eurofins | Medical Device Testing



Sterile Barrier System (SBS)

Regulatory agencies across the globe recognize the critical nature of a Sterile Barrier System (SBS) by considering it a component of a medical device. One key function of an SBS is to maintain the safety of a terminally sterilized medical device until the point of use in a healthcare setting.

Eurofins Medical Device Testing can evaluate the sterile integrity of your final packaging design through a series of seal integrity and seal strength testing outlined in ISO 11607 - Packaging for Terminally Sterilized Medical Devices.

Seal integrity testing identifies any leaks around the seal area of your packaging system. Seal integrity testing is followed by seal strength testing to evaluate the mechanical strength of your packaging system and the force needed to separate and open the seal. A high numerical force value could indicate challenges in opening your packaging system by hand; and a low numerical force value could indicate poor bonding of materials.

Choose Eurofins Medical Device Testing to help you:

- Validate your final packaging design.
- Monitor proper device performance during the manufacturing process.
- Establish material compatibility and proper bonding to maintain the sterile environment throughout the shelf life of your product.
- Ensure the seal of your packaging system does not change after exposure to environmental stressors (distribution or shelf life).

Testing Available

Seal Integrity Testing

- Visual Inspection (ASTM F1886)
- Dye Penetration (ASTMs F1929 & F3039)
- Bubble Emission (ASTM F2096)
- Vacuum Leak (ASTM D3078)
- Helium Leak Detection (ASTM F2391)
- High Voltage Leak Detection
- Dye & Bacterial Immersion
- Microbial Ranking (ASTM F1608)
- Oxygen Headspace Analysis
- Burst Testing
- Pressure Decay

Seal Strength Testing

- Peel/Seal Strength Testing (ASTM F88, EN 868-5 Annex D)
- Burst Testing (ASTMs F1140 & ASTM F2054)
- Tear Resistance (Pendulum Method) (ASTM D1922)