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Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products[1]

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1. Scope

1.1 This guide provides directions for the design and evaluation of primary flexible packages for medical products. The package materials must be selected appropriately for manufacturing process, end use, and the product being packaged.

1.2 This guide provides a compendium of test methods, practices, and procedures. Specific individual test methods must be selected based on the pertinent characteristics of the specific product to be packaged and the purpose for testing, research and development, or compliance. Not all test methods will be applicable.

1.3 This guide does not address acceptability criteria, which need to be determined jointly by the package producer and the medical products manufacturer.

1.4 This guide does not assess the product to be packaged or the sterilization method to be used.

1.5 The units cited in the referenced standard should be used.

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D374 Test Methods for Thickness of Solid Electrical Insulation (Metric) D0374_D0374M

D589 Test Method for Opacity of Paper (15° Diffuse Illuminant ***A***, 89 % Reflectance Backing and Paper Backing) (Withdrawn 2010)[3]

D638 Test Method for Tensile Properties of Plastics

D645/D645M Test Method for Thickness of Paper and Paperboard (Withdrawn 2010)[3]

D685 Practice for Conditioning Paper and Paper Products for Testing

D726 Test Method for Resistance of Nonporous Paper to Passage of Air (Withdrawn 2009)[3]

D882 Test Method for Tensile Properties of Thin Plastic Sheeting

D1003 Test Method for Haze and Luminous Transmittance of Transparent Plastics

D1251 Test Method for Water Vapor Permeability of Packages by Cycle Method (Withdrawn 1999)[3]

D1434 Test Method for Determining Gas Permeability Characteristics of Plastic Film and Sheeting

D1709 Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method

D1777 Test Method for Thickness of Textile Materials

D1894 Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting (Withdrawn 2023)[3]

D1922 Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method

D1938 Test Method for Tear-Propagation Resistance (Trouser Tear) of Plastic Film and Thin Sheeting by a Single-Tear Method

D2019 Test Method for Dirt in Paper and Paperboard (Withdrawn 2010)[3]

D2457 Test Method for Specular Gloss of Plastic Films and Solid Plastics

D3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission

D3079 Test Method for Water Vapor Transmission of Flexible Heat-Sealed Packages for Dry Products (Withdrawn 2018)[3]

D3335 Test Method for Low Concentrations of Lead, Cadmium, and Cobalt in Paint by Atomic Absorption Spectroscopy

[1] This guide is under the jurisdiction of ASTM Committee F02 on Primary Barrier Packaging and is the direct responsibility of Subcommittee F02.50 on Package Design and Development.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] The last approved version of this historical standard is referenced on www.astm.org.

D3420 Test Method for Pendulum Impact Resistance of Plastic Film
D3718 Test Method for Low Concentrations of Chromium in Paint by Atomic Absorption Spectroscopy
D3776 Test Methods for Mass Per Unit Area (Weight) of Fabric
D3985 Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using a Coulometric Sensor
D4169 Practice for Performance Testing of Shipping Containers and Systems
D4279 Test Methods for Water Vapor Transmission of Shipping Containers—Constant and Cycle Methods
D4321 Test Method for Package Yield of Plastic Film
D4332 Practice for Conditioning Containers, Packages, or Packaging Components for Testing
D4754 Test Method for Two-Sided Liquid Extraction of Plastic Materials Using FDA Migration Cell
D5264 Practice for Abrasion Resistance of Printed Materials by the Sutherland Rub Tester
D7386 Practice for Performance Testing of Packages for Single Parcel Delivery Systems
E167 Practice for Goniophotometry of Objects and Materials (Withdrawn 2005)[3]
E171/E171M Practice for Conditioning and Testing Flexible Barrier Packaging
E398 Test Method for Water Vapor Transmission Rate of Sheet Materials Using Dynamic Relative Humidity Measurement
F17 Terminology Relating to Primary Barrier Packaging
F88 Test Method for Seal Strength of Flexible Barrier Materials
F99 Guide for Writing a Specification for Flexible Barrier Rollstock Materials
F151 Test Method for Residual Solvents in Flexible Barrier Materials (Withdrawn 2004)[3]
F372 Test Method for Water Vapor Transmission Rate of Flexible Barrier Materials Using an Infrared Detection Technique (Withdrawn 2009)[3]
F392 Practice for Conditioning Flexible Barrier Materials for Flex Durability
F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices
F813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices
F895 Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity
F904 Practice for Separation of Plies for Bond Strength of Laminated Flexible Materials
F1140 Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
F1249 Test Method for Water Vapor Transmission Rate Through Plastic Film and Sheeting Using a Modulated Infrared Sensor
F1306 Test Method for Slow Rate Penetration Resistance of Flexible Barrier Films and Laminates
F1307 Test Method for Oxygen Transmission Rate Through Dry Packages Using a Coulometric Sensor
F1608 Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)
F1884 Test Methods for Determining Residual Solvents in Packaging Materials
F1886 Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
F1921 Test Methods for Hot Seal Strength (Hot Tack) of Thermoplastic Polymers and Blends Comprising the Sealing Surfaces of Flexible Webs
F1927 Test Method for Determination of Oxygen Gas Transmission Rate, Permeability and Permeance at Controlled Relative Humidity Through Barrier Materials Using a Coulometric Detector
F1929 Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
F1980 Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
F2029 Practices for Making Laboratory Heat Seals for Determination of Heat Sealability of Flexible Barrier Materials as Measured by Seal Strength
F2054 Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates
F2095 Test Methods for Pressure Decay Leak Test for Flexible Packages With and Without Restraining Plates
F2096 Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
F2203 Test Method for Linear Measurement Using Precision Steel Rule
F2217 Practice for Coating/Adhesive Weight Determination
F2227 Test Method for Non-Destructive Detection of Leaks in Non-sealed and Empty Packaging Trays by CO_2 Tracer Gas Method
F2228 Test Method for Non-Destructive Detection of Leaks in Packaging Which Incorporates Porous Barrier Material by CO_2 Tracer Gas Method
F2250 Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials
F2251 Test Method for Thickness Measurement of Flexible Packaging Material
F2252 Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape
F2338 Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method
F2391 Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas
F2475 Guide for Biocompatibility Evaluation of Medical Device Packaging Materials
F2476 Test Method for the Determination of Carbon Dioxide Gas Transmission Rate (CO_2TR) Through Barrier Materials Using an Infrared Detector
F2559 Guide for Writing a Specification for Sterilizable Peel Pouches
F2622 Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using Various Sensors