



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

HIGHPOWER VALIDATION TESTING & LAB SERVICES INC.  
125 Highpower Road  
Rochester, NY 14623  
Dave Adams Phone: 585 743 1948

BIOLOGICAL

Valid To: December 31, 2026

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, and medical device raw materials:

<b>Test:</b>	<b>Test Method(s):</b>
Airbourne Microbial Challenge Test	PDA Tech. Report No. 27
Biological Indicators – D-Value Verification	USP <55>; ANSI/AAMI/ISO 11138-1
Chemical Indicators – Compliance Testing (Dry Heat, Steam)	ANSI/AAMI/ISO 11140-1
Material Compatibility/Reusability of Medical Devices	AAMI TIR 17
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 TIR 22
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 TIR 22

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<b>Test:</b>	<b>Test Method(s):</b>
Validation of Cleaning Efficacy of Reusable Medical Devices	AAMI ST98
Validation of Low Temperature Vaporized Hydrogen Peroxide Sterilizers	ISO 22441, FDA Guidance on Premarket Notification 510(k) Submissions for Sterilizers Intended for Use in Health Care Facilities
Validation of Steam Sterilizers	AAMI ST-08, AAMI ST 55, FDA Guidance on Premarket Notification 510(k) Submissions for Sterilizers Intended for Use in Health Care Facilities
Validation of Sterilization	ANSI/AAMI/ISO 14937; ANSI/AAMI/ISO 17665-1; AAMI TIR 12
Validation of Thermal Disinfection of Reusable Medical Devices	ISO 15883-1, ISO 15883-2





## 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 17025:2017 *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 April 2017).



Presented this 3<sup>rd</sup> day of February 2025.

A blue ink signature of Mr. Trace McInturff, written over a horizontal line.

Mr. Trace McInturff, Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 3718.01  
Valid to December 31, 2026

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