eurofins | Medical Device Testing



Shelf Life & Accelerated Aging

Every medical device is required to be labeled with an expiration date that is supported by shelf-life data. Accelerated-aging tests are employed to generate this data for design-history files, technical dossiers, and 510 (k) submissions, while concurrently running real-time studies.

For many medical devices that are manufactured from metals and robust plastics, the evaluation time for a product's shelf life can be significantly shortened by aging the materials at elevated temperatures (often as high as 55°C). Other products, such as biologic materials or products made of thermally sensitive materials, require a more thorough aging study design with environmental chambers relevant to more unique product requirements.

With more than 5,600 m^3 (200,000 ft^3) of environmental chamber space worldwide, meeting ASTM, ISO, and ICH conditions, Eurofins Medical Device Testing has the largest global capacity for accelerated and real-time shelf-life studies. Eurofins' chambers are housed in secured areas, continuously monitored and integrated into a fully validated, computerized, Laboratory Information Management System (LIMS).

Choose Eurofins Medical Device Testing to help you:

- Establish product shelf life under both accelerated and real-time conditions.
- Meet regulatory requirements following ISO 11607-1, ASTM F1980, or any custom-testing protocol needed to establish your product's expiration date.
- Get comprehensive analysis through one provider, including package integrity, sterility, and product functionality testing such as mechanical, electrical, and physicochemical testing.

- Access study progress through our secure online data access portal, LabAccess.com℠.
- Ensure easy monitoring of multiple long-term studies and a device's overall protocol plan using a document control system.
- Utilize an International Shipping Specialist to ship products anywhere in the world, navigating permitting, importing and customs.
- Support protocol writing and method development/validation.

Storage Systems and Capacity

- Over 200,000 ft^3 of storage space in more than 100 chambers worldwide.
- Temperature mapped and validated environmental chambers with full redundancy on critical systems, including backup power generators.
- With 40 established conditions, ranging from vapor phase liquid nitrogen through 60°C, additional custom conditions are available.
- Light chambers for assessments of photosensitive materials.