eurofins

Medical Device Testing

Package Testing

Choose Eurofins Medical Device Testing to help you:

- ✓ Validate your shipping configurations will withstand the rigors of global transit
- ✓ Assess your packaging design and material selections
- ✓ Ensure the integrity of your product's primary sterile barrier
- ✓ Confirm your labels adhere to UDI regulations and remain readable through your entire distribution channel
- ✓ Establish your product's shelf-life through accelerated and real-time aging

Package Testing

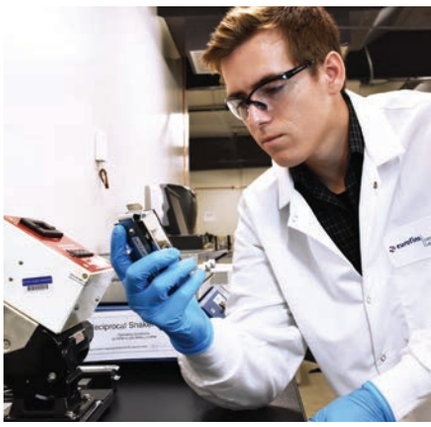
In addition to validating the design and functionality of your medical device, there are a myriad of testing requirements needed to ensure your product reaches the end user intact. From primary seal testing through pallet-level transit testing, our state-of-the-art Package Testing Facility provides complete capabilities for evaluating every aspect of your package and labeling configurations, to ensure your product will survive the rigors of being transported around the world.

Eurofins Medical Device Testing's state-of-the-art Package Testing Facility is equipped to perform functional testing, material testing, and shelf-life testing of primary and secondary packaging, as well as shipping configurations. Our scientists and engineers will help you evaluate every aspect of your packaging from sterile seal integrity through distribution and transit testing of full pallet-sized loads, and durability of your labels. We also provide a wide range of physical property testing to characterize and assess alternate packaging materials.

Sterile Seal Integrity

Perhaps the most critical aspect of packaging for a terminally sterilized device is the barrier seal that maintains the sterility of the product. Eurofins Medical Device Testing can assess the sterile seal integrity of many or most device and/or packaging configurations. We have the most appropriate technology and capabilities for your specific application, including:

- Bacterial Challenges Testing
- Dye Penetration or Dye Leak Testing
- Burst and Bubble Testing



Shelf-Life Testing

With more than 5,300m^3 (187,000 ft^3) of environmental chamber space, we have the capacity to execute all of your accelerated and real-time shelf aging studies. Our chambers are continuously monitored with validated electronic tracking systems integrated into our LIMS system. Our online portal, LabAccess.com, also allows you to track the progress of your studies via our shelf-life calendar and provides you with 24/7 visibility to your data.

Transit Testing

Eurofins Medical Device Testing can perform all of the validation testing needed to meet international product submission requirements and ensure that your packaging is robust enough to survive the rigors of transit, whether you are shipping individual units or full pallet-level deliveries, including:

- Loose Load & Vehicle Vibration
- Manual Handling & Drop
- Focused Drop Impact
- Vertical Stacking & Crush
- Low Pressure/Altitude

Materials Testing

Whether you are developing a new packaging design, evaluating a new material or sterilization technique or qualifying a new supplier, we can perform characterization and performance evaluation studies to meet the range of ASTM and ISO standards, as well as custom methodologies, for materials testing, including:

- Tensile or Flexural Strength
- Moisture or Gas Transmission
- Tear & Puncture Resistance
- Seal Strength and Burst Testing
- Flammability
- Chemical Identification & Purity
- Peel Testing

Labeling

Unreadable barcodes or misread text can result not only in complaints and product returns, but can also compromise patient safety. Our team can help you ensure your products meet the latest UDI regulations and that your barcodes remain readable through the entire distribution chain with our comprehensive portfolio of label testing services, including:

- Barcode Verification
- Sutherland Rub
- Ink Adhesion Using Tape

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Belgium	Germany	Netherlands	Switzerland
Denmark	Ireland	Spain	U.S.

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