



Medical Product and Packaging Material Testing

Standard	Title
<u>ASTM</u>	
D412	Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers - Tension
D618	Standard Practice for Conditioning Plastics for Testing
D624	Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers
D638	Standard Test Method for Tensile Properties of Plastic
D695	Standard Test Method for Compressive Properties of Rigid Plastics
D790	Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials
D882	Standard Test Method for Tensile Properties of Thin Plastic Sheeting
D903	Standard Test Method for Peel or Stripping Strength of Adhesive Bonds
D1002	Standard Test Method for Apparent Shear Strength of Single-Lap-Joint Adhesively Bonded Metal Specimens by Tension Loading (Metal-to-Metal)
D1004	Standard Test Method for Tear Resistance (Graves Tear) of Plastic Film and Sheeting
D1424	Standard Test Method for Tearing Strength of Fabrics by Falling-Pendulum Type (Elmendorf) Apparatus
D1708	Standard Test Method for Tensile Properties of Plastics by Use of Microtensile Specimens
D1709	Standard Test Method for Impact Resistance of Plastic Film by the Free-Falling Dart Method.
D1876	Standard Test Method for Peel Resistance of Adhesives (T-Peel Test)
D1894	Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting
D1922	Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method
D1938	Standard Test Method for Tear-Propagation Resistance (Trouser Tear) of Plastic Film and Thin Sheeting by a Single-Tear Method
D2463	Standard Test Method for Drop Impact Resistance of Blow-Molded Thermoplastic Containers (Procedure A - Static Drop Height Method, Procedure B - Bruceton Staircase Method)
D2659	Standard Test Method for Column Crush Properties of Blown Thermoplastic Containers
D3163	Standard Test Method for Determining Strength of Adhesively Bonded Rigid Plastic Lap-Shear Joints in Shear by Tension Loading
D3164	Standard Test Method for Strength Properties of Adhesively Bonded Plastic Lap-Shear Sandwich Joints in Shear by Tension Loading
D3330	Standard Test Method for Peel Adhesion of Pressure-Sensitive Tape
D3332	Standard Test Methods for Mechanical-Shock Fragility of Products, Using Shock Machines
D3420	Standard Test Method for Pendulum Impact Resistance of Plastic Film
D3759	Standard Test Method for Breaking Strength and Elongation of Pressure-Sensitive Tape
D3763	Standard Test Method for High Speed Puncture Properties of Plastics Using Load and Displacement Sensors
D5034	Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
D5035	Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Strip Test)
D5264	Standard Practice for Abrasion Resistance of Printed Materials by the Sutherland Rub Tester
D5420	Standard Test Method for Impact Resistance of Flat, Rigid Plastic Specimen by Means of a Striker Impacted by a Falling Weight (Gardner Impact)
D5628	Standard Test Method for Impact Resistance of Flat, Rigid Plastic Specimens by Means of a Falling Dart (Tup or Falling Mass)
D5868	Standard Test Method for Lap Shear Adhesion for Fiber Reinforced Plastic (FRP) Bonding
D6272	Standard Test Method for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials by Four-Point Bending
D6862	Standard Test Method for 90 Degree Peel Resistance of Adhesives
D7192	Standard Test Method for High Speed Puncture Properties of Plastic Films Using Load and Displacement Sensors
E96	Standard Test Methods for Water Vapor Transmission of Materials
F623	Standard Performance Specification for Foley Catheter
F1306	Standard Test Method for Slow Rate Penetration Resistance of Flexible Barrier Films and Laminates
F2051	Standard Specification for Implantable Saline Filled Breast Prosthesis
F2132	Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps
F2878	Standard Test Method for Protective Clothing Material Resistance to Hypodermic Needle Puncture

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Standard	Title
<u>TAPPI</u>	
T 410	Grammage of paper and paperboard
T 411	Thickness (Caliper) of Paper, Paperboard and Combined Board
T 414	Internal Tearing resistance of Paper (Elmendorf)
T 460	Air Resistance of Paper (Gurley)
T 494	Tensile Properties of Paper and Paperboard
T 807	Bursting Strength of Paperboard and Linerboard
T 810	Bursting Strength of Corrugated and Solid Fiberboard
T 811	Edgewise Compressive Strength of Corrugated Fiberboard (short column test)
T 839	Edgewise Compressive Strength of Corrugated Fiberboard using the Clamp Method

Standard	Title
<u>ISO</u>	
37	Rubber, vulcanized or thermoplastic - Determination of tensile stress-strain properties
178	Plastics - Determination of flexural properties
291	Plastics - Standard atmospheres for conditioning and testing
594-1	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
594-2	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
5636-5	Paper and board - Determination of air permeance and air resistance (medium range)
6383-2	Plastics - Film and sheeting - Determination of tear resistance - Part 2: Elmendorf method
7864	Sterile hypodermic needles for single use
7886-1	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use.
7886-2	Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps.
7886-3	Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed-dose immunization.
7886-4	Sterile hypodermic syringes for single use - Part 4: Syringes with re-use prevention feature.
8536-1	Infusion equipment for medical use - Part 1: Infusion glass bottles
8536-2	Infusion equipment for medical use - Part 2: Closures for infusion bottles
8536-3	Infusion equipment for medical use - Part 3: Aluminum caps for infusion bottles
8536-4	Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed
8536-5	Infusion equipment for medical use - Part 5: Burette infusion sets for single use, gravity feed
8536-6	Infusion equipment for medical use - Part 6: Freeze drying closures for infusion bottles
8536-7	Infusion equipment for medical use - Part 7: Caps made of aluminum-plastics combinations for infusion bottles
8536-8	Infusion equipment for medical use - Part 8: Infusion sets for single use with pressure infusion equipment
8536-9	Infusion equipment for medical use - Part 9: Fluid lines for single use with pressure infusion equipment
8536-10	Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with pressure infusion equipment
8536-11	Infusion equipment for medical use - Part 11: Infusion filters for single use with pressure infusion equipment
8536-12	Infusion equipment for medical use - Part 12: Check valves
8537	Sterile single-use syringes, with or without needle, for insulin
9626	Stainless steel needle tubing for manufacture of medical devices
10555-1	Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements
10555-3	Intravascular catheters - Sterile and single-use catheters - Part 3: Central venous catheters
10555-4	Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters
10555-5	Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters
10555-6	Intravascular catheters - Sterile and single-use catheters - Part 6: Subcutaneous implanted ports
11040-4	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling
11040-6	Prefilled syringes - Part 6: Plastic barrels for injectables
11070	Sterile single-use intravascular catheter introducers
11608-1	Needle-based injection systems for medical use - Part 1: Needle-based injection systems
11608-2	Needle-based injection systems for medical use - Part 2: Needles
23908	Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
80369-1	Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
80369-3	Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications
80369-6	Small-bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications
80369-7	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

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Standard	Title
<u>EN</u>	
BS EN 1615	<i>Enteral feeding catheters and enteral giving sets for single use and their connectors - Design and testing</i>
BS EN 1616	<i>Sterile urethral catheters for single use</i>
BS EN 1617	<i>Sterile drainage catheters and accessory devices for single use</i>
BS EN 1618	<i>Catheters other than intravascular catheters - Test methods for common properties</i>
BS EN 1707	<i>Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment. Lock fittings.</i>
BS EN 20594-1	<i>Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment. General requirements.</i>
DIN EN 13868	<i>Test methods for kinking of single lumen catheters and medical tubing</i>

Standard	Title
<u>JIS</u>	
T 3201	<i>Glass syringes</i>
T 3209	<i>Sterile injection needle</i>
T 3214	<i>Urethral catheters</i>
T 3222	<i>Sterile winged intravenous devices</i>
T 3223	<i>Sterile, single-use intravascular catheters over-needle peripheral catheters</i>
T 3224	<i>Sterile syringe filter</i>
T 3228	<i>Biopsy needles for single use</i>

Standard	Title
<u>IEC</u>	
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>

Standard	Title
<u>USP</u>	
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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