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# Standard Specification for Rubber Contraceptives (Male Condoms)[1]

This standard is issued under the fixed designation D 3492; 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.

## 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 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:*

D 412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension[2]

D 573 Test Method for Rubber—Deterioration in an Air Oven[2]

D 1076 Specification for Rubber—Concentrated, Ammonia Preserved, Creamed, and Centrifuged Natural Latex[2]

D 3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission[3]

D 3767 Practice for Rubber—Measurement of Dimensions[2]

D 4483 Practice for Determining Precision for Test Method Standards in the Rubber and Carbon Black Industries[2]

E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method[4]

2.2 *Other Document:*

ANSI/MIL-STD 105E Sampling Procedures and Tables for Inspection by Attributes[5]

## 3. Materials and Manufacture

3.1 Condoms shall be manufactured from natural rubber latex conforming to Specification D 1076.

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.

NOTE 2—Condom lubricants that contain Nonoxynol 9 spermicide are known to cause irritation in a small proportion of the user population.

## 4. Requirements

4.1 *General*:

4.1.1 *Sampling*—Samples will be selected randomly from the defined "lot." The sampling plan must conform to the requirements listed in Table 1.

4.1.2 *Sample Handling*—To avoid inadvertent damage, operators must wear rubber gloves, finger cots, or other suitable hand/finger covers and exercise reasonable caution in handling the packet or condom in order to minimize the possibility of damage during the testing procedure.

4.1.3 *Process Controls*—Manufacturers may use process control tests to determine condom properties. Finished condoms shall be used for qualification and referee tests.

4.1.4 *Lot*—A collection of condoms of the same design, color, shape, size, and formulation manufactured continuously, using the same process, raw materials, or the same specification, common equipment, and packaged with the same lubricant and any other additives or dressing in the same type of individual container. The maximum lot size shall be 500 000 condoms.

4.2 *Dimensions*—Condoms shall meet the requirements listed in Table 2.

[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] *Annual Book of ASTM Standards*, Vol 09.01.

[3] *Annual Book of ASTM Standards*, Vol 15.09.

[4] *Annual Book of ASTM Standards*, Vol 14.02.

[5] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

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