PRODUCT AND PACKAGE TESTING

Our comprehensive package testing services support medical device and pharmaceutical manufacturing Customers and the sterilization process by validating packaging systems in accordance with ISO 11607. Additionally, STERIS offers product testing services to support medical and pharmaceutical device design verification and custom testing services using a variety of methods.

Product Testing

Product testing is used to verify that a medical devices or pharmaceutical device meets the defined product design specifications. Specifications are set to ensure that safety, efficacy, and reliability requirements are adequately addressed. Tests are prescribed by notified bodies with reference to international standards.

Our product testing services include:

- Accelerated lifecycle testing
- Luer connectors
- Design verification
- Medical electrical equipment

Package Testing

Package testing is used to manage the risks inherent to the manufacturing, packaging and distribution, of medical and pharmaceutical 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 simulate 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 package testing services include:

- Accelerated and real-time aging
- Distribution/transportation simulation
- Cold chain testing
- Sterile barrier integrity and seal strength
- Shelf-life extension for sterile medical and pharmaceutical devices

FOR MORE INFORMATION

STERIS