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Standard Specification for Polycarbonate Resin for Medical Applications¹

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^{ε1} NOTE—Editorial corrections were made to 2.3 and 6.1 in May 2001.

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:

- D 256 Test Methods for Impact Resistance of Plastics and Electrical Insulating Materials²
- D 570 Test Method for Water Absorption of Plastics²
- D 638 Test Method for Tensile Properties of Plastics²
- D 648 Test Method for Deflection Temperature of Plastics

Under Flexural Load²

- D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials²
 - D 792 Test Methods for Specific Gravity (Relative Density) and Density of Plastics by Displacement²
 - D 883 Terminology Relating to Plastics²
 - D 955 Test Method of Measuring Shrinkage From Mold Dimensions of Molded Plastics²
 - D 1003 Test Method for Haze and Luminous Transmittance of Transparent Plastics²
 - D 1238 Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer²
 - D 1600 Terminology for Abbreviated Terms Relating to Plastics²
 - D 1898 Practice for Sampling of Plastics²
 - D 3892 Practice for Packaging/Packing of Plastics³
 - D 3935 Specification for Polycarbonate (PC) Unfilled and Reinforced Materials³
 - F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices⁴
- #### 2.2 Underwriter's Laboratories Document:
- UL Standard 94 Tests and Flammability of Plastic Materials for Parts in Devices and Appliances⁵
- #### 2.3 Code of Federal Regulations:
- Title 21 CFR Subpart 177.1580⁶

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 D 3935.

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 *Annual Book of ASTM Standards*, Vol 08.01.

³ *Annual Book of ASTM Standards*, Vol 08.02.

⁴ *Annual Book of ASTM Standards*, Vol 13.01.

⁵ Available from Underwriter's Laboratories, Publication Stock, 333 Pfingsten Rd., Northbrook, IL 60062.

⁶ Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.