Designation: D7198 – 05 (Reapproved 2012)

Standard Specification for Disposable Embalming Gloves for Single-Use Applications[1]

This standard is issued under the fixed designation D7198; 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 certain requirements for natural rubber (Latex), synthetic rubber (Polychloroprene and Nitrile), and vinyl (PVC) disposable gloves for use in conducting single-use embalming procedures.

1.2 This specification covers natural rubber (Latex), synthetic rubber (Polychloroprene and Nitrile), and Vinyl (PVC) disposable gloves that fit either hand, paired gloves, gloves by size, and gloves packed in bulk.

1.3 An assessment to measure the chemical resistance performance of the glove can be made based on the ultimate permeation (breakthrough) of embalming chemicals through the glove material over a specified period of time.

1.4 This specification is similar to the following specifications: D3578, D4679, D5250, D6319, and D6977.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

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:*[2]

D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

D573 Test Method for Rubber—Deterioration in an Air Oven

D3578 Specification for Rubber Examination Gloves

D3767 Practice for Rubber—Measurement of Dimensions

D4679 Specification for Rubber General Purpose, Household or Beautician Gloves

D5151 Test Method for Detection of Holes in Medical Gloves

D5250 Specification for Poly(vinyl chloride) Gloves for Medical Application

D5712 Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method

D6124 Test Method for Residual Powder on Medical Gloves

D6319 Specification for Nitrile Examination Gloves for Medical Application

D6499 Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products

D6977 Specification for Polychloroprene Examination Gloves for Medical Application

F739 Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact

2.2 *ISO Standard:*

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes[3]

2.3 *Other Document:*

U.S. Pharmacopeia[4]

3. Significance and Use

3.1 This specification is intended to be a specification for evaluating the performance and quality of disposable natural rubber, synthetic rubber, and vinyl (PVC) gloves for single-use embalming applications.

3.2 The safe and proper use of disposable natural rubber, synthetic rubber (polychloroprene and nitrile), and vinyl gloves is beyond the scope of this specification.

3.3 The chemical permeation tests described in this specification are intended to be "Type Tests" for these types of gloves.

3.3.1 The chemical permeation tests are not intended to be testing instructions nor testing protocols to be used for routine lot release.

[1] This specification is under the jurisdiction of ASTM Committee D11 on Rubber and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

Current edition approved Dec. 1, 2012. Published February 2013. Originally approved in 2005. Last previous edition approved in 2005 as D7198 – 05. DOI: 10.1520/D7198-05R12.

[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 American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

[4] *U. S. Pharmacopeia*, latest edition, Mack Publishing Co., Easton, PA 19175.

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4. Materials and Manufacture

4.1 Any natural rubber, synthetic rubber, and plastic polymer compound may be used that permits the glove to meet the requirements of this specification.

4.2 A lubricant that meets the current requirements of the U.S. Pharmacopoeia for absorbable dusting powder may be applied to the glove. Other lubricants may be used if their safety and efficacy have been previously established.

4.3 The inside and outside surface of the natural rubber, synthetic rubber, and plastic disposable gloves shall be free of talc.

5. Sampling

5.1 For referee purposes, gloves shall be sampled from finished product and inspected in accordance with ISO 2859. The inspection levels and acceptable quality levels (AQL) shall conform to those specified in Table 1, or as agreed upon between the purchaser and the seller, if the latter is more comprehensive.

6. Performance Requirements

6.1 Gloves shall be sampled in accordance with Section 5.

6.2 Gloves shall meet the referee performance requirements as described in Table 1.

6.2.1 Shall comply with freedom from holes when tested in accordance with 7.2.

6.2.2 Have consistent physical dimensions in accordance with 7.3.

6.2.3 Have acceptable physical property characteristics in accordance with 7.4.

6.2.4 Powder-free gloves shall have a recommended maximum powder residue limit of 2.0 mg per glove in accordance with 7.5 and A2.1.

6.2.5 Powdered gloves shall have a recommended maximum powder limit of 10 mg/dm^2 in accordance with 7.6 and A2.2.

TABLE 1 Quality Performance and Barrier Property Requirements: Natural Rubber (Latex), Synthetic Rubber (Polychloroprene and Nitrile), and Vinyl (PVC)

Characteristic	Related Defects	Inspection Level	AQL
Freedom from holes	holes	G-1	2.5
Dimensions	width, length, thickness	S-2	4.0
Physical properties	before aging, after accelerated aging	S-2	4.0
Powder-free residue	exceeds recommended maximum limit per Annex A2.1	N=5	N/A
Powder amount	exceeds recommended maximum limit per Annex A2.2	N=2	N/A
Protein content (Latex only)	exceeds recommended maximum limit per Annex A1	N=3	N/A
Antigenic protein (Latex only)	exceeds recommended maximum limit per Annex A3	N=1	N/A
Permeation	steady-state is reached maximum rate is reached permeation at increased rate	N=3	N/A

6.2.6 Have a recommended aqueous soluble protein content limit of 200 µg/dm^2 in accordance with 7.7 and Annex A1 or have a recommended antigenic protein content limit of 10 µg/dm^2 in accordance with 7.8 and Annex A3.

7. Test Methods

7.1 The following tests shall be conducted to ensure the requirements of Section 8 are met, as prescribed in Table 1.

7.2 *Freedom from Holes*—Testing for freedom from holes shall be conducted in accordance with Test Method D5151.

7.3 *Physical Dimensions Test:*

7.3.1 The gloves shall comply with the dimension requirements prescribed in Tables 2-4.

7.3.2 The length shall be expressed in millimeters as measured from the outside tip of the middle finger to the outside edge of the cuff.

7.3.3 The width of the palm shall be expressed in millimeters as measured at a level between the base of the index finger and the base of the thumb. Values of width per size other than listed shall meet the stated tolerance specified in Tables 2-4.

7.3.4 The minimum finger, palm, and cuff thicknesses shall be expressed in millimeters as specified in Tables 2-4 when using a dial or digital micrometer that meets requirements described in Test Methods D412 and Practice D3767, and in the locations indicated in Fig. 1. For referee tests, cutting the glove is necessary to obtain single-wall thickness measurements. (See Practice D3767 for more information.)

7.4 *Physical Requirements Test:*

7.4.1 Before and after accelerated aging, the gloves shall conform to the physical requirements specified in Tables 5-9. Tests shall be conducted in accordance with Test Methods D412.

7.4.2 *Accelerated Aging*—The gloves shall be aged in accordance with Test Method D573. Test the gloves in accordance with the following methods:

7.4.3 After being subjected to a temperature of 70 ± 2°C for 166 ± 2 h, the tensile strength and ultimate elongation shall not be less than the values specified in Tables 5-9. This method shall be the conditions for referee tests.

7.4.4 Or, after being subjected to a temperature of 100 ± 2°C for 22 ± 0.3 h (if validated by manufacturer), the tensile strength and ultimate elongation shall not be less than the values specified in Tables 5-9.

7.5 *Powder Free Gloves:*

7.5.1 Determine the powder residue for powder-free gloves using Test Method D6124.

7.5.2 The powder residue shall not exceed the recommended average powder mass referenced in A2.1 when tested in accordance with Test Method D6124 for powder-free gloves.

7.6 *Powdered Gloves:*

7.6.1 Determine the powder amount for powdered gloves using Test Method D6124.

7.6.2 The powder amount shall not exceed the recommended average powder mass referenced in A2.2 when tested in accordance with Test Method D6124 for powdered gloves.

7.6.3 Determine the square decimeters for the glove size as described in section 7.7.3 or 7.7.3.1.

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