International Standard

ISO 4074

Natural rubber latex male condoms — Requirements and test methods

Préservatifs externes en latex de caoutchouc naturel — Exigences et méthodes d'essai

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 4074:2015), which has been technically revised.

The main changes are as follows.

— The Scope (Clause 1) has been amended because this document now covers all condom sizes including those with dimensions specified in Annex P, which has been made normative.

— A statement has been added to Annex A regarding the sample sizes used for reduced inspection.

— The use of technical grade propan-2-ol is permitted for removing lubricant from condoms when determining the lubricant quantity according to Annex C.

— In Annex G, it has been made clear that a Stomacher® is a specific type of mixer that can be used along with other types of mixers when preparing samples for microbiological testing of condoms. Some amendments to the test procedures have been made based on current best practices.

— Improvements have been made to inflation test procedure specified in Annex H.

— The condom handling procedures described in ISO/TR 19969:2018 have been integrated into Annex H, testing for burst properties, and Annex M, testing for freedom from holes.

— Annex K has been updated to provide clearer and more detailed information about conducting real time stability tests.

— Annex L has been updated to include a more rapid accelerated stability test to assess the effect of process and formulation changes on the stability of a product and provide a stress test for condoms that might be stored in high temperature environments.

— The electrical test for freedom from holes in Annex M has been amended to improve the probability of finding small holes in the teat (reservoir tip) and closed end of the condom.

— An alternative dry vacuum method for testing the integrity of individual condom containers has been included in Annex N.

— Annex O has been made normative and amended to include a new section to verify that technicians can unroll the condoms correctly when conducting the burst test.

— A new Annex Q has been added to specify requirements and procedures for validating new or modified test procedures and verifying that the test methods for freedom from holes meet the specified performance requirements. As a consequence, Annex M has been made informative.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Condoms made from intact latex film have been shown to be a barrier to human immunodeficiency virus (HIV), other infectious agents responsible for the transmission of sexually transmitted infections (STIs), and to spermatozoa. Numerous clinical studies have confirmed that male latex condoms are effective in helping to prevent pregnancy and reduce the risk of transmission of most STIs including HIV.

To help ensure that condoms are effective for contraceptive purposes and in assisting in the prevention of transmission of STIs, it is essential that condoms fit the penis properly, are free from holes, have adequate physical strength so as not to break during use, are correctly packaged to protect them during storage, and are correctly labelled to facilitate their use. All these issues are addressed in this document.

Condoms are medical devices. To ensure high quality product, it is essential that condoms are produced under a good quality management system. See ISO 13485[7] for quality management requirements and ISO 14971 for risk management requirements.

Condoms are non-sterile medical devices, but manufacturers are advised to take appropriate precautions to minimize microbiological contamination of the product throughout the manufacturing and packaging processes. Recommendations for manufacturers to periodically monitor microbial contamination during production are included in this document. Methods that can be used to determine bioburden levels are included in Annex G.

This document requires manufacturers to conduct stability tests to estimate the shelf life of any new condom design before the product is placed on the market and to initiate real-time stability studies. Manufacturers are also required to consider the stability of any modified condom design. These requirements are described in Clause 11. The real-time stability test can be considered as part of the manufacturers' requirement to conduct post-marketing surveillance on their products. These requirements are intended to ensure that manufacturers have adequate data to support shelf life claims before products are placed on the market and that these data are available for review by regulatory authorities, third party test laboratories, and purchasers. They are also intended to limit the need for third parties to conduct long-term stability studies.

Condoms can be subject to specific local requirements as required by national regulatory bodies in addition to those specified in this document.

ISO 16038[8] provides guidance for the application of this document. It includes additional information on the test methods and requirements specified in this document.

Pictures and diagrams in this document are to enhance clarity and do not indicate a preference for any specific equipment type or design.

There are no requirements for determining the tensile properties of condoms in this document. Nevertheless, tensile testing is sometimes used for quality control and development purposes. Annex J includes guidance on how to determine force and elongation at break of condoms.

The need for a transition period when implementing the requirements of this document should be considered to allow manufacturers to make the changes required to maintain conformance.

Natural rubber latex male condoms — Requirements and test methods

1 Scope

This document specifies requirements and test methods for male condoms made from natural rubber latex.

This document does not specify requirements related to any medicinal substances applied to or delivered by the condom.

NOTE The safety and effectiveness of any medicinal substance are assessed according to national and regional regulations.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer— Part 1: General requirements*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 2859-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
acceptance quality limit
AQL
quality level that is the worst tolerable process average when a continuing series of *lots* (3.11) is submitted for acceptance sampling

[SOURCE: ISO 2859-1:1999, 3.1.26]

3.2
male condom
medical device used by consumers, which is intended to cover and be retained on the penis during sexual activity, for purposes of contraception and prevention of sexually transmitted infections