



Designation: D5250 – 19

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

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

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. Current edition approved Nov. 1, 2019. Published December 2019. Originally approved in 1992. Last previous edition approved in 2015 as D5250 – 06 (2015). DOI: 10.1520/D5250-19.

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.

2.2 Other Document:

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes³

U. S. Pharmacopeia⁴

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**.

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.