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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.

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—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 Protein In Natural Rubber and its Products³

D 6124 Test Method for Residual Powder on Medical Gloves³

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 rubber polymer compound that permits the glove to

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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, 11 W. 42nd St., 13th Floor, New York, NY 10036.

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

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

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 $\mu\text{g}/\text{dm}^2$ in accordance with 8.7 and Annex A2.

7.1.7 Have a recommended maximum powder limit in accordance with 8.8.

TABLE 2 Performance Requirements

Characteristic	Related Defects	Inspection Level	AQL
Sterility	fails sterility	^A	N/A
Freedom from holes	holes	I	2.5
Dimensions	width, length, and thickness	S-2	4.0
Physical properties	before aging, after accelerated aging	S-2	4.0
Powder Free Residue	Exceeds Maximum Limit	N=5	N/A
Protein Content	Exceeds Recommended Maximum Limit	N=3	N/A
Powder Amount	Exceeds Recommended Maximum Limit	N=2	N/A

^ASee U.S. Pharmacopeia

8. Referee Test Methods

8.1 The following tests shall be conducted to ensure the requirements of Section 8, as prescribed in Table 2:

8.2 *Sterility Test*—Testing for sterility shall be conducted in accordance with the latest edition of The U.S. Pharmacopeia.

8.3 *Freedom From Holes*—Testing for freedom from holes shall be conducted in accordance with Test Method D 5151.

8.4 *Physical Dimensions Test*:

8.4.1 The gloves shall comply with the dimension requirements prescribed in Table 3.

8.4.2 The length shall be expressed in millimetres as measured from the tip of the middle finger to the outside edge of the cuff as indicated in Fig. 1.

8.4.3 The width of the palm shall be expressed in millimetres as measured at a level between the base of the index finger and the base of the thumb. Values of width per size other than listed shall meet the stated tolerance specified in Table 3.

8.4.4 The minimum thickness shall be expressed in millimetres as specified in Table 3 when using a dial micrometer described in Test Methods D 412 and in the locations indicated on Fig. 1. For referee tests, cutting the glove is necessary to obtain single-thickness measurements.

8.5 *Physical Requirements Test*:

8.5.1 Before and after accelerated aging, the gloves shall conform to the physical requirements specified in Table 1. Tests shall be conducted as specified in Test Methods D 412.

8.5.2 Accelerated aging tests shall be conducted in accordance with Test Method D 573. Test the gloves by either one of the following methods:

8.5.2.1 After being subjected to a temperature of $70 \pm 2^\circ\text{C}$. for 166 ± 2 h, the tensile strength and ultimate elongation shall not be less than the values specified in Table 1. This method shall be the condition for referee tests.

8.5.2.2 After being subjected to a temperature of $100 \pm 2^\circ\text{C}$ for 22 ± 0.3 h, the tensile strength and ultimate elongation shall not be less than the values specified in Table 1.

8.6 *Powder Free Gloves*:

8.6.1 The powder residue shall not exceed the average powder mass and schedule referenced in Annex A1 when tested in accordance with Test Method D 6124.

8.7 *Aqueous Extractable Protein Content*:

8.7.1 Determine the aqueous extractable protein ($\mu\text{g/mL}$) using Test Method D 5712 for each glove sample tested.

8.7.2 Determine the total μg of aqueous extractable protein in each glove sample by multiplying the result from 8.7.1 by the total volume of extractant used for that specific glove sample. If the glove sample is less than a whole glove, then adjust the protein results to reflect the amount of protein in the whole glove.

8.7.3 Determine the square decimeters for the glove size. Multiply the minimum length and nominal width found in Table 3 and convert to dm^2 using $(\text{dm}^2/\text{mm}^2) (\text{mm}^2/10\,000)$ (4). Four (4) is the factor for all inside and outside surface areas.

8.7.4 Determine the aqueous extractable protein content of a glove sample by dividing the result from 8.7.2 (total μg of protein) by 8.7.3 (total surface area of glove).

8.7.5 If the sample is more than one (1) glove, use the average $\mu\text{g}/\text{dm}^2$ of protein for the number of gloves tested in the sample.

8.8 *Powdered Gloves*:

8.8.1 The amount of powder shall not exceed the recommended average powder mass schedule referenced in Annex A3 when tested in accordance with Test Method D 6124 for powdered gloves.

8.8.2 Determine the square decimeters for the glove size as in 8.7.3.

9. Acceptance

9.1 Gloves will be considered to meet the referee performance requirements when test results conform to the requirements prescribed in Table 2.

9.2 Retests or reinspections are permissible under the provisions of the U.S. Pharmacopeia and ISO 2859.

10. Packaging and Marking

10.1 *Sterile Packaging*:

10.1.1 The unit of packaging shall normally be one glove or one pair of gloves.

10.1.2 A glove or pair of gloves, normally, shall be enclosed

TABLE 3 Dimensions and Tolerances

Designation	Size							Tolerance, mm
	6	6½	7	7½	8	8½	9	
Width by size, mm	75	83	89	95	102	108	114	± 6
Width by	Extra Small	Small	Unsize	Medium			Large	
mm	70	80	85	95			111	± 10
Length, mm	220	220	220	230			230	Min
Thickness, mm:				For All Sizes				
Finger				0.08				Min
Palm				0.08				Min