



# CERTIFICATE OF ACCREDITATION

*This is to attest that*

**UL INTERNATIONAL POLSKA SP. Z.O.O.**  
RÓWNOLEGŁA 4  
WARSZAWA 02-235, REPUBLIC OF POLAND

**Testing Laboratory TL-863**

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*. This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date July 30, 2022



A handwritten signature in black ink, reading 'Raj Nathan'.

**President**

Visit [www.iasonline.org](http://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](http://www.iasonline.org)

## UL INTERNATIONAL POLSKA SP. Z.O.O.

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

**Contact Name** Marcin Wagner

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*Accredited to ISO/IEC 17025:2017*

*Effective Date July 30, 2022*

*FDA ASCA Pilot Program*

### FDA ASCA Pilot Program Scope

<b>Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems and Laboratory Medical Equipment</b>	
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) [19-4]	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
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)]
IEC 60601-1-6 Edition 3.1 2013-10 [5-89]	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (applicable test standard IEC 60601-1)
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 (applicable test standard IEC 60601-1)
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 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

### Regular Scope

<b>Electrical</b>	
ANSI/AAMI ES60601-1 IEC/EN 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

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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
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 60601-2-52	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 80601-2-60	Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental 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
<b>Battery</b>	
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
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