



Medical Device Testing

WHAT IS MEDICAL DEVICE TESTING?

Medical Device Package Validation incorporates package performance testing, accelerated aging, material evaluation, and sterile integrity testing, following the guidelines of ISO 11607. Westpak provides product validation services for both first articles and production devices.

SERVICES

Customized Test Protocols

Depending on your needs we can assist in protocol development or provide a company specific document with a detailed test plan. Consult our experienced staff when you need answers about testing.

Package Performance Testing

Package performance testing simulates environmental hazards within a controlled laboratory environment. By performing these tests inside a laboratory, the inputs have a high degree of repeatability that yields accurate results with a high level of confidence. Environmental hazards include temperature, humidity, altitude, random vibration, impacts, compression, and others.

Sterile Package Integrity

Sterile Package Integrity testing can be conducted using several methods, such as Bubble Emission, Vacuum Leak, and Dye Penetration. These tests easily ascertain failures due to material fatigue or channel leaks within the seal of pouches or trays.

Seal Strength Testing

Peel and Burst Testing measure the strength of heat seals within flexible barrier and thermoform packaging materials. These tests are used to validate the heat-sealing process and to determine if the seals of postproduction package systems are within acceptable limits.

Accelerated Aging Studies

Accelerated Aging studies establish product shelf-life data in order to get products to market. Aging studies require verification from real-time storage testing. Call Westpak for assistance with identifying the correct duration, temperature, and humidity levels.

Altitude Testing

Many products can be sensitive to the reduced atmospheric pressure experienced at high altitudes. An altitude test identifies product sensitivity prior to shipment.

Medical Device Product Evaluation Services

Tensile Strength Testing, Compression/Bend Testing, Assembly Strength Testing, Shock, Vibration Testing, and Material Evaluation.



Locations:

83 Great Oaks Boulevard
San Jose
California
95119
Phone: 408.224.1300
Fax: 408.224.5113

10326 Roselle Street
Suite 101
San Diego
California
92121
Phone: 858-623-8100
Fax: 858-623-8101

www.westpak.com