

Accelerated Aging Testing - AAT

Medical Devices That Require Accelerated Aging Testing

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Sterile Barrier Packaging Systems

- Medical pouches, trays, and wraps
- Blister packs for surgical instruments
- Sterilization bags and barrier materials

Implantable Medical Devices

- Cardiac pacemakers and leads
- Artificial joints (hip, knee, spinal implants)
- Stents and vascular grafts

Single-Use Disposable Devices

- Catheters and IV sets
- Syringes and needles
- Surgical gloves and gowns

Drug-Device Combination Products

- Pre-filled syringes (e.g., insulin pens, epinephrine injectors)
- Drug-eluting stents
- Inhalers and nebulizers

Diagnostic and Testing Equipment

- Point-of-care testing kits (e.g., blood glucose meters, pregnancy tests)
- Laboratory reagents and diagnostic test strips

Electromechanical and Battery-Powered Devices

- External defibrillators
- Infusion pumps
- Wearable medical sensors (continuous glucose monitors, ECG patches)

Wound Care and Dressings

- Hydrogel and foam dressings
- Negative pressure wound therapy (NPWT) systems
- Antimicrobial bandages

Surgical and Endoscopic Instruments

- Laparoscopic and robotic surgical tools
- Endoscopes and camera systems
- Disposable scalpels and cautery pens

Personal Protective Equipment (PPE)

- N95 masks and surgical masks
- Face shields and respirators
- Medical gowns and coveralls

IVD (In Vitro Diagnostic) Consumables

- Blood collection tubes
- PCR test kits
- Reagents and culture media

Why is Accelerated Aging Testing Important?

- **Regulatory Compliance** – Required by **ISO 11607**, **FDA 21 CFR Part 820**, and other international standards for medical device packaging validation.
- **Shelf-Life Verification** – Ensures that products maintain their sterility, structural integrity, and functionality until the end of their labeled shelf life.
- **Risk Mitigation** – Identifies potential material degradation or failures that could impact patient safety.
- **Product Development Efficiency** – Helps manufacturers quickly assess durability and make improvements without waiting for real-time aging.