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Standard Specification for Rubber Examination Gloves¹

This standard is issued under the fixed designation D3578; 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.

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

1. Scope

1.1 This specification covers 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.

1.3 *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

D3767 Practice for Rubber—Measurement of Dimensions

D5151 Test Method for Detection of Holes in Medical Gloves

D5712 Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method

D6124 Test Method for Residual Powder on Medical Gloves

D6499 Test Method for Immunological Measurement of Antigenic Protein in Hevea Natural Rubber (HNR) and its Products

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 Other Documents:

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes³

U. S. Pharmacopeia⁴

3. Classification

3.1 *Type I*—Gloves with a minimum tensile strength of 18 MPa and a maximum stress at 500 % elongation of 5.5 MPa.

3.2 *Type II*—Gloves with a minimum tensile strength of 14 MPa and a maximum stress at 500 % elongation of 2.8 MPa.

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 1**, 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:

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

⁴ U.S. Pharmacopeia, latest edition, Mack Publishing Co., Easton, PA, 19175.