

Medical Product and Package Material Testing by Product



Catheters

ASTM F623	<i>Standard Performance Specification for Foley Catheter</i>
ISO 10555-1	<i>Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements</i>
ISO 10555-3	<i>Intravascular catheters - Sterile and single-use catheters - Part 3: Central venous catheters</i>
ISO 10555-4	<i>Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters</i>
ISO 10555-5	<i>Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters</i>
ISO 10555-6	<i>Intravascular catheters - Sterile and single-use catheters - Part 6: Subcutaneous implanted ports</i>
ISO 11070	<i>Sterile single-use intravascular catheter introducers</i>
ISO 594-1	<i>Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements</i>
ISO 594-2	<i>Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings</i>
ISO 23908	<i>Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling</i>
BS EN1707	<i>Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment. Lock fittings.</i>
BS EN20594-1	<i>Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment. General requirements</i>
BS EN1615	<i>Enteral feeding catheters and enteral giving sets for single use and their connectors - Design and testing</i>
BS EN1616	<i>Sterile urethral catheters for single use</i>
BS EN1617	<i>Sterile drainage catheters and accessory devices for single use</i>
BS EN1618	<i>Catheters other than intravascular catheters - Test methods for common properties</i>
DIN EN13868	<i>Test methods for kinking of single lumen catheters and medical tubing</i>
JIS T3223	<i>Sterile, single-use intravascular catheters over-needle peripheral catheters</i>
JIS T3214	<i>Urethral catheters</i>

Needles

ASTM F2132	<i>Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps</i>
ASTM F2878	<i>Standard Test Method for Protective Clothing Material Resistance to Hypodermic Needle Puncture</i>
ISO 7864	<i>Sterile hypodermic needles for single use</i>
ISO 9626	<i>Stainless steel needle tubing for manufacture of medical devices</i>
ISO 23908	<i>Sharps injury protection - Requirements and test methods- Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling</i>
ISO 594-1	<i>Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements</i>
ISO 594-2	<i>Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings</i>
BS EN1707	<i>Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment. Lock fittings</i>
BS EN20594-1	<i>Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment. General requirements</i>
JIS T3228	<i>Biopsy needles for single use</i>
JIS T3222	<i>Sterile winged intravenous devices</i>
JIS T3209	<i>Sterile injection needle</i>

Thermoplastic Containers

ASTM D2463	<i>Standard Test Method for Drop Impact Resistance of Blow-Molded Thermoplastic Containers (Procedure A - Static Drop Height Method, Procedure B - Bruceston Staircase Method)</i>
ASTM D2659	<i>Standard Test Method for Column Crush Properties of Blown Thermoplastic Containers</i>

Fabrics/Tyvek

ASTM D751	<i>Standard Test Methods for Coated Fabrics</i>
ASTM D1424	<i>Standard Test Method for Tearing Strength of Fabrics by Falling-Pendulum Type (Elmendorf) Apparatus</i>
ASTM D5034	<i>Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)</i>
ASTM D5035	<i>Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Strip Test)</i>
ASTM F2878	<i>Standard Test Method for Protective Clothing Material Resistance to Hypodermic Needle Puncture</i>

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Plastic Films	
ASTM D618	<i>Standard Practice for Conditioning Plastics for Testing</i>
ASTM D638	<i>Standard Test Method for Tensile Properties of Plastic</i>
ASTM D882	<i>Standard Test Method for Tensile Properties of Thin Plastic Sheeting</i>
ASTM D1004	<i>Standard Test Method for Tear Resistance (Graves Tear) of Plastic Film and Sheeting</i>
ASTM D1708	<i>Standard Test Method for Tensile Properties of Plastics by Use of Microtensile Specimens</i>
ASTM D1709	<i>Standard Test Method for Impact Resistance of Plastic Film by the Free-Falling Dart Method.</i>
ASTM D1894	<i>Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting</i>
ASTM D1922	<i>Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method</i>
ASTM D1938	<i>Standard Test Method for Tear-Propagation Resistance (Trouser Tear) of Plastic Film and Thin Sheeting by a Single-Tear Method</i>
ASTM D3420	<i>Standard Test Method for Pendulum Impact Resistance of Plastic Film</i>
ASTM D7192	<i>Standard Test Method for High Speed Puncture Properties of Plastic Films Using Load and Displacement Sensors</i>
ASTM F1306	<i>Standard Test Method for Slow Rate Penetration Resistance of Flexible Barrier Films and Laminates</i>
ISO 5636-5	<i>Paper and board - Determination of air permeance and air resistance (medium range)</i>
ISO 6383-2	<i>Plastics - Film and sheeting - Determination of tear resistance - Part 2: Elmendorf method</i>
Rigid Plastics	
ASTM D618	<i>Standard Practice for Conditioning Plastics for Testing</i>
ASTM D638	<i>Standard Test Method for Tensile Properties of Plastic</i>
ASTM D695	<i>Standard Test Method for Compressive Properties of Rigid Plastics</i>
ASTM D732	<i>Standard Test Method for Shear Strength of Plastics by Punch Tool</i>
ASTM D790	<i>Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials</i>
ASTM D1708	<i>Standard Test Method for Tensile Properties of Plastics by Use of Microtensile Specimens</i>
ASTM D3763	<i>Standard Test Method for High Speed Puncture Properties of Plastics Using Load and Displacement</i>
ASTM D5420	<i>Standard Test Method for Impact Resistance of Flat, Rigid Plastic Specimen by Means of a Striker Impacted by a Falling Weight (Gardner Impact)</i>
ASTM D5628	<i>Standard Test Method for Impact Resistance of Flat, Rigid Plastic Specimens by Means of a Falling Dart (Tup or Falling Mass)</i>
ASTM D6272	<i>Standard Test Method for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials by Four-Point Bending</i>
ISO 178	<i>Plastics - Determination of flexural properties</i>
ISO 291	<i>Plastics - Standard atmospheres for conditioning and testing</i>
Rubber/ Elastomers	
ASTM D412	<i>Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers - Tension</i>
ASTM D624	<i>Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers</i>
ASTM F2051	<i>Standard Specification for Implantable Saline Filled Breast Prosthesis</i>
ISO 37	<i>Rubber, vulcanized or thermoplastic - Determination of tensile stress-strain properties</i>
Adhesives and Tapes	
ASTM D903	<i>Standard Test Method for Peel or Stripping Strength of Adhesive Bonds</i>
ASTM D1002	<i>Standard Test Method for Apparent Shear Strength of Single-Lap-Joint Adhesively Bonded Metal Specimens by Tension Loading (Metal-to-Metal)</i>
ASTM D1876	<i>Standard Test Method for Peel Resistance of Adhesives (T-Peel Test)</i>
ASTM D3163	<i>Standard Test Method for Determining Strength of Adhesively Bonded Rigid Plastic Lap-Shear Joints in Shear by Tension Loading</i>
ASTM D3164	<i>Standard Test Method for Strength Properties of Adhesively Bonded Plastic Lap-Shear Sandwich Joints in Shear by Tension Loading</i>
ASTM D3330	<i>Standard Test Method for Peel Adhesion of Pressure-Sensitive Tape</i>
ASTM D3759	<i>Standard Test Method for Breaking Strength and Elongation of Pressure-Sensitive Tape</i>
ASTM D5868	<i>Standard Test Method for Lap Shear Adhesion for Fiber Reinforced Plastic (FRP) Bonding</i>
ASTM D6862	<i>Standard Test Method for 90 Degree Peel Resistance of Adhesives</i>
ASTM F88	<i>Standard Test Method for Seal Strength of Flexible Barrier Materials</i>
ASTM F2824	<i>Standard Test Method for Mechanical Seal Strength Testing for Round Cups and Bowl Containers with Flexible Peelable Lids</i>

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Luer/ Small Bore Connectors

ISO 594-1	<i>Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements</i>
ISO 594-2	<i>Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings</i>
ISO 80369-1	<i>Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements</i>
ISO 80369-3	<i>Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications</i>
ISO 80369-6	<i>Small-bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications</i>
ISO 80369-7	<i>Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications</i>
BS EN1707	<i>Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment. Lock fittings.</i>
BS EN20594-1	<i>Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment. General requirements.</i>

Syringes and Injectors

ISO 594-1	<i>Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements</i>
ISO594-2	<i>Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings</i>
ISO 7886-1	<i>Sterile hypodermic syringes for single use - Part 1: Syringes for manual use</i>
ISO 7886-2	<i>Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps.</i>
ISO 7886-3	<i>Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed-dose immunization</i>
ISO 7886-4	<i>Sterile hypodermic syringes for single use - Part 4: Syringes with re-use prevention feature</i>
ISO 8537	<i>Sterile single-use syringes, with or without needle, for insulin</i>
ISO 11040-4	<i>Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling</i>
ISO 11040-6	<i>Prefilled syringes - Part 6: Plastic barrels for injectables</i>
ISO 11608-1	<i>Needle-based injection systems for medical use - Part 1: Needle-based injection systems</i>
ISO 11608-2	<i>Needle-based injection systems for medical use - Part 2: Needles</i>
BS EN1707	<i>Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment. Lock fittings.</i>
BS EN20594-1	<i>Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment. General requirements.</i>
JIS T3201	<i>Glass Syringes</i>

Infusion Equipment and Sets

ISO 8536-1	<i>Infusion equipment for medical use - Part 1: Infusion glass bottles</i>
ISO 8536-2	<i>Infusion equipment for medical use - Part 2: Closures for infusion bottles</i>
ISO 8536-3	<i>Infusion equipment for medical use - Part 3: Aluminum caps for infusion bottles</i>
ISO 8536-4	<i>Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed</i>
ISO 8536-5	<i>Infusion equipment for medical use - Part 5: Burette infusion sets for single use, gravity feed</i>
ISO 8536-6	<i>Infusion equipment for medical use - Part 6: Freeze drying closures for infusion bottles</i>
ISO 8536-7	<i>Infusion equipment for medical use - Part 7: Caps made of aluminum-plastics combinations for infusion bottles</i>
ISO 8536-8	<i>Infusion equipment for medical use - Part 8: Infusion sets for single use with pressure infusion equipment</i>
ISO 8536-9	<i>Infusion equipment for medical use - Part 9: Fluid lines for single use with pressure infusion equipment</i>
ISO 8536-10	<i>Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with pressure infusion equipment</i>
ISO 8536-11	<i>Infusion equipment for medical use - Part 11: Infusion filters for single use with pressure infusion equipment</i>
ISO 8536-12	<i>Infusion equipment for medical use - Part 12: Check valves</i>

Fiberboard

TAPPI T807	<i>Bursting Strength of Paperboard and Linerboard</i>
TAPPI T810	<i>Bursting Strength of Corrugated and Solid Fiberboard</i>
TAPPI T811	<i>Edgewise Compressive Strength of Corrugated Fiberboard (short column test)</i>
TAPPI T839	<i>Edgewise Compressive Strength of Corrugated Fiberboard using the Clamp Method</i>

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Levi Loesch, Product and Materials Engineer
Levite.loesch@testedandproven.com
 (952)283-2056

Paper Products	
TAPPI T410	<i>Grammage of paper and paperboard</i>
TAPPI T411	<i>Thickness (Caliper) of Paper, Paperboard and Combined Board</i>
TAPPI T414	<i>Internal Tearing resistance of Paper (Elmendorf)</i>
TAPPI T460	<i>Air Resistance of Paper (Gurley)</i>
TAPPI T494	<i>Tensile Properties of Paper and Paperboard</i>
TAPPI T807	<i>Bursting Strength of Paperboard and Linerboard</i>
ISO 5636-5	<i>Paper and board - Determination of air permeance and air resistance (medium range)</i>
Other	
ASTM D880	<i>Standard Test Method for Impact Testing for Shipping Containers and Systems</i>
ASTM D3332	<i>Standard Test Methods for Mechanical-Shock Fragility of Products, Using Shock Machines</i>
ASTM D3580	<i>Standard Test Methods for Vibration (Vertical Linear Motion) Test of Products</i>
ASTM D5264	<i>Standard Practice for Abrasion Resistance of Printed Materials by the Sutherland Rub Tester</i>
ASTM E96	<i>Standard Test Methods for Water Vapor Transmission of Materials</i>
ASTM F1929	<i>Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration</i>
IEC 60601-2-2	<i>Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories</i>
IEC60529	<i>Degrees of protection provided by enclosures (IP Code)</i>
JIS T3224	<i>Sterile syringe filter</i>
USP Suture Monograph	<i>Suture Length</i>
USP<861>	<i>Suture Diameter</i>
USP<871>	<i>Suture Needle Attachment</i>
USP<881>	<i>Suture Tensile Strength</i>

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