



Designation: F997 – 98a (Reapproved 2003)

Standard Specification for Polycarbonate Resin for Medical Applications¹

This standard is issued under the fixed designation F997; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers polycarbonate resin and provides requirements and associated test methods for this thermoplastic when it is to be used in the manufacture of medical devices or components of medical devices.

1.2 As with any material, some characteristics may be altered by the processing techniques (such as molding, extrusion, machining, assembly, sterilization, and so forth) required for the production of a specific part or device. Therefore, properties of fabricated forms of this resin should be evaluated using those test methods that are appropriate to assure safety and efficacy.

1.3 The properties included in this specification are those applicable for polycarbonate only. The biocompatibility of plastic compounds made up of polycarbonate resin containing colorants, fillers, processing aids, or other additives, as well as polymer blends which contain polycarbonate, should not be assumed. The biocompatibility of these modified polycarbonates must be established by testing the final (end-use) compositions using the appropriate methods of evaluation. In addition, the biocompatibility of the material depends to a large degree on the nature of the end-use application. It is, therefore, necessary to specify a set of biocompatibility test methods for each new and distinct application.

1.4 *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:*²

D256 Test Methods for Determining the Izod Pendulum Impact Resistance of Plastics

D570 Test Method for Water Absorption of Plastics

D638 Test Method for Tensile Properties of Plastics

D648 Test Method for Deflection Temperature of Plastics Under Flexural Load in the Edgewise Position

D790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials

D792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement

D883 Terminology Relating to Plastics

D955 Test Method of Measuring Shrinkage from Mold Dimensions of Thermoplastics

D1003 Test Method for Haze and Luminous Transmittance of Transparent Plastics

D1238 Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer

D1600 Terminology for Abbreviated Terms Relating to Plastics

D1898 Practice for Sampling of Plastics

D3892 Practice for Packaging/Packing of Plastics

D3935 Specification for Polycarbonate (PC) Unfilled and Reinforced Material

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

2.2 *Underwriter's Laboratories Document:*

UL Standard 94 Tests and Flammability of Plastic Materials for Parts in Devices and Appliances³

2.3 *Code of Federal Regulations:*

Title 21 CFR Subpart 177.1580⁴

3. Significance and Use

3.1 This specification is designed to recommend physical, chemical, and biological test methods to establish a reasonable level of confidence concerning the performance of unfilled polycarbonate resins for use in medical devices. The properties listed should be considered in selecting material according to the specific end-use requirements.

4. Classification

4.1 Types of polycarbonate plastics, molding, and extrusion grades are described in Specification **D3935**.

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

Current edition approved Apr. 10, 2003. Published May 2003. Originally approved in 1986. Last previous edition approved in 1998 as F997 – 98a^{ε1}. DOI: 10.1520/F0997-98AR03.

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 Available from Underwriter's Laboratories, Publication Stock, 333 Pfingsten Rd., Northbrook, IL 60062.

⁴ Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.