



HIGHPOWER

Validation Testing & Lab Services

Highpower Labs
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VITAL STATISTICS

Year Founded: 1987
Number of Employees: 20
Number of Facilities: One 16,000 sq. ft. facility located in Rochester, NY
Certifications: A2LA ISO 17025 accredited facility (certificate no. 3718.01)

WHO WE ARE



HIGHPOWER Validation Testing & Lab Services Inc. (HIGHPOWER) is an independent, privately owned reusable medical device validation and testing laboratory with over 25 years of experience. HIGHPOWER provides a wide range of verification, validation and testing services, as well as consulting services to medical device manufacturers.

Operating out of a state of the art facility, with every major FDA cleared sterilization process in-house, allows our team of scientists and technicians to assist device manufacturers in all of their validation or regulatory compliance needs.

HIGHPOWER strives for continuous improvement while performing studies that involve verification and/or validation of biological indicators, chemical indicators, packaging materials, material compatibility, sterilization efficacy and device cleaning.



MAJOR MARKETS

HIGHPOWER Validation Testing & Lab Services provides services to the following industries:

- Medical Devices/Products
- Dental Devices/Products
- Pharmaceutical Products
- Industrial Products
- Detergent/Cleaning Products

SERVICES OFFERED

Testing services focus on reusable medical devices that require cleaning, packaging and sterilization. HIGHPOWER also provides biological/chemical indicator testing along with material compatibility testing in the various cleaning and sterilization processes. Test protocols and final reports follow the most current national or international standards, and are tailored to each specific device.

Both manual and mechanical cleaning processes are in-house, with multiple markers such as protein, hemoglobin and TOC available.

HIGHPOWER can provide validation to the ISO 11607 packaging standard, along with real and accelerated shelf life testing and whole package integrity testing.

Sterilization Efficacy testing in Steam, E.O. Gas, Dry Heat, Chemical Immersion and Hydrogen Peroxide sterilization processes are available.

Human factors testing on reusable devices as well as materials compatibility testing in Steam, E.O. Gas, Dry Heat, Chemical Immersion and Hydrogen Peroxide sterilization processes are also available.

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