



Standard Specification for Polychloroprene Examination Gloves for Medical Application¹

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1. Scope

1.1 This specification provides certain requirements for polychloroprene rubber gloves used in conducting medical examinations and diagnostic and therapeutic procedures.

1.2 This specification covers polychloroprene rubber examination gloves that fit either hand, paired gloves, and gloves by size. It also provides for packaged sterile or non-sterile or bulk non-sterile polychloroprene rubber examination gloves.

1.3 This specification is similar to that of D 3578 Standard Specification for Rubber Examination Gloves, and D 6319 Standard Specification for Nitrile Examination Gloves for Medical Applications.

2. Referenced Documents

2.1 ASTM Standards:²

D 412 Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers—Tension
D 573 Test Method for Rubber-Deterioration in an Air Oven
D 3578 Specification for Rubber Examination Gloves
D 3767 Practice for Rubber-Measurement of Dimensions
D 5151 Test Method for Detection of Holes in Medical Gloves

D 6124 Test Method for Residual Powder on Medical
D 6319 Specification for Nitrile Examination Gloves for Medical Application Gloves

D 6355 Test Method for Human Repeat Insult Patch Testing of Medical Gloves

2.2 ISO Standard:

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes³

2.3 Other Document:

U.S. Pharmacopeia⁴

3. Significance and Use

3.1 This specification is intended as a referee procedure for evaluating the performance and safety of polychloroprene rubber examination gloves. It is not intended for testing prior to routine lot release. The safe and proper use of polychloroprene rubber examination gloves is beyond the scope of this specification.

4. Material

4.1 Any polychloroprene rubber compound that produces examination gloves that meet the requirements of this specification are allowed.

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 polychloroprene rubber examination gloves shall be free of talc.

TABLE 1 Performance Requirements

Characteristic	Related Defects	Inspection Level	AQL
Sterility	fails sterility	^A	N/A
Freedom from holes	holes	G-1	2.5
Dimensions	width, length, 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
Powder Amount	exceeds recommended maximum limit	N=2	N/A

^A See U.S. Pharmacopeia.

5. Performance Requirements

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

5.1.1 Products comply with requirements for sterility when tested in accordance with 7.2 when labeled sterile,

5.1.2 Shall comply with freedom from holes when tested in accordance with 7.3,

5.1.3 Have consistent physical dimensions in accordance with 7.4,

5.1.4 Have acceptable physical property characteristics in accordance with 7.5,

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 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.

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.