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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

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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

3.3
modified condom design
established condom design that has been subjected to changes in formulation, manufacturing process, manufacturing site, lubrication, or individual sealed container

3.4
consumer package
box, bag or container intended for distribution to a consumer, containing one or more individual containers of condoms

3.5
expiry date
date after which the condom should not be used

3.6
identification number
number, or combination of numerals, symbols, or letters, used by a manufacturer on *consumer packages* (3.4) to identify uniquely the *lot numbers* (3.12) of individual condoms contained in that package, and from which it is possible to trace those *lots* (3.11) through all stages of manufacturing, packaging and distribution

Note 1 to entry: When the consumer package contains only one type of condom, then the identification number may be the same as the lot number; but if the consumer package contains several different types of condoms, for instance condoms of different shapes or colours, then the identification number will be different from the lot numbers.

3.7
individual container
primary package containing a single condom

3.8
inspection level
index of the relative amount of inspection of an acceptance sampling scheme, chosen in advance, and relating the sample size to the lot size

[SOURCE: ISO 3534-2:2006, 4.3.5]

3.9
inflation length
length of the condom to be inflated during the burst test

3.10
integral bead
ring formed at the open end of the condom, usually by rolling down a portion of the partially dried and cured latex film, to assist rolling and handling the condom

3.11
lot
collection of condoms of the same design, colour, shape, size, and formulation, manufactured at essentially the same time, using the same process, raw materials of the same specifications, common equipment, and packed with the same lubricant and any other additive or dressing in the same type of individual container

3.12
lot number
number, or combination of numerals, symbols, or letters, used by the manufacturer to identify a *lot* (3.11) of individually packaged condoms, and from which it is possible to trace that lot through all stages of manufacture up to packaging

3.13
non-visible hole
puncture or tear in a condom that is not visible under normal or corrected vision but is detected by the water leak test or electrical test

3.14
sampling plan
specific plan which indicates the number of units of product from each *lot* (3.11) which are to be inspected (sample size or series of sample sizes) and the associated criteria for determining the acceptability of the lot (acceptance and rejection numbers)

3.15
shelf life
period from date of manufacture during which condoms are required to conform to the requirements for bursting pressure, bursting volume, freedom from holes and pack integrity

3.16
visible hole
puncture or tear in the condom that is visible under normal or corrected vision before the condom is filled with water or electrolyte during testing for freedom from holes

3.17
date of manufacture
date specified by the manufacturer when the product was made

Note 1 to entry: See 11.1.

3.18
visible defect
broken, missing, or severely distorted bead and permanent creases with adhesion of the film

Note 1 to entry: This refers to visible defects other than holes.

4 Quality verification

Condoms are regulated medical devices in most countries and should be manufactured and tested using an appropriate quality management system (QMS). A suitable QMS for the manufacture of medical devices is described in ISO 13485.[7]

Condoms are mass produced articles. Inevitably, there will be some variation between individual condoms, and a small proportion of condoms in each production run might not meet the requirements in this document. Further, most of the test methods described in this document are destructive. For these reasons, the only practicable method of assessing conformity with this document is by testing a representative sample from a lot or series of lots. Basic sampling plans are given in ISO 2859-1. Reference should be made to the ISO/TR 8550 series[2] for guidance on the use of acceptance sampling system, scheme, or plan for the inspection of discrete items in lots. For testing purposes, sampling shall be conducted by lot number, not by identification number.

Sampling plans shall be selected to provide an acceptable level of consumer protection. Suitable sampling plans are given in Annexes A and B.

a) Annex A describes sampling plans based on ISO 2859-1 and is most applicable to manufacturers or purchasers assessing the conformity of a continuing series of lots. The full level of consumer protection available depends upon the switch to tightened inspection if deterioration in quality is detected. The switching rules, described in ISO 2859-1:1999, Clause 9, cannot offer their full protection for the first two lots tested but become progressively more effective as the number of lots in a series increases. The sampling plans in Annex A shall be used when a continuing series of five or more lots are being tested.

b) When testing isolated lots or fewer than 5 lots, the level of consumer protection is reduced because the switching rules cannot be applied. If in such cases it is necessary to maintain high levels of consumer protection the sampling plans in Annex B are recommended. The sampling plans in Annex B provide approximately the same level of consumer protection as those given in Annex A when used with the switching rules. Examples of when the sampling plans in Annex B should be used include cases of dispute, for referee purposes, for type testing, for qualification purposes, and for short runs of continuing lots.

It is necessary to know the lot size to derive from ISO 2859-1 the number of condoms to be tested. The lot size will vary between manufacturers and is regarded as part of the process and quality controls used by the manufacturer.

If the lot size is not known or cannot be confirmed by the manufacturer, then a lot size of 500 000 condoms shall be assumed for determining the sample sizes for testing.

5 Lot size

The maximum individual lot size for production shall be 500 000 condoms.

This document does not specify the size of a lot, but it is possible for a purchaser to do so as part of the purchasing contract. Purchasers are encouraged to specify a lot size compatible with the manufacturer's quality management system.

6 Biocompatibility

For any new product biocompatibility assessments shall be conducted in accordance with ISO 10993-1. When testing is required, in-vitro tests are preferred if possible. In-vivo (animal) testing should be kept to a minimum. For a modified condom design, manufacturers shall conduct a risk assessment in accordance with ISO 14971 to determine whether the biocompatibility assessment needs to be repeated.

NOTE 1 Regulatory authorities usually require evaluations to be completed for cytotoxicity according to ISO 10993-5, irritation according to ISO 10993-23, and sensitization according to ISO 10993-10. Some authorities might require additional evaluations.

The condom together with any lubricant, additive, dressing material, or powder applied to it shall be evaluated.

The laboratory used for any biocompatibility testing shall conform to the requirements of ISO/IEC 17025. The results shall be interpreted by a qualified toxicologist or other appropriately qualified expert. The biological assessment report shall justify that the product is safe for its intended use.

NOTE 2 Many latex products that have been established as safe, including condoms and medical gloves, can exhibit a positive cytotoxic response when tested according to ISO 10993-5. While any cytotoxic effect can be of concern, it is primarily an indication of potential for in vivo toxicity. A condom cannot necessarily be determined to be unsuitable for use based solely on cytotoxicity data.

7 Microbial contamination

Manufacturers are recommended to establish procedures for the control and periodic monitoring of microbial contamination (bioburden) as part of their quality management system. *Staphylococcus aureus, Pseudomonas aeruginosa*, and *Enterobacteriaceae,* including *Escherichia coli*, are pathogenic organisms that can potentially be found on condoms and can cause urinary tract or other infections. It is recommended that these organisms are absent from condoms. The procedures should include requirements for absence of specific pathogens and limits for total viable counts on finished condoms. Methods of determining bioburden levels on condoms are given in Annex G.

NOTE General methods for determining microbial contamination on sterile medical devices are given in ISO 11737-1.[6] It includes methods for validation testing (ISO 11737-1). The methods described in Annex G have been found to be suitable for use with condoms taking into account specific issues associated with testing these products. These issues include the residual antimicrobial activity of some of compounds used in latex formulations which can interfere with the assays.

To control microbial contamination on the finished product, manufacturers are recommended to control the manufacturing environment to reduce the risk of contaminating the product, establish general cleaning and sanitizing procedures throughout the operation, and monitor bioburden levels on raw materials and equipment.

8 Product claims

Condoms meeting the requirements of this document are used for contraceptive purposes and to help protect against sexually transmitted infections. Manufacturers shall justify any additional claims made for their products. If a manufacturer makes a claim relating to improved efficacy or safety, then the claim shall be substantiated by appropriate clinical investigation to demonstrate superiority. Information supporting such claims shall be made available on request to interested parties.

9 Design

9.1 Dimensions

9.1.1 Length

The length of the condom shall be determined according to the method given in Annex D using a sample of 13 condoms from each lot. No individual measurement shall be below 160 mm except for condoms with dimensions specified in Annex P. For condoms shorter than 160 mm, the length shall be within ±5 mm of the nominal length specified by the manufacturer.

9.1.2 Nominal width

The width of the condom shall be determined according to the method given in Annex E using a sample of 13 condoms. The measurements shall be made at the narrowest part of the condom in the range of 20 mm to 50 mm from the open end. No measurement of the width shall deviate from the nominal width stated by the manufacturer by more than ±2 mm.

9.1.3 Thickness

This document does not specify limits for condom thickness. If verification is required of the thickness of a condom design, the average thickness of the samples measured in accordance with one of the methods given in Annex F, shall be equal to the claimed nominal thickness, subject to a tolerance of:

— ±0,008 mm for condoms with nominal claimed thickness less than 0,05 mm;

— ±0,01 mm for condoms with nominal claimed thickness equal to or greater than 0,05 mm.

The method to be used for verification shall be specified by the manufacturer.

9.2 Integral bead

The open end of the condom shall terminate in an integral bead.

9.3 Lubrication

This document does not specify requirements for the quantity and type of lubricant. If verification is required of the quantity of lubricant on a condom (and in the package), either of the methods given in Annex C shall be used.

The methods in Annex C also recover part of the dressing powder on the condom. An allowance should be made for this when manufacturers or purchasers specify lubricant levels.

10 Bursting volume and pressure

The bursting properties of condoms shall be determined according to the method specified in Annex H. For condoms that are equal to or greater than 160 mm in length, an inflation length of (150 ± 3) mm shall be used. The minimum bursting pressures and volumes are specified in Table 1.

Table 1 — Minimum bursting pressure and volume for condoms ≥160 mm long

Width of condom mm	Minimum bursting pressure kPa	Minimum bursting volume dm^3
45,0 to 49,5	1,0	16,0
50,0 to 55,5	1,0	18,0
56,0 to 64,5	1,0	22,0
65,0 to 75,0	0,8	28,0

For the purpose of this test, the mid-body width shall be the mean width rounded to the nearest 0,5 mm of 13 condoms measured in accordance with Annex E at a point equal to half the inflation length ±5 mm from the closed end excluding the teat. For example, condoms longer than 160 mm have an inflation length of 150 mm and a mid-body width measured at 75 ± 5 mm from the closed end, excluding the teat.

For condoms that are shorter than 160 mm in length, the inflation lengths and minimum burst properties are specified in Annex P.

The conformance level for each lot shall be an AQL of 1,5 for condoms that fail the requirement for bursting volume or bursting pressure or both.

11 Stability and shelf life

11.1 General

Manufacturers shall verify that the condoms conform with the requirements of Clauses 10, 12, and 14 until the end of the labelled shelf life. Products on the market prior to publication of ISO 4074:2015 (2015-10-15) shall be deemed to conform with the shelf life verification requirements of this document, unless the product is a modified design. Shelf life claims shall not exceed 5 years from the date of manufacture.

The date of manufacture can be the date of dipping or the date of packaging in individual sealed containers, depending upon the procedures specified by the manufacturer. The date of manufacture shall not exceed 2 years from the date of dipping.

Unpackaged condoms shall be stored under controlled conditions as specified by the manufacturer between dipping and packaging. Manufacturers shall have documented procedures for validating the storage conditions and maximum storage periods. The stored condoms shall be protected from exposure to excessive temperatures, light, ozone, and any other condition that can affect the shelf life of the packaged condoms.

Assessment for minimum stability (11.2) and shelf life claims (11.3 and 11.4) shall be verified on condoms that have been stored in bulk for the maximum permitted period between dipping and packaging under the conditions specified by the manufacturer.

Data supporting the shelf life claims made by the manufacturer shall be made available on request to interested parties.

Before conformance with this document can be claimed for a new or modified condom design, the manufacturer shall provide evidence that the following requirements have been met:

— the condom shall conform with the minimum stability requirements as described in 11.2;

— a real-time study as described in 11.3 to determine shelf life shall have commenced;

— pending completion of the real-time study, manufacturers shall substantiate provisional shelf-life claims as described in 11.4.

NOTE 1 Conformance with the requirements of 11.2 does not imply that the shelf life of the product has been determined.

NOTE 2 A practical limit of 5 years has been set for the shelf life because manufacturers have no control over storage conditions once condoms have been distributed.

Shelf life estimates (11.4) shall be based on a temperature of $\left(30^{+5}_{-2}\right)$ °C for all climatic conditions and should be carried out on condoms from the same production lots as used for real-time determination of shelf life (11.3).

NOTE 3 The choice of $\left(30^{+5}_{-2}\right)$ °C as the reference temperature for shelf life estimates is based on studies that have confirmed the mean kinetic temperate of the most extreme temperature zones is approximately 30 °C[14,15]. See Annex L for more details.

11.2 Minimum stability requirements

Test three lots of condoms for conformity with this document, except for subclause 15.2 and 15.3.

Only lots meeting all the requirements of Clauses 9, 10, 12, 13, and 14 shall be used for this test.

Condition samples in their individual sealed containers according to Annex I, one set for (168 ± 2) h (1 week) at (70 ± 2) °C and the other set for (90 ± 1) days at (50 ± 2) °C. At the end of the incubation periods, withdraw the condoms and test for conformance with the requirements of Clauses 10, 12, and 14 using as a minimum the sampling plans specified in Annex A or preferably the sampling plans in Annex B.

This test ensures that the condoms have adequate stability to be placed on the market pending verification of shelf life claims. It is not predictive of shelf life. Purchasers, test laboratories, regulatory authorities, and other interested parties can confirm that condoms meet the minimum stability requirements by testing condom lots for conformance with the requirements of Clause 10 after oven conditioning for (168 ± 2) h (1 week) at (70 ± 2) °C. When such testing is carried out, it might be appropriate to use reduced inspection levels.

The test report shall include the relevant requirements of Annexes H, K, M and N, and Clause 16.

NOTE Data to verify conformance with 11.2 can be extracted from studies for estimates of shelf life (11.4).

11.3 Procedure for determining shelf life by real-time stability studies

Real-time stability testing shall be conducted on three lots of condoms meeting all the requirements of Clauses 9, 10, 12, 13, and 14. Real-time stability studies shall continue for the full period of the shelf life claim. In no case shall shelf life claim exceed 5 years.

For condoms placed on the market based upon accelerated stability studies, if the real-time data indicates a shorter shelf life than that claimed based on accelerated ageing (11.4), the manufacturer shall notify the relevant regulatory authorities and direct purchasers. The manufacturer shall change the shelf life claim for the product to one based upon the real-time study.

Test three lots of condoms for conformity with this document, except for 15.2 and 15.3.

After conditioning according to Annex K using the sampling plans specified in Annex A or preferably the sampling plans in Annex B, the condoms shall meet the requirements specified in Clauses 10, 12, and 14.

The test report shall conform to the requirements of Clause 16 and include the results of testing according to Annexes H, M and N, and the shelf life together with the methods used to determine the shelf life and supporting data.

11.4 Estimating shelf life based upon accelerated stability studies

Pending the completion of real-time studies, manufacturers shall substantiate provisional shelf life claims. Accelerated stability studies may be used for this purpose.

Test three lots of condoms for conformity with this document, except for 15.2 and 15.3.