Designation: D 3578 – 01a$^{\epsilon 2}$

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.

ε[1] 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.
ε[2] NOTE—Sections 7.1.5 and 7.1.7 were revised editorially to correct measurement units in April 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— 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.

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.

[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.

Current edition approved Nov. 10, 2001. Published January 2002. Originally published as D 3578 – 77. Last previous edition D 3578 – 01$^{\epsilon 1}$.

[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.

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

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
Antigenic Protein Content	Exceeds Recommended Maximum Limit	N=1	N/A

[A] See U.S. Pharmacopeia.

7.1.4 Have acceptable physical property characteristics in accordance with 8.5.

7.1.5 Have a powder residue limit of 2.0 mg 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 or have a recommended antigenic protein content limit of 10 µg/dm^2 in accordance with 8.9 and Annex A2.

7.1.7 Have a recommended maximum powder limit of 10 mg/dm^2 in accordance with 8.8.

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 ± 2°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 ± 2°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 Determine the powder residue using Test Method D 6124.

8.7 *Aqueous Extractable Protein Content*:

8.7.1 Determine the aqueous extractable protein (µg/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 (dm^2/mm^2) (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 µg/dm^2 of protein for the number of gloves tested in the sample.

8.8 *Powdered Gloves*:

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	Unisize	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

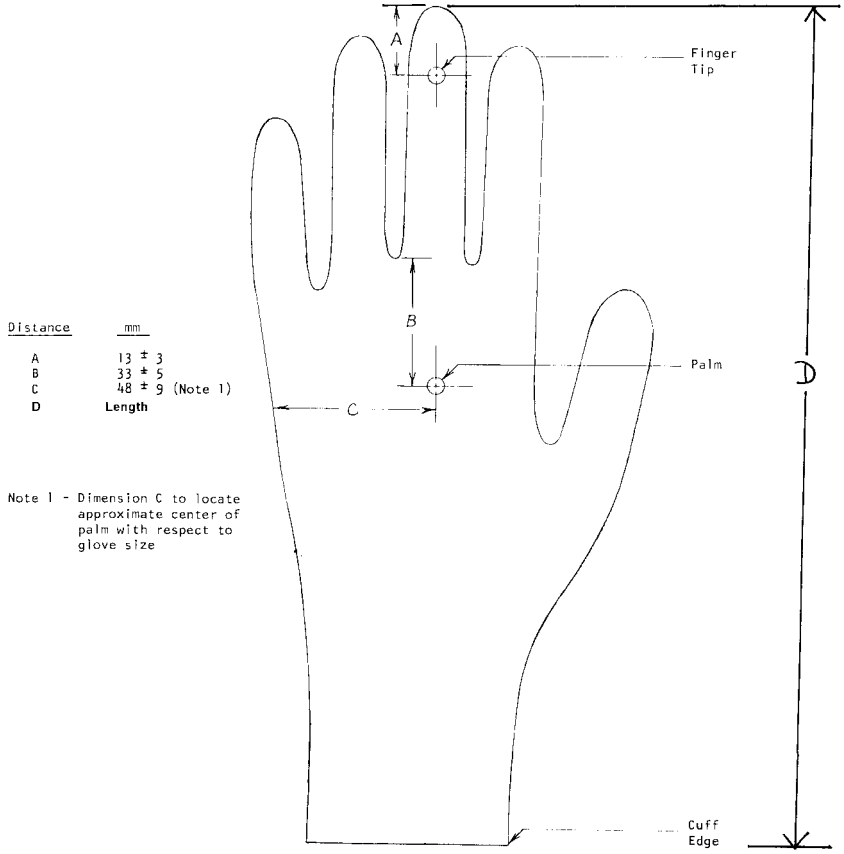

FIG. 1 Location of Thickness and Length Measurements

8.8.1 Determine the recommended maximum powder limit using Test Method D 6124 for powdered gloves.

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

8.9 *Antigenic Protein Content*:

8.9.1 Determine the extractable antigenic protein (µg/mL) using Test Method D 6499 for each glove sample tested.

8.9.2 Determine the total microgram of extractable antigenic protein in each glove sample by multiplying the result from 8.9.1 by the total volume of extractant used for that specific glove sample.

8.9.3 Determine the square decimeter for the glove size as in 8.7.3.

8.9.4 Determine the extractable antigenic protein content of a glove sample by dividing the result from 8.9.2 (total microgram of antigenic protein) by 8.9.3 (total surface area of glove).

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 in an inner wallet or wrapper. The wrapper shall be of sufficient size when opened to provide a field for glove-donning purposes.

10.1.3 The glove or pair, and accompanying wrapper if utilized, shall be totally enclosed in an outer package that shall allow sterilization of the product.

10.1.4 The outer package shall have a method of closure sufficient to assure the sterility of the product until opened or damaged.

10.1.5 The outer package shall have sufficient strength and integrity to withstand normal transportation and storage within the intermediate or shipping cartons, or both.

10.1.6 The method of closure of the outer package shall be such that prior opening will be detectable by the user.

10.1.7 None of the packaging material shall contain any material likely to impair the quality and use of the gloves.

10.1.8 Intermediate cartons and shipping cases shall be of sufficient strength to maintain the quality and sterility of the product during normal transportation and storage.

10.2 *Nonsterile and Bulk Packaging*:

10.2.1 The unit of packaging shall normally be more than one glove and of a specific amount.

10.2.2 The gloves shall be enclosed in an outer package that has sufficient strength to withstand normal transportation and storage within the cartons or shipping cases, or both.

10.2.3 None of the packaging material shall contain any material likely to impair the quality and use of the gloves.

10.2.4 Cartons and shipping cases shall be of sufficient strength to maintain the quality of the product during normal transportation and storage.

10.3 *Marking*:

10.3.1 Sterile packages shall bear markings for the contents to include the glove size, instructions for opening, the legend "sterile," and a manufacturing lot number.

10.3.2 Nonsterile and bulk packages shall bear markings for the contents to include the glove size and a manufacturing lot number.

10.3.3 The outermost case shall be labeled with the glove size and a manufacturing lot number. Sterile product cases shall also be marked with the legend "sterile."

10.3.4 All levels of packaging shall conform to all appropriate government labeling regulations.

11. Keywords

11.1 examination; gloves; rubber

ANNEXES

Mandatory Information

A1. PROTEIN CONTENT

A1.1 The current assay precision is large enough that only a recommended limit can be considered.

A1.2 Consideration should be given to the relative repeatability and reproducibility when reporting test method results.

A1.3 Reasonable allowance should be given for test results in excess of the recommended limit until greater precision of the method can be attained.

A2. ANTIGENIC PROTEIN CONTENT

A2.1 The current assay precision is large enough that only a recommended limit can be considered.

A2.2 Consideration should be given to the relative repeatability and repoducibility when reporting test methods.

A2.3 A pooled sample from three individual NR specimens or products as extracted in accordance with Test Method D 5712 is permitted for use as the extraction sample.

APPENDIX

(Nonmandatory Information)

X1. Rationale

X1.1 At a meeting of the Glove Task Force of ASTM D11.40, it was determined to expand the physical requirement values allowing consumers more choice in fit, feel, and comfort by having two types of examination gloves.