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Standard Specification for Rubber Examination Gloves[1]

This standard is issued under the fixed designation D 3578; 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 Department of Defense.

1. Scope

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

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

2. Referenced Documents

2.1 *ASTM Standards:*

D 412 Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers— Tension[2]

D 573 Test Method for Rubber—Deterioration in an Air Oven[2]

D 3767 Practice for Rubber—Measurement of Dimensions[2]

D 5151 Test Method for Detection of Holes in Medical Gloves[3]

D 5712 Test Method for the Analysis of Aqueous Extractable Protein In Natural Rubber and its Products Using the Modified Lowry Method[3]

D 6124 Test Method for Residual Powder on Medical Gloves[3]

D 6499 Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and it s Products[3]

2.2 *Other Documents:*

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes [4]

U. S. Pharmacopeia[5]

3. Classification

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

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

TABLE 1 Physical Requirements

	Before Aging			After Accelerated Aging	
	Tensile Strength	Stress at 500% Elongation	Ultimate Elongation	Tensile Strength	Ultimate Elongation
Type I	18 MPa min	5.5 MPa max	650 % min	14 MPa min	500 % min
Type II	14 MPa min	2.8 MPa max	650 % min	14 MPa min	500 % min

4. Materials and Manufacture

4.1 Any rubber polymer compound that permits the glove to meet the requirements of this standard.

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 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 rubber examination gloves. The safe and proper use of rubber examination gloves is beyond the scope of this standard.

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

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.

7.1.5 Have a powder residue limit in accordance with 8.6.

7.1.6 Have a recommended aqueous soluble protein content limit of 200 µg/dm^2 in accordance with 8.7 and Annex A1.

[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.

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