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Natural rubber latex male condoms - Requirements and test methods (ISO/DIS 4074:2024)

Kondome aus Naturkautschuklatex für Männer- Anforderungen und Prüfverfahren (ISO/DIS 4074:2024)

Préservatifs masculins en latex de caoutchouc naturel - Exigences et méthodes d'essai (ISO/DIS 4074:2024)

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Natural rubber latex male condoms — Requirements and test methods

Préservatifs masculins 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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

This fourth edition cancels and replaces the third edition (ISO 4074:2015), which has been technically revised. The main changes are as follows:

a) Annex P has been made normative. The standard now covers all condom sizes including those with dimensions specified in Annex P.

b) 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.

c) A new Annex Q is included in the standard which describes procedures for verifying the test methods for freedom from holes described in Annex M of this standard and ASTM D3492 [7] are meeting performance requirements. The procedures may also be used for personnel training and competency assessment purposes.

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

e) 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.

f) A statement has been added to Annex A emphasising that when a minimum sample size is specified by reference to a specific code letter for a test procedure, that minimum sample size applies even if reduced inspection is implemented through the use of the switching rules unless it is agreed between the manufacturer and the purchaser that reduced sampling may be implemented.

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

h) In Annex G it has been made clear that a Stomacher® is a specific type of mixer that may 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.

i) An alternative dry vacuum method for testing the integrity of individual condom containers has been included in Annex N. This method provides extra security against leakage, for example when condoms are being shipped by air freight or to high altitude countries.

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

k) 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 may be stored in high temperature environments.

l) Annex O has been made normative and amended to include a new section to verify that technicians can unroll the condoms correctly.

Regulatory agencies, notified bodies, and purchasers should consider the need for a transition period when implementing the requirements of this International Standard to allow manufacturers to make the changes required to maintain compliance.

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 International Standard.

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[4] 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 International Standard. Methods that can be used to determine bioburden levels are included in Annex G.

This International Standard 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 might be subject to specific local requirements as required by national regulatory bodies in addition to those specified in this International Standard.

ISO 16038[5] provides guidance for the application of ISO 4074:2015. It includes additional information on the test methods and requirements specified in this International Standard.

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

Natural rubber latex male condoms — Requirements and test methods

1 Scope

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

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

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for skin sensitization*

ISO 10993-23, *Biological evaluation of medical devices — Part 23: Tests for irritation*

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

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

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

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

3 Terms and definitions

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

3.1
acceptance quality limit
AQL
quality level that is the worst tolerable process average when a continuing series of lots 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
package, 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 to identify uniquely the lot numbers of individual condoms contained in that package, and from which it is possible to trace those lots 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 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
hole in a condom that is not visible under normal or corrected vision but is detected by the water leak test or the electrical test described in this International Standard

3.14
sampling plan
specific plan which indicates the number of units of product from each lot 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 specified in this International Standard

3.16
visible hole
hole 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 subject to the requirements specified in 11.1

3.18
visible defects (other than holes and tears)
broken, missing, or severely distorted bead and permanent creases with adhesion of the film

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[4].

Condoms are mass produced articles manufactured in very large quantities. 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 International Standard. Further, most of the test methods described in this International Standard are destructive. For these reasons the only practicable method of assessing conformity with this International Standard 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 ISO/TR 8550[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 are recommended when five or more lots are being tested.

b) Annex B describes sampling plans, based on ISO 2859-1, that are recommended for the assessment of isolated lots. 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. It is recommended that these sampling plans are used for the assessment of fewer than five lots, for example in cases of dispute, for referee purposes, for type testing, for qualification purposes, or 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.

NOTE This International Standard 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 according to 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 and 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 1 General methods for determining microbial contamination on sterile medical devices are given in ISO 11737-1[3]. It includes methods for validation testing (ISO 11737-1:). The methods described in Annex G of this International Standard 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.

NOTE 2 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.