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

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1. Scope

1.1 This guide provides directions for the design and evaluation of primary 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. 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; the sterilization method to be used; or package performance through sterilization, distribution, and handling.

2. Referenced Documents

2.1 *ASTM Standards:*

D 374 Test Methods for Thickness of Solid Electrical Insulation[2]

D 589 Test Method for Opacity of Paper (15 % Diffuse Illuminant A, 89 % Reflectance Backing and Paper Backing)[3]

D 645/D 645M Test Method for Thickness of Paper and Paperboard[3]

D 726 Test Methods for Resistance of Nonporous Paper to Passage of Air[3]

D 882 Test Methods for Tensile Properties of Thin Plastic Sheeting[4]

D 1003 Test Method for Haze and Luminous Transmittance of Transparent Plastics (Gardner)[4]

D 1709 Test Methods for Impact Resistance of Plastic Film by Free-Falling Dart Method[4]

D 1777 Test Method for Thickness of Textile Materials[5]

D 1894 Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting[4]

D 1922 Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method[4]

D 1938 Test Method for Tear Propagation Resistance of Plastic Film and Thin Sheeting by a Single Tear Method[4]

D 2019 Test Method for Dirt in Paper and Paperboard[3]

D 2457 Test Method for Specular Gloss of Plastic Film and Solid Plastics[6]

D 3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission[3]

D 3335 Test Method for Low Concentrations of Lead, Cadmium, and Cobalt in Paint by Atomic Absorption Spectroscopy[7]

D 3420 Test Method for Dynamic Ball Burst Pendulum Impact Resistance of Plastic Film[6]

D 3718 Test Method for Low Concentrations of Chromium in Paint by Atomic Absorption Spectroscopy[7]

D 3776 Test Methods for Mass per Unit Area (Weight) of Woven Fabric[8]

D 3985 Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using a Columetric Sensor[3]

D 4279 Test Methods for Water Vapor Transmission of Shipping Containers—Constant and Cycle Methods[3]

D 4321 Test Method for Package Yield of Plastic Film[6]

D 4754 Test Method for Two-Sided Liquid Extraction of Plastic Materials Using FDA Migration Cell[9]

D 5264 Practice for Abrasion Resistance of Printed Materials by the Sutherland Rub Tester[3]

F 88 Test Method for Seal Strength of Flexible Barrier Materials[3]

F 151 Test Method for Residual Solvents in Flexible Barrier Materials[3]

F 372 Test Method for Water Vapor Transmission Rate of Flexible Barrier Materials Using an Infrared Detection Technique[3]

F 392 Test Method for Flex Durability of Flexible Barrier Materials[3]

[1] This guide is under the jurisdiction of ASTM Committee F02 on Flexible Barrier Materials and is the direct responsibility of Subcommittee F02.60 on Medical Packaging.

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[2] *Annual Book of ASTM Standards*, Vol 10.01.

[3] *Annual Book of ASTM Standards*, Vol 15.09.

[4] *Annual Book of ASTM Standards*, Vol 08.01.

[5] *Annual Book of ASTM Standards*, Vol 07.01.

[6] *Annual Book of ASTM Standards*, Vol 08.02.

[7] *Annual Book of ASTM Standards*, Vol 06.01.

[8] *Annual Book of ASTM Standards*, Vol 07.02.

[9] *Annual Book of ASTM Standards*, Vol 08.03.

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