



Standard Specification for Nitrile Examination Gloves for Medical Application¹

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^{ε1} NOTE—Dates in Annex A2.1.1 were revised editorially in September 2001.

^{ε2} NOTE—Both annexes were deleted and the information was included in the Performance Requirements section editorially in March 2002.

^{ε3} 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 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 nonsterile nitrile rubber examination gloves.

1.3 This specification is similar to that of Specification D 3578 for rubber examination gloves.

2. Referenced Documents

2.1 ASTM Standards:

D 412 Test Methods for Vulcanized Rubber 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 Gloves

2.2 ISO Standard:

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes⁴

2.3 Other Documents:

U.S. Pharmacopeia⁵

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.

It is not intended for testing prior to routine lot release. 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.

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/dm² in accordance with 7.7.

7. Referee Test Methods

7.1 The following tests shall be conducted to ensure the

¹ This specification is under the jurisdiction of ASTM Committee D11 on Rubber and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

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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.