Designation: D5250 – 19

Standard Specification for Poly(vinyl chloride) Gloves for Medical Application[1]

This standard is issued under the fixed designation D5250; 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 poly(vinyl chloride) gloves used in conducting medical examinations and diagnostic and therapeutic procedures. It also covers poly(vinyl chloride) gloves used in handling contaminated medical material.

1.2 This specification provides for poly(vinyl chloride) gloves that fit either hand, paired gloves, and gloves by size. It also provides for packaged sterile or nonsterile or bulk nonsterile poly(vinyl chloride) gloves.

1.3 This specification does not cover two-dimensional heat sealed poly(vinyl chloride) gloves.

1.4 This specification is similar to that of Specification D3578 for rubber examination gloves.

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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

2.2 *Other Document:*

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

U. S. Pharmacopeia[4]

3. Materials

3.1 Any poly(vinyl chloride) polymer compound may be used that permits the glove to meet the requirements of this standard.

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

3.3 The inside and outside surface of the poly(vinyl chloride) examination gloves shall be free of talc.

4. Significance and Use

4.1 The specification is intended as a referee procedure for evaluating the performance and safety of poly(vinyl chloride) examination gloves. The safe and proper use of poly(vinyl chloride) examination gloves is beyond the scope of this standard.

5. Sampling

5.1 For referee purposes, gloves shall be sampled from finished product, after sterilization, 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 seller, if the latter is more comprehensive.

6. Performance Requirements

6.1 Gloves, sampled in accordance with Section 5, shall meet the following referee performance requirements:

6.1.1 Comply with requirements for sterility when tested in accordance with 7.2.

6.1.2 Be free from holes when tested in accordance with 7.3.

6.1.3 Have consistent physical dimensions in accordance with 7.4.

[1] This specification is under the jurisdiction of D11 on Rubber and Rubber-like Materials and is the direct responsibility of D11.40 on Consumer Rubber Products.

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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, 25 W. 43rd St., 4th Floor, New York, NY 10036.

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

TABLE 1 Performance Requirements

Characteristic	Related Defects	Inspection Level	Acceptable Quality Levels
Sterility	falls sterility	[A]	N/A
Freedom from holes	holes	I	2.5
Dimensions	width, length, and thickness	S-2	4.0
Physical requirements	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.

6.1.4 Have acceptable physical property characteristics in accordance with 7.5.

6.1.5 Have a powder residue limit of 2.0 mg in accordance with 7.6.

6.1.6 Have a recommended maximum powder limit of 10 mg/dm^2 in accordance with 7.7.

7. Referee Test Methods

7.1 The following tests shall be conducted to ensure the requirements of Section 6, 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 millimetres as measured from the tip of the second finger to the outside edge of the cuff.

7.4.3 The width of the palm shall be expressed in millimetres 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 millimetres as specified in Table 2 when using a dial micrometer described in Test Methods D412, and in the locations indicated in Fig. 1. To avoid cutting the glove, single wall thickness may be determined by measuring the double wall thickness and taking the single wall thickness as one half of the measured double wall thickness. (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 as specified in Test Methods D412. Die C is recommended.

7.5.2 Accelerated aging tests shall be conducted on samples cut from the glove in accordance with Test Method D573 by exposing the glove to 70 ± 2°C for 72 ± 2 h. The glove shall withstand these conditions without evidence of tackiness, exudation, or other deterioration.

7.5.3 For gloves that are older than 6 months from the date of manufacture or for which the date of manufacture cannot be determined, no accelerated aging shall be performed.

7.6 *Powder Free Gloves*—Determine the powder residue using Test Method D6124.

7.7 *Powdered Gloves:*

7.7.1 Determine the recommended maximum powder limit using Test Method D6124 for powdered gloves.

7.7.2 Determine the square decimetres for the glove size as in 8.7.3 in Specificiation 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 provisions of the U.S. Pharmacopeia and ISO 2859.

9. Packaging and 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, 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.

TABLE 2 Dimensions and Tolerances

Designation	Size							Tolerance, mm
	6	6.5	7	7.5	8	8.5	9	
Width by size, mm	76	83	89	95	102	108	114	6
Width by small, medium, large, and extra large, mm	small		medium		large		x-large	5
	85		95		105		115	
Length, mm				230 for all sizes				min
Thickness, mm				For All Sizes				
Finger				0.08				min
Palm				0.08				min