Designation: D 5250 – 00ε4

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

This standard is issued under the fixed designation D 5250; 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.

ε[1] NOTE—Dates in A2.1.1 were revised editorially in September 2001.
ε[2] NOTE—Table titles and references were revised editorially in February 2002.
ε[3] NOTE—Both annexes were deleted and the information was included in the Performance Requirements section editorially in March 2002.
ε[4] NOTE—Sections 6.1.5 and 6.1.6 were revised editorially to correct measurement units in April 2002.

1. Scope

1.1 This specification provides 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 D 3578 for rubber examination gloves.

2. Referenced Documents

2.1 *ASTM Standards:*

D 412 Test Method for Vulcanized Rubbers and Thermoplastic Rubbers and Thermoplastic Elastomers—Tension[2]

D 573 Test Method for Rubber—Deterioration in an Air Oven[2]

D 3578 Specification for Rubber Examination Gloves[3]

D 3767 Practice for Rubber—Measurement of Dimensions[2]

D 5151 Test Method for Detection of Holes in Medical Gloves[3]

D 6124 Test Method for Residual Powder on Medical Gloves[3]

2.2 *Other Document:*

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes[4]

U. S. Pharmacopeia[5]

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. It is not intended for testing prior to routine lot release. 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 Committee D11 on Rubber and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

Current edition approved Jan. 10, 2000. Published February 2000. Originally published as D 5250-92. Last previous edition D 5250-99ε1.

[2] *Annual Book of ASTM Standards*, Vol 09.01.

[3] *Annual Book of ASTM Standards*, Vol 09.02.

[4] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

[5] 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 D 5151.

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 D 412, and in the locations indicated in Fig. 1. For referee tests, cutting the glove is necessary to obtain single-thickness measurements. (See Practice D 3767 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 D 412.

7.5.2 Accelerated aging tests shall be conducted on samples cut from the glove in accordance with Test Method D 573 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.

7.6 *Powder Free Gloves*:

7.6.1 Determine the powder residue using Test Method D 6124.

7.7 *Powdered Gloves*:

7.7.1 Determine the recommended maximum powder limit using Test Method D 6124 for powdered gloves.

7.7.2 Determine the square decimeters for the glove size as in 8.7.3 in Specificiation D 3578.

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.

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 *Nonsterile and Bulk Packaging*:

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
Length, mm	85		95	230 for all sizes	105		115	min
Thickness, mm								
Finger				0.05				min
Palm				0.08				min

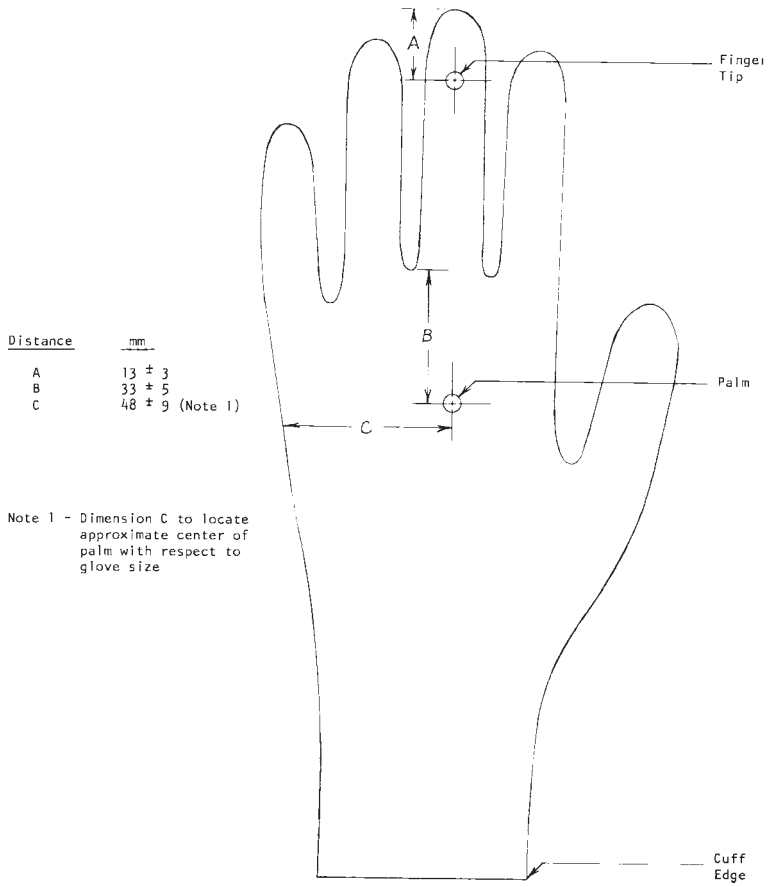

FIG. 1 Location of Thickness Measurements

TABLE 3 Physical Requirements

Tensile Strength, MPa, min	Ultimate Elongation,% , min
9	300

9.2.1 The unit of packaging shall normally be more than one glove and of a specific amount.

9.2.2 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.

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

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

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 Nonsterile and bulk packages shall bear markings for the contents to include the glove size and a 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.