



INTERNATIONAL
ACCREDITATION
SERVICE®

CERTIFICATE OF ACCREDITATION

This is to attest that

INTERTEK SEMKO A.B

TORSHAMNSGATAN 43
STOCKHOLM 16440, KINGDOM OF SWEDEN

Testing Laboratory TL-1017

has met the requirements of AC89, *IAS Accreditation Criteria for Testing Laboratories* 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 October 20, 2024



International Accreditation Service
Issued under the authority of IAS management

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

INTERTEK SEMKO A.B

www.intertek.se

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Accredited to ISO/IEC 17025:2017

Effective Date October 20, 2024

Medical	
ANSI AAMI ES60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
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
ANSI UL 61010-1	Standard for Safety for Electrical Equipment For Measurement, Control and Laboratory Use; Part 1: General Requirements
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
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

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	electrical equipment and medical electrical systems intended for use in the emergency medical services environment
IEC 61010-1	Safety requirements for electrical equipment for measurement control and laboratory use – Part 1: General requirements
IEC TS 60601-4-2	Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical equipment and medical electrical systems
ISO 80601-2-12	Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
ISO 80601-2-13	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
ISO 80601-2-55	Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

ANSI: American National Standards Institute

IEC: International Electrotechnical Commission

ISO: International Standards Organization

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