



Standard Specification for Rubber Surgical Gloves¹

This standard is issued under the fixed designation D3577; 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 packaged sterile rubber surgical gloves used in conducting surgical procedures.

1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.3 The following safety hazards caveat pertains only to the test method portion, Section 8, of this specification: *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

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 The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products

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. 1, 2015. Published December 2015. Originally approved in 1977. Last previous edition approved in 2009 as D3577 – 09^{ε1}. DOI: 10.1520/D3577-09R15.

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 1*—Gloves compounded primarily from natural rubber latex.

3.2 *Type 2*—Gloves compounded from a rubber cement or from synthetic rubber latex.

4. Materials and Manufacture

4.1 Any rubber polymer 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 rubber surgical 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 surgical gloves. The safe and proper use of rubber surgical 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, 25 West 43rd St., 4th Floor, New York, NY 10036.

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