CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Washington Laboratories, Ltd.
4840 Winchester Blvd., Suites 5 and 6
Frederick, Maryland 21703

Fulfills the requirements of

ISO/IEC 17025:2017

and

FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program – Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment

In the field of

TESTING

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org

Jason Stine, Vice President

Expiry Date: 30 June 2026

Certificate Number: AT-1448.01

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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TESTING

ISO/IEC 17025 Accreditation Granted: **30 June 2024**

Certificate Number: **AT-1448.01** Certificate Expiry Date: **30 June 2026**

Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment [1]

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Medical Electrical Equipment + Medical Systems	Electromagnetic disturbances	19-8, IEC 60601-1-2 Edition 4.0 2014-02	-
General II (ES/EMC)	Electromagnetic disturbances	19-36, IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	-
Anesthesiology	Oxygen concentrator equipment	1-148, ISO 80601-2-69 Second edition 2020-11	-
General II (ES/EMC)	Electromagnetic immunity	19-19, IEC TR 60601-4-2 Edition 1.0 2016-05	-
General I (QS/RM)	Usability	5-132, IEC60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	-
General I (QS/RM)	Alarm systems in medical electrical equipment and medical electrical systems	5-131 IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	Complete Standard
General II (ES/EMC)	Medical electrical equipment and medical electrical systems used in the home healthcare environment	19-38, IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	To the extent of the FDA ASCA partial recognition

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Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment [1]

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
General II (ES/EMC)	Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	19-39, IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION	Complete Standard
General II (ES/EMC)	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements	19-34, IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION 19-49, IEC 61010-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	Complete Standard
Cardiovascular	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	3-105, 60601-2-25 Edition 2.0 2011-10	To the extent of the FDA ASCA partial recognition
Cardiovascular	Medical electrical equipment -- Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	3-155, ANSI AAMI IEC 60601-2-47:2012/(R)2016	Complete Standard
General Plastic Surgery/General Hospital	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)].	6-421, 80601-2-56 Second Edition 2017-03	Complete Standard
Anesthesiology	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	1-139, ISO 80601-2-61 Second Edition 2017-12 (Corrected Version 2018-02)	To the extent of the FDA ASCA partial recognition

Note:

1. Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, FDA Accreditation Scheme for Conformity Assessment (ASCA) Program – Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment. Laboratories meeting these requirements are eligible to apply to participate in the FDA ASCA program. Participation in the FDA ASCA program can be confirmed by visiting their website https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-accredited-testing-laboratories.

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