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Standard Specification for Polychloroprene Examination Gloves for Medical Application[1]

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1. Scope

1.1 This specification provides certain requirements for polychloroprene rubber gloves used in conducting medical examinations and diagnostic and therapeutic procedures.

1.2 This specification covers polychloroprene rubber examination gloves that fit either hand, paired gloves, and gloves by size. It also provides for packaged sterile or non-sterile or bulk non-sterile polychloroprene rubber examination gloves.

1.3 This specification is similar to that of D3578 Standard Specification for Rubber Examination Gloves, and D6319 Standard Specification for Nitrile Examination Gloves for Medical Applications.

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

D5151 Test Method for Detection of Holes in Medical Gloves

D6124 Test Method for Residual Powder on Medical Gloves

D6319 Specification for Nitrile Examination Gloves for Medical Application

D6355 Test Method for Human Repeat Insult Patch Testing of Medical Gloves

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 as a referee procedure for evaluating the performance and safety of polychloroprene rubber examination gloves. It is not intended for testing prior to routine lot release. The safe and proper use of polychloroprene rubber examination gloves is beyond the scope of this specification.

4. Material

4.1 Any polychloroprene rubber compound that produces examination gloves that meet the requirements of this specification are allowed.

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 polychloroprene rubber examination gloves shall be free of talc.

5. Performance Requirements

5.1 Gloves, sampled in accordance with Section 6, shall meet the following referee performance requirements:

5.1.1 Products comply with requirements for sterility when tested in accordance with 7.2 when labeled sterile,

5.1.2 Shall comply with freedom from holes when tested in accordance with 7.3,

5.1.3 Have consistent physical dimensions in accordance with 7.4,

5.1.4 Have acceptable physical property characteristics in accordance with 7.5,

5.1.5 Have a powder residue limit in accordance with 7.6, and

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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.

[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.

5.1.6 Have a recommended maximum powder limit in accordance with 7.7.

6. Sampling

6.1 For referee purposes, gloves shall be sampled from finished product, after sterilization when labeled sterile, 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.

7. Referee Test Methods

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

7.2 *Sterility Test*—Testing for sterility shall be conducted in accordance with the latest edition of the *U.S. Pharmacopeia*.

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

7.4 *Physical Dimensions Test:*

7.4.1 The gloves shall comply with the dimension requirements prescribed in Table 2.

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

7.4.3 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 Table 2.

7.4.4 The minimum thickness shall be expressed in millimeters as specified in Table 2 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-thickness measurements. (See Practice D3767 for more information.)

7.5 *Physical Requirements Test:*

7.5.1 Before and after accelerated aging, the gloves shall conform to the physical requirements specified in Table 3. Tests shall be conducted in accordance with Test Methods D412. Die C is recommended.

7.5.2 *Accelerated Aging*—The gloves shall be aged in accordance with Test Method D573. Test the gloves by either one of the following methods:

TABLE 1 Performance Requirements

Characteristic	Related Defects	Inspection Level	AQL
Sterility	fails sterility	[A]	N/A
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 maximum limit	N=5	N/A
Powder Amount	exceeds recommended maximum limit	N=2	N/A

[A] See *U.S. Pharmacopeia*.

7.5.2.1 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 Table 3. This method shall be the conditions for referee tests.

7.5.2.2 After being subjected to a temperature of 100 ± 2°C for 22 ± 0.3 h, the tensile strength and ultimate elongation shall not be less than the values specified in Table 3.

7.6 *Powder Free Gloves*—The powder residue shall not exceed the average powder mass in A1.1 when tested in accordance with Test Method D6124.

7.7 *Powdered Gloves:*

7.7.1 The amount of powder shall not exceed the recommended average powder mass limit in A1.2 when tested in accordance with Test Method D6124 for powdered gloves.

7.7.2 Determine the square decimeters for the glove size as in section 8.7.3 of Specification D3578.

8. Acceptance

8.1 Gloves will be considered to meet the referee performance requirements when test results conform to the requirements prescribed in Table 1.

8.2 Retests or reinspections are permissible under the provision of the *U.S. Pharmacopeia* and ISO 2859.

9. Package Marking

9.1 *Sterile Packaging:*

9.1.1 The unit of packaging shall normally be one glove or one pair of gloves.

9.1.2 A glove or pair of gloves, normally, shall be enclosed in an inner wallet or wrapper. The wrapper shall be of sufficient size when opened to provide a field for glove-donning purposes.

9.1.3 The glove or pair of gloves, and accompanying wrapper if utilized, shall be totally enclosed in an outer package that will allow sterilization of the product.

9.1.4 The outer package shall have a method of closure sufficient to ensure the sterility of the product until opened or damaged.

9.1.5 The outer package shall have sufficient strength and integrity to withstand normal transportation and storage within the intermediate or shipping cartons, or both.

9.1.6 The method of closure of the outer package shall be such that prior opening will be detectable by the user.

9.1.7 None of the packaging material shall contain any material likely to impair the quality and use of the gloves.

9.1.8 Intermediate cartons and shipping cases shall be of sufficient strength to maintain the quality and sterility of the product during normal transportation and storage.

9.2 *Non-sterile and Bulk Packaging:*

9.2.1 The gloves shall be enclosed in an outer package that has sufficient strength to withstand normal transportation and storage within the cartons or shipping cases, or both.

9.2.2 None of the packaging material shall contain any material likely to impair the quality and use of the gloves.

9.2.3 Cartons and shipping cases shall be of sufficient strength to maintain the quality of the product during normal transportation and storage.

TABLE 2 Dimensions and Tolerances

Designation	Size							
	6	6½	7	7½	8	8½	9	Tolerance, mm
Width by size	75	83	89	95	102	108	114	± 6
Width by	X-Small	Small	Unisize	Medium	Large	X-large	XX-large	± 10
	70	80	85	95	110	120	130	
Length	220	220	230	230	230	230	230	minimum
Thickness, mm:								
Finger, 0.05 min								
Palm, 0.05 min								
Cuff, 0.05 min								

NOTE 1—Sizing that falls within the tolerance overlaps between two sizes may be labeled as a size range including both sizes; for example, small/medium and medium/large.

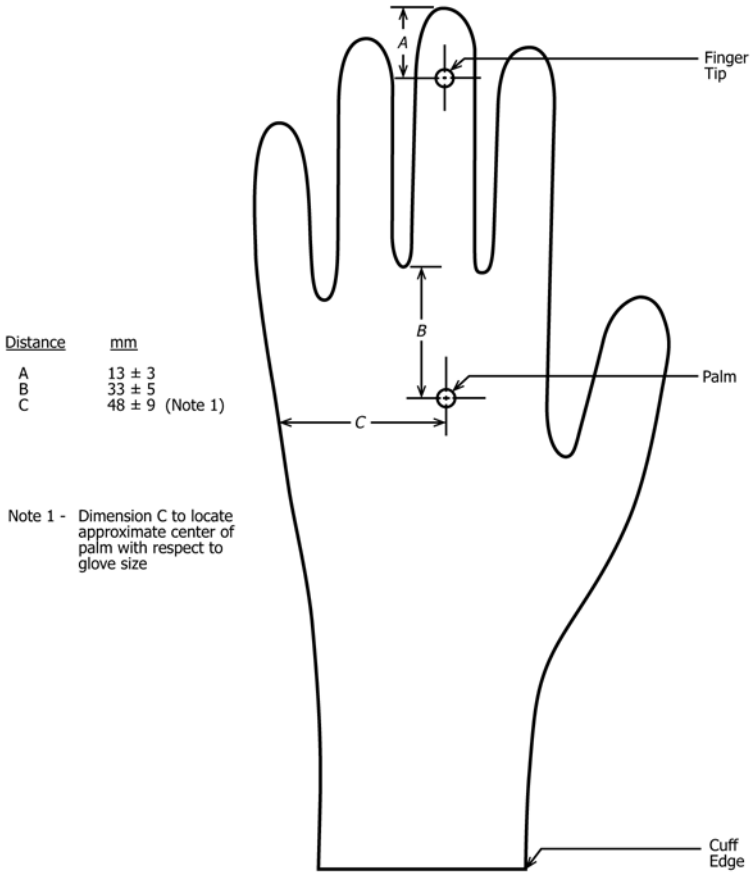

FIG. 1 Location of Thickness and Length Measurements

TABLE 3 Physical Requirements

Before Aging		After Accelerated Aging	
Tensile Strength	Ultimate Elongation	Tensile Strength	Ultimate Elongation
14 MPa min	500 % min	14 MPa min	400 % min

9.3 *Package Marking:*

9.3.1 Sterile packages shall bear markings for the contents to include the glove size, instructions for opening, the legend "sterile" and a manufacturing lot number.

9.3.2 Non-sterile and bulk packages shall bear markings for the contents to include the glove size and manufacturing lot number.

9.3.3 The outermost case shall be labeled with the glove size and a manufacturing lot number. Sterile product cases shall also be marked with the legend "sterile."

9.3.4 All levels of packaging shall conform to all appropriate government labeling regulations.

10. Keywords

10.1 examination gloves; polychloroprene; rubber; synthetic rubber; single-use

ANNEX

(Mandatory Information)

A1.

A1.1 Powder Residue Limit for Powder-free Gloves

A1.1.1 *Average Powder Mass Limit*—The recommended limit is not more than 2 mg per glove.

A1.2 Powder Amount Limit for Powdered Gloves

A1.2.1 *Average Powder Mass Limit*—The recommended limit is not more than 10 mg per square decimeter.