



Designation: D 5250 – 00

Standard Specification for Poly(vinyl chloride) Gloves for Medical Application¹

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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—Tension²

D 573 Test Method for Rubber—Deterioration in an Air Oven²

D 3578 Specification for Rubber Examination Gloves³

D 3767 Practice for Rubber—Measurement of Dimensions²

D 5151 Test Method for Detection of Holes in Medical Gloves³

D 6124 Test Method for Residual Powder on Medical Gloves³

2.2 Other Document:

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes⁴

U. S. Pharmacopeia⁵

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. Performance

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

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

5.1.2 Be free 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.

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, 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.

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 D 5151.

7.4 *Physical Dimensions Test*:

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

¹ This specification is under the jurisdiction of Committee D-11 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 5250-99^{ε1}.

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, 11 W. 42nd St., 13th Floor, New York, NY 10036.

⁵ U.S. Pharmacopeia, latest edition, Mack Publishing Co., Easton, PA, 19175.