



Medical Device Testing

WHAT IS MEDICAL DEVICE TESTING?

In the Medical Device Industry, the Sterile Barrier System must protect and maintain the sterility of the product from manufacture through the distribution environment to the point of end-use. The Sterile Barrier System will be subjected to a variety of tests which include package performance testing, accelerated aging, material evaluation, and sterile integrity testing. Following the guidelines of ANSI/AAMI/ISO 11607 Part 1 and 2, Westpak provides product and package testing services for both first articles and production devices.

SERVICES

Customized Test Protocols

Depending on the needs of the customer, we can assist in protocol development or provide a company specific document with a detailed test plan. Westpak can also provide the necessary answers through our network of professionals and our experienced staff.

Package Performance Testing

Package performance testing simulates environmental hazards within a controlled laboratory environment.

By performing these tests inside laboratory, the inputs have a high degree of repeatability that yields accurate results with a high level of confidence. Environmental hazards include temperature, humidity, impacts, compression, altitude, vibration, among others.

Sterile Package Integrity

Sterile Package Integrity testing can be conducted using several methods such as Bubble Emission and Dye Penetration. Although these tests are qualitative, these tests have the ability to ascertain failures due to material fatigue or channel links within the seal of pouches or trays.

Seal Strength Tests

Peel and Burst tests conducted on the Sterile Barrier Systems to measure Seal Strength. These tests are used to validate the heat sealing process and to determine if the seals of the Sterile Barrier System are within acceptable limits.

Accelerated Aging Studies

Accelerated Aging studies establish product shelf-life data in order to get products to market. Aging studies are verified by conducting real-time storage testing for the same time period. With our newly expanded aging facility Westpak can provide both Accelerated and Real-Time aging of the Sterile Barrier System.

Altitude Testing

Many products can be sensitive to the reduced atmospheric pressure experienced at high altitudes. An Altitude tests can identify product sensitivity to this hazard prior to shipment.



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