



Standard Guide for Evaluation of Thermoplastic Polyurethane Solids and Solutions for Biomedical Applications¹

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1. Scope

1.1 This guide covers the evaluation of thermoplastic polyurethanes in both solid and solution form for biomedical applications. The polymers have been reacted to completion and require no further chemical processing.

1.2 The tests and methods listed in this guide may be referenced in specification containing minimum required values and tolerances for specific end use products.

1.3 Test values shall be stated in SI units with inch-pound units in parentheses.

1.4 Standard tests for biocompatibility are included to aid in the assessment of safe utilization in biomedical applications. Compliance with these criteria shall not be constructed as an endorsement of implantability. Since many compositions, formulations, and forms of thermoplastic polyurethanes in solid and solution forms are within this material class, the formulator or fabricator must evaluate the biocompatibility of the specific composition or form in the intended use and after completion of all manufacturing processes including sterilization.

1.5 Purchase specifications may be prepared by agreement between the buyer and seller by selection of appropriate tests and methods from those listed applicable to the specific biomedical end use.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:

D 149 Test Method for Dielectric Breakdown Voltage and Dielectric Strength of Solid Electrical Insulating Materials at Commercial Power Frequencies²

D 150 Test Methods for A-C Loss Characteristics and Permittivity (Dielectric Constant) of Solid Electrical Insulating Materials²

D 257 Test Methods for D-C Resistance or Conductance of Insulating Materials²

D 395 Test Methods for Rubber Property—Compression Set³

D 412 Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers-Tension³

D 570 Test Method for Water Absorption of Plastics⁴

D 575 Test Methods for Rubber Properties in Compression³

D 671 Test Method for Flexural Fatigue of Plastics by Constant-Amplitude-of-Force⁴

D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials⁴

D 792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement⁴

D 1238 Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer⁴

D 1242 Test Methods for Resistance of Plastic Materials to Abrasion⁴

D 1434 Test Method for Determining Gas Permeability Characteristics of Plastic Film and Sheet⁵

D 1544 Test Method for Color of Transparent Liquids (Gardner Color Scale)⁶

D 1638 Methods of Testing Urethane Foam Isocyanate Raw Materials⁷

D 2124 Test Method for Analysis of Components in Poly-(Vinyl Chloride) Compounds Using an Infrared Spectrophotometric Technique⁸

D 2240 Test Method for Rubber Property—Durometer Hardness³

D 2857 Test Method for Dilute Solution Viscosity of Polymers⁹

D 2990 Test Methods for Tensile, Compressive, and Flexural Creep and Creep Rupture of Plastics⁹

D 3137 Test Method for Rubber Property—Hydrolytic Stability³

¹ This guide is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.11 on Polymeric Materials.

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² Annual Book of ASTM Standards, Vol 10.02.

³ Annual Book of ASTM Standards, Vol 09.01.

⁴ Annual Book of ASTM Standards, Vol 08.01.

⁵ Annual Book of ASTM Standards, Vol 15.09.

⁶ Annual Book of ASTM Standards, Vol 06.01.

⁷ Annual Book of ASTM Standards, Vol 06.03.

⁸ Annual Book of ASTM Standards, Vol 08.01.

⁹ Annual Book of ASTM Standards, Vol 08.02.