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Standard Specification for Rubber Examination Gloves¹

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This standard has been approved for use by agencies of the Department of Defense.

^{ε1} NOTE—An annex was deleted and the information was included editorially in the Performance Requirements section in March 2002. Clarifying language was added editorially to Sections 1, 4, and 5 in March 2002.

1. Scope

1.1 This specification describes certain requirements for natural rubber gloves used in conducting medical examinations and diagnostic and therapeutic procedures. It also covers natural rubber gloves used in handling contaminated medical material.

1.2 This specification provides for natural rubber gloves that fit either hand, paired gloves, and gloves by size. It also provides for packaged sterile natural rubber gloves and packaged or bulk nonsterile natural rubber 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 3767 Practice for Rubber—Measurement of Dimensions²

D 5151 Test Method for Detection of Holes in Medical Gloves³

D 5712 Test Method for the Analysis of Aqueous Extractable Protein in Natural Rubber and its Products Using the Modified Lowry Method³

D 6124 Test Method for Residual Powder on Medical Gloves³

D 6499 Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and its Products³

2.2 Other Documents:

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes⁴

U. S. Pharmacopeia⁵

3. Classification

3.1 *Type I*—Gloves conforming to Table 1.

3.2 *Type II*—Gloves conforming to Table 1.

4. Materials and Manufacture

4.1 Any natural rubber compound 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 natural rubber examination gloves shall be free of talc.

5. Significance and Use

5.1 The specification is intended as a reference to the performance and safety of natural rubber examination gloves. The safe and proper use of natural rubber examination gloves is beyond the scope of this specification.

6. Sampling

6.1 For referee purposes, gloves shall be sampled and inspected in accordance with ISO 2859. The inspection levels and acceptable quality levels (AQL) shall conform to those specified in Table 2, or as agreed between the purchaser and the seller, if the latter is more comprehensive.

7. Performance Requirements

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

7.1.1 Comply with requirements for sterility when tested in accordance with 8.2.

7.1.2 Be free from holes when tested in accordance with 8.3.

7.1.3 Have consistent physical dimensions in accordance with 8.4.

7.1.4 Have acceptable physical property characteristics in accordance with 8.5.

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

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.