



PACKAGING TESTING

What is Packaging Testing?

Packaging testing is a key validation requirement for medical devices. Adherence to the test requirements within ISO 11607 demonstrates the strength and integrity of a sterile barrier system throughout the distribution cycle and shelf life of the product.

What is Packaging Testing Used For?

Packaging testing is used to manage the risks inherent to the manufacturing, packaging and distribution of medical devices that must remain sterile until the point of use. Standardized testing is used to demonstrate that a packaging system has adequate protective capabilities. This is achieved by subjecting the packaging to laboratory tests that stimulate hazards encountered during real-world shipping and storage conditions. They are then assessed for the presence of a sterile barrier, thereby providing confidence in their protective capability.

Our packaging testing services include:

- Distribution simulation, including:
 - Climatic conditioning
 - Compression
 - Vibration
 - Shock/drop
- Accelerated aging and real-time aging

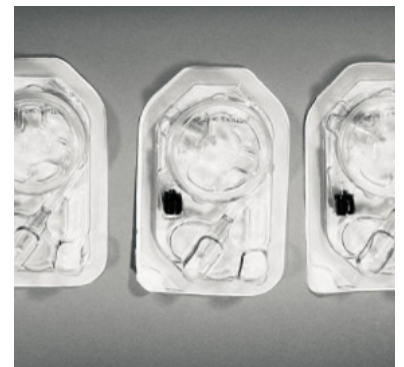
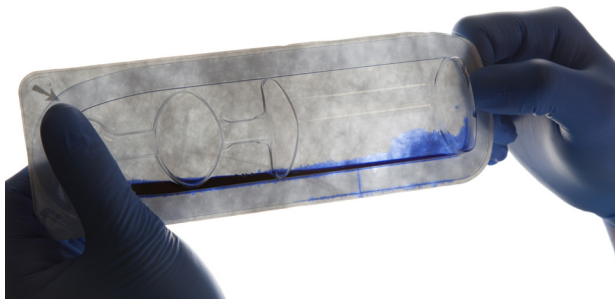
- Package integrity testing
 - Visual inspection
 - Bubble leak
 - Dye penetration
- Seal strength/peel testing
- Technical guidance services
 - Packaging design support
 - Protocols and test planning

Benefits of Packaging Testing

The optimal way to establish that a packaging system is meeting specific requirements is to leverage proven test standards. The benefits of performing a packaging validation include:

- Avoidance of product recalls
- Compliance with industry requirements
- Minimized risk of product damage
- Identification of design faults in either products or packaging at an early stage

To ensure an efficient and effective test process, protocols are generated that define the entire sequence of testing. Our test laboratories are ISO 17025 accredited and ISTA certified, while our test engineers are specialized in ASTM and other standards.



FOR MORE INFORMATION

STERIS Applied Sterilization Technologies
15-16E Mervue Business Park
Galway, H91 D3T0, Ireland
Web: steris-ast.com // Phone: +353 (0)91 740 350

