



Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products¹

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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.

2. Referenced Documents

2.1 *ASTM Standards:*²

D374 Test Methods for Thickness of Solid Electrical Insulation (Withdrawn 2013)³

D589 Test Method for Opacity of Paper (15° Diffuse Illuminant A, 89 % Reflectance Backing and Paper Backing) (Withdrawn 2010)³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D645/D645M Test Method for Thickness of Paper and Paperboard (Withdrawn 2010)³

D726 Test Method for Resistance of Nonporous Paper to Passage of Air (Withdrawn 2009)³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

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

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D2019 Test Method for Dirt in Paper and Paperboard (Withdrawn 2010)³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

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

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

¹ This guide is under the jurisdiction of ASTM Committee F02 on Flexible 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.