This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Designation: D6324 – 11 (Reapproved 2023)

Standard Specification for Male Condoms Made from Polyurethane[1]

This standard is issued under the fixed designation D6324; 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 polyurethane. This specification also describes the minimum inspection and quality levels that shall be utilized in referee tests. It is not intended to be a routine quality control specification for polyurethane condom manufacturing operations.

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

1.3 The annexes in these test methods include important information, such as that on apparatus or materials, that are a mandatory part of these test methods but too detailed for inclusion in the main text.

1.4 The appendixes in these test methods contain information intended to provide guidance.

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

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 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D374 Test Methods for Thickness of Solid Electrical Insulation (Metric) D0374_D0374M

D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

D618 Practice for Conditioning Plastics for Testing

D638 Test Method for Tensile Properties of Plastics

D882 Test Method for Tensile Properties of Thin Plastic Sheeting

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

D3492 Specification for Rubber Contraceptives (Male Condoms)

D3767 Practice for Rubber—Measurement of Dimensions

2.2 *Other Documents:*

ANSI/ASQC Z1.4–2003 Sampling Procedures and Tables for Inspection by Attributes[3]

ISO 37 Rubber, Vulcanized or Thermoplastic—Determination of Tensile Stress-Stain Properties Preclinical and Clinical Requirements for Approval to Market Non-latex Condoms, World Health Organization, 1997[3]

ISO 10993 Biological Evaluation of Medical Devices, Part 2[3]

ISO 23409 Synthetic Condom Standard[3]

3. Significance and Use

3.1 New polymer materials for male condoms are being developed. Several products have been developed and are currently marketed in international commerce. This standard is intended to provide specifications to adequately describe the design and the quality of condoms made of polyurethane material.

[1] This specification is under the jurisdiction of Committee D11 on Rubber and Rubber-like Materials 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, http://www.ansi.org.

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