



Designation: D6319 – 19 (Reapproved 2023)

Standard Specification for Nitrile Examination Gloves for Medical Application¹

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1. Scope

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

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

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

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

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 ASTM Committee D11 on Rubber and Rubber-like Materials and is the direct responsibility of Subcommittee 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.

2.2 *ISO Standard:*

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes³

2.3 *Other Documents:*

U.S. Pharmacopeia⁴

3. Significance and Use

3.1 The specification is intended as a referee procedure for evaluating the performance and safety of nitrile rubber examination gloves. The safe and proper use of nitrile rubber examination gloves is beyond the scope of this specification.

4. Material

4.1 Any nitrile rubber polymer compound may be used that permits the glove to meet the requirements of this specification.

4.2 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.

4.3 The inside and outside surface of the nitrile rubber examination gloves shall be free of talc.

5. Sampling

5.1 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.

6. Performance Requirements

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

6.1.1 Product comply with requirements for sterility when tested in accordance with 7.2 when labeled sterile.

6.1.2 Shall comply with freedom 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.