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* 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 June 10, 2024

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

INTERTEK SEMKO A.B

www.intertek.se

Contact Name Henrik Wikstroem **Contact Phone** +46-708752070

Accredited to ISO/IEC 17025:2017 *Effective Date June 10, 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)]
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 60601-1-2:2014 [Including AMD1:2021] [19-36]	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]
ANSI AAMI IEC 60601-1-8:2006 and A1:2012 [Including AMD 2:2021] [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 [Including Amendment 2 (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 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 Edition 3.2 2020-08 CONSOLIDATED VERSION	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

[19.49]	
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION [19-36]	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 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 2.2 2020-07 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 1.1 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 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
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 80601-2-13 First edition 2011-08-11 [1-141]	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation [Including: Amendment 1 (2015) and Amendment 2 (2018)]
ISO 80601-2-13 Second edition 2022-04 [1-165]	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
ISO 80601-2-55 Second edition 2018-02 [1-140]	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