



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

HIGHPOWER VALIDATION TESTING & LAB SERVICES INC.

125 Highpower Road

Rochester, NY 14623

Gary J. Socola Phone: 585 743 1935

BIOLOGICAL

Valid To: December 31, 2016

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:

<u>Test</u>	<u>Test Method</u>
Biological Indicators – D-Value Verification	USP <55>, ANSI/AAMI/ISO 11138-1
Chemical Indicators – Compliance Testing	ANSI/AAMI/ISO 11140-1
Sterilization Packaging Systems – Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	ANSI/AAMI/ISO 11607-1, AAMI TIR22:2007, ASTM F1929-98
Sterilization Packaging Systems – Real Time Shelf Life	ANSI/AAMI/ISO 11607-1, AAMI TIR22:2007
Sterilization Packaging Systems – Whole Package Integrity Test	ANSI/AAMI/ISO 11607-1, AAMI TIR22:2007
Validation of Cleaning Efficacy of Reusable Medical Devices	AAMI TIR 30
Validation of Sterilization/Reprocessing of Reusable Medical Devices	ANSI/AAMI/ISO 14937, AAMI TIR 12



American Association for Laboratory Accreditation

## *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 27<sup>th</sup> day of October 2014.



  
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President & CEO

For the Accreditation Council  
Certificate Number 3718.01  
Valid to December 31, 2016

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