



Designation: F997 – 10

Standard Specification for Polycarbonate Resin for Medical Applications¹

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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](#)

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.

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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.

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 \(Withdrawn 1998\)](#)³

[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 Appliances](#)⁴

2.3 *Code of Federal Regulations:*

[Title 21 CFR Subpart 177.1580](#)⁵

2.4 *ISO Standard:*

[ISO 10993 Biological Evaluation of Medical Devices](#)⁶

3. Significance and Use

3.1 This specification is designed to recommend physical, chemical, and biological test methods to establish a reasonable

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

⁴ Available from Underwriters Laboratories (UL), 333 Pfingsten Rd., Northbrook, IL 60062-2096, <http://www.ul.com>.

⁵ Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

⁶ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.