Accredited Laboratory

A2LA has accredited

HIGHPOWER VALIDATION TESTING & LAB SERVICES INC.

Rochester, NY

for technical competence in the field of

Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*. 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 8 January 2009*).

Presented this 10th day of January 2017.

President and CEO
For the Accreditation Council
Certificate Number 3718.01
Valid to December 31, 2018

For the tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

HIGHPOWER VALIDATION TESTING & LAB SERVICES INC.
125 Highpower Road
Rochester, NY 14623
Brandon Taylor Phone: 585 743 1933

BIOLOGICAL

Valid To: December 31, 2018 Certificate Number: 3718.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on reusable medical devices, medical devices, biological indicators, chemical indicators, medical device raw materials:

Test	**Test Method**
Biological Indicators – D-Value Verification	USP <55>; ANSI/AAMI/ISO 11138-1
Chemical Indicators – Compliance Testing (Dry Heat, Steam, Steam+Formaldehyde)	ANSI/AAMI/ISO 11140-1
Sterilization Packaging Systems – Accelerated Aging of Sterile Barrier Systems for Medical Devices	ASTM F1980
Sterilization Packaging Systems – Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	ANSI/AAMI/ISO 11607-1; AAMI TIR22; ASTM F1929
Sterilization Packaging System – Dry Time Testing	ANSI/AAMI ST77; AAMI TIR 12
Sterilization Packaging Systems – Real Time Shelf Life	ANSI/AAMI/ISO 11607-1; AAMI TIR22
Sterilization Packaging Systems – Sterilant Penetration/ Thermal Profile	ANSI/AAMI ST77; AAMI TIR 12
Sterilization Packaging Systems – Whole Package Integrity Test	ANSI/AAMI/ISO 11607-1; AAMI TIR22
Validation of Cleaning Efficacy of Reusable Medical Devices	AAMI TIR 30
Validation of Thermal Disinfection of Reusable Medical Devices	ISO 15883-1, ISO 15883-2
Validation of Sterilization/Reprocessing of Reusable Medical Devices	ANSI/AAMI/ISO 14937; AAMI TIR 12

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Joint IAF-ILAC-ISO Communiqué
on the
Management Systems Requirements of ISO/IEC 17025:2005,
General requirements for the competence of testing and calibration laboratories

A laboratory's fulfilment of the requirements of ISO/IEC 17025:2005 means the laboratory meets both the technical competence requirements and **management system requirements** that are necessary for it to consistently deliver technically valid test results and calibrations. The **management system requirements** in ISO/IEC 17025:2005 (Section 4) are written in language relevant to laboratory operations and meet the principles of ISO 9001:2008 **Quality Management Systems — Requirements** and are aligned with its pertinent requirements.

IAF Chair	ILAC Chair	ISO Secretary General

January 2009