Corrigendum 1 (2019)]
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

Regular Scope

Electrical	
ANSI/AAMI ES60601-1 IEC/EN 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (exclude clause 10.1, 10.3, 10.4 and 17)
ANSI/UL/IEC/EN 61010-2-201	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-201: Particular requirements for control equipment
IEC 61010-1 Edition 3.1 2017-01	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements (exclude clause 12)
IEC/EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (applicable test standard IEC 60601-1)
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
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 60601-2-24	Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers
IEC/EN 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC/EN 60601-2-27	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
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 60601-2-49	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors
IEC/EN 60601-2-52	Medical electrical equipment – Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
IEC/EN 60950-1	Information technology equipment – Safety – Part 1: General requirements
IEC/EN 62368-1	Audio/video, information and communication technology equipment – Part 1: Safety requirements
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

IEC/EN 80601-2-61	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
UL/IEC/EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
UL/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
UL/IEC/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
Battery	
16 CFR 1263	Button cell and coin batteries and consumer products containing such batteries
IEC/EN 60086-4	Primary batteries – Part 4: Safety of lithium batteries
IEC/EN 62133	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
IEC/EN 62133-1	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 1: Nickel systems
IEC/EN 62133-2	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems
IEC/EN 62281	Safety of primary and secondary lithium cells and batteries during transport
UL 4200A	Products incorporating button batteries or coin cell batteries
UN ST/SG/AC.10/11	Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria. Clause 38.3 Lithium metal and lithium ion batteries