



Standard Specification for Rubber Contraceptives (Male Condoms)¹

This standard is issued under the fixed designation D3492; 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 the minimum requirements for individually packaged male condoms made from natural rubber latex and intended for single use. This specification does not cover the specifications for lubricants or other dressing materials that may be applied to condoms except as noted in 3.2.

1.2 This specification is intended to assist buyers in obtaining condoms of consistent quality. The safe and proper use of condoms is excluded from the scope of this specification.

1.3 The applicability of this specification is as a design guideline and a reference test specification. It is not intended to be a routine quality control specification for condom manufacturing operations.

1.4 The annexes in this specification include important information, such as that on apparatus or materials, that is a mandatory part of the specification but too detailed for inclusion in the main text.

1.5 The appendixes in this specification contain information intended to provide guidance only and are not a mandatory part of the specification.

1.6 It shall be the responsibility of the manufacturer for any condom design that falls outside the specifications of this standard to determine testing methodology and substantiate the appropriateness of that methodology to assure the quality of the condoms to the purchaser and to the government regulatory authority having jurisdiction.

1.7 Regulatory bodies may require additional information, such as clinical data, to support the condom sizes subject to this standard.

1.8 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

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

D1076 Specification for Rubber—Concentrated, Ammonia Preserved, Creamed, and Centrifuged Natural Latex

D3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission

D3767 Practice for Rubber—Measurement of Dimensions

D4483 Practice for Evaluating Precision for Test Method Standards in the Rubber and Carbon Black Manufacturing Industries

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

2.2 ISO Standard:³

ISO 4074 Natural Latex Rubber Condoms – Requirements and Test Methods

ISO 10993 Biological Evaluations of Medical Devices

2.3 Other Document:³

ANSI/MIL-STD 105E Sampling Procedures and Tables for Inspection by Attributes

3. Materials and Manufacture

3.1 Condoms shall be manufactured from natural rubber latex conforming to Specification **D1076**.

3.2 The condoms and any dressing materials applied to them shall not liberate substances that are known to be toxic, sensitizing, locally irritating, or otherwise harmful to the general population under normal conditions of use.

NOTE 1—Natural rubber latex products are known to cause irritation or sensitivity in a small proportion of the user population.

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.