Medical Device Testing Standards

MET has expertise in testing to a wide range of standards, here are just a few of them.

Devices

- **EN 1283**: Haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and their extracorporeal circuits
- **ISO 7198**: Cardiovascular implants – Tubular vascular prostheses
- **ISO 7864**: Sterile hypodermic needles for single use
- **ISO 8536**: Infusion equipment for medical use, various parts
- **ISO 8669**: Urine collecting bags – Requirements and test methods
- **ISO 10993**: Biological evaluation of medical devices – various parts
- **ISO 11608**: Pen-injectors for medical use – Parts 1-4: Pen-injectors – Requirements and test methods
- **ISO 11948**: Urine absorbing aids – Whole product testing
- **ISO 14708**: Implants for surgery – Active implantable medical devices – various parts
- **ISO 15137**: Self-adhesive hanging devices for infusion bottles and injection vials – Requirements and test methods
- **ISO 15747**: Plastics containers for intravenous injection
- **ISO 18671**: Intravenous infusion needles for single use
- **ISO 21649**: Needle-free injectors for medical use – Requirements and test methods
- **ISO 22413**: Transfer sets for pharmaceutical preparations – Requirements and test methods
- **ISO 25539**: Cardiovascular implants – various parts
- **ISO 28620**: Medical devices – Non-electrically driven portable infusion devices

Orthopaedics

Test facilities for a wide variety of ASTM and ISO standards.

Materials

- **ASTM D882**: Standard Test Method for Tensile Properties of Thin Plastic Sheeting
- **ASTM D1003**: Standard Test Method for Haze and Luminous Transmittance of Transparent Plastics
- **ASTM D1079**: Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method
- **ISO 180**: Plastics determination of Izod impact strength
- **ISO 527**: Plastics determination of tensile properties
Primary Packaging

- ISO 11607: Packaging for terminally sterilized medical devices, parts 1 and 2
- ASTM F1140: Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
- ASTM F1886: Standard Test method for Determining Integrity of Seals for Medical Packaging by Visual Inspection
- ASTM F2096: Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)

Shipping

- ASTM D4169: Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM D4332: Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ASTM D6344: Standard Test Method for Concentrated Impacts to Transport Packages
- ISTA Procedures: International Safe Transit Association