



**MEDICAL
ENGINEERING
TECHNOLOGIES**

TECHNICAL
AND SCIENTIFIC
SOLUTIONS

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 clecting 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 D3078** Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- **ASTM D4991** Standard Test Method for Leakage Testing of Empty Rigid Containers by Vacuum Method
- **ASTM D6653** Standard Test Method for Determining the Affects of High Altitude on Packaging Systems by Vacuum Method
- **ASTM F88/F88M** Standard Test Method for Seal Strength of Flexible Barrier Materials
- **ASTM F1140** Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
- **ASTM F1585** Standard Guide for Integrity Testing of Porous Barrier Medical Packages¹
- **ASTM F1886** Standard Test method for Determining Integrity of Seals for Medical Packaging by Visual Inspection
- **ASTM F1929** Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- **ASTM F1980** Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- **ASTM F2054** Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization within Restraining Plates
- **ASTM F2096** Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)
- **ASTM F2338** Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method

Shipping

- **ASTM D880** Standard Test Method for Impact Testing for Shipping Containers and Systems
- **ASTM D999** Standard Test Method for Vibration Testing of Shipping Containers
- **ASTM D3103** Standard Test Method for Thermal Insulation Performance of Distribution Packages
- **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 D4728** Standard Test Method for Random Vibration Testing of Shipping Containers
- **ASTM D6344** Standard Test Method for Concentrated Impacts to Transport Packages
- **ISTA Procedures** International Safe Transit Association