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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 second edition cancels and replaces the first edition (ISO 4074:2002), which has been technically revised. It also incorporates the Technical Corrigenda ISO 4074:2002/Cor.1:2003 and ISO 4074:2002/Cor.2:2008. The modifications are as follows:

a) The maximum lot size has been limited to 500 000.

b) Specific requirements for biocompatibility assessments, as defined in ISO 10993-1, have been added.

c) It is recommended that manufacturers establish procedures for the periodic monitoring of microbial contamination (bioburden) as part of their quality management system including requirements for the 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.

d) Specific requirements for extra strength condoms have been deleted but there is now a general requirement for manufacturers to justify any additional claims made for their products; claims relating to improved efficacy or safety have to be substantiated by clinical investigation.

e) A minimum airburst volume of 28,0 dm^3 has been introduced for condoms with mid-body widths that are greater than or equal to 65,0 mm and not more than 75,0 mm.

f) The radius of the inner edge of the clamping collar wherever it contacts the inflated condom has to be a minimum of 2 mm (Annex H).

g) The volumes of electrolyte used in the electrical test for determining freedom from holes described in Annex M have been brought into line with the volumes used for the water leak test.

h) The volumes of water or electrolyte specified in the freedom from holes test have been increased for condoms that have mid-body widths greater than or equal to 56 mm and/or are longer that 210 mm.

i) When conducting the electrical test for freedom from holes, the voltage is now measured from the time that the condom is first immersed and for up to 10 s after full immersion.

j) The method of testing for freedom from holes specified in ASTM D3492[8] has been included by reference.

k) A limit has been introduced for the number of individual containers with visibly open seals, to be evaluated when the containers are inspected during the freedom from holes test described in Annex M.

l) Recommended requirements for minimum airburst properties and freedom from holes testing for condoms narrower than 45 mm and/or shorter than 160 mm have been introduced in informative Annex P to provide guidance to regulatory authorities, Notified Bodies and other interested parties when assessing condoms that fall outside of the normative size range specified in the standard.

m) Amendments have been made to the methods for determining the shelf life of condoms including a simplified procedure for determining the shelf life by accelerated stability studies based on fixed ageing periods at 50 °C.

n) Testing for freedom from holes, airburst properties and package integrity are required when conducting stability studies to establish that condoms meet the minimum stability requirements specified in the standard and when determining condom shelf lives.

o) The procedure for determining the thickness of a condom by the micrometer method is described in detail.

p) An alternative method of removing the lubricant from the condom using an aqueous surfactant solution has been introduced into the method for determining the amount of lubricant on the condom.

q) Revisions have been made to labelling requirements including the additional information supplied with the condom.

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. This applies particularly to the changes in packaging and labelling specified in Clause 15.

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.

In order 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[5] 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 or modified condom before the product is placed on the market and to initiate real-time stability studies. These requirements are described in Clause 11. The real-time stability test may 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[6] provides guidance for the application of this International Standard. It includes additional information on the test methods and requirements specified in this International Standard.

Natural rubber latex male condoms — Requirements and test methods

1 Scope

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 irritation and skin sensitization*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — 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*

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

3.4
expiry date
date after which the condom should not be used

3.5
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.

3.6
individual container
primary package containing a single condom

3.7
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]

3.8
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

3.9
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

3.10
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

3.11
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)

3.12
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

3.13
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

3.14
date of manufacture
date specified by the manufacturer when the product was made subject to the requirements specified in 11.1

3.15
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 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, the majority 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.

When on-going verification is required of the quality of condoms, it is suggested that, instead of concentrating solely on evaluation of the final product, attention is also directed at the manufacturer's quality system. In this connection it should be noted that ISO 13485[4] covers the provision of an integrated quality system for the manufacture of medical devices.

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 in order 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 or following a significant change to the formulation or manufacturing process, biocompatibility assessments shall be conducted in accordance with ISO 10993-1. Evaluation for cytotoxicity according to ISO 10993-5, irritation according to ISO 10993-10 and sensitization (delayed contact hypersensitivity) according to ISO 10993-10 shall be conducted. The condom together with any lubricant, additive, dressing material, or powder applied to it shall be evaluated.

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

NOTE 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. The standard includes methods for validating testing (ISO 11737-1:2006, Annex C). 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 need 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 International Standard may be 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 including regulatory authorities and Notified Bodies.

9 Design

9.1 Integral bead

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

9.2 Lubrication

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 criteria of compliance shall be as agreed between the parties concerned.

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.

9.3 Dimensions

9.3.1 Length

When tested by the method given in Annex D, taking 13 condoms from each lot, no individual measurement shall be below 160 mm.

Condoms that do not comply with the limit specified above cannot be claimed to meet ISO 4074.

9.3.2 Width

When tested by the method given in Annex E measuring at the narrowest part of the condom in the range of 20 mm to 50 mm from the open end, taking 13 condoms from each lot, no measurement of the width shall deviate from the nominal width stated by the manufacturer by more than ± 2 mm.

9.3.3 Thickness

If verification is required of the thickness of a condom, the average thickness, determined 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;

10 Bursting volume and pressure

When determined in accordance with Annex H, the bursting pressure shall not be less than 1,0 kPa and the bursting volume shall be not less than:

— 16,0 dm^3 for condoms with a mid-body width greater than or equal to 45,0 mm and less than 50,0 mm; or

— 18,0 dm^3 for condoms with a mid-body width greater than or equal to 50,0 mm and less than 56,0 mm; or

— 22,0 dm^3 for condoms with a mid-body width greater than or equal to 56,0 mm and less than 65,0 mm: or

— 28,0 dm^3 for condoms with a mid-body width greater than or equal to 65,0 mm and not more than 75,0 mm.

For the purpose of this test, the mid-body width is the mean flat width rounded to the nearest 0,5 mm of 13 condoms measured in accordance with Annex E at a point (75 ± 5) mm from the closed end excluding the reservoir tip.

The compliance 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.

Condoms that do not comply with the limits specified above cannot be claimed to meet ISO 4074.

For condoms that have a mid-body width less than 45,0 mm and/or are shorter than 160 mm excluding the reservoir tip, guidelines for bursting pressures and volumes are given in Annex P. Marketing of these products is at the discretion of the appropriate regulatory authorities or Notified Bodies.

11 Stability and shelf life

11.1 General

Manufacturers shall verify that the condoms comply with the requirements of Clauses 10, 12 and 14 until the end of the labelled shelf life. Products on the market at the time of publication of this International Standard whose shelf lives have been established according to the procedures specified in ISO 4074:2002 shall be deemed to comply with the shelf life claims of this International Standard unless the manufacturer has made significant changes to the process, formulation or packaging type. 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 period. The stored condoms shall be protected from exposure to excessive temperatures, light, ozone and any other factor that could affect the shelf life of the packaged condoms.

Assessment for minimum stability and shelf life claims shall be verified on condoms that have been stored in bulk for the maximum permitted period between dipping and packaging, and 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 including regulatory authorities, Notified Bodies and testing laboratories.

Before compliance with this International Standard may be claimed for a new or modified condom design, the manufacturer shall provide evidence that the following requirements have been met:

— the condom shall comply 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 shelf-life claims as described in 11.4.

NOTE 1 A modified condom design is one in which there have been significant changes to the formulation, manufacturing process or individual sealed containers.

NOTE 2 Compliance with the requirements of 11.2 does not imply that the shelf life of the product has been determined.

NOTE 3 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 mean kinetic 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).

11.2 Minimum stability requirements

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

Only lots meeting all of 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 compliance 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.

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

NOTE 1 Data to verify compliance with 11.2 may be extracted from studies for estimates of shelf life (11.4).

NOTE 2 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 and other interested parties may use this test to confirm that condoms meet the minimum stability requirements.

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 of 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 on the basis of 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 International Standard, except for 15.2 and 15.3.

After testing 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 include the requirements of Annexes H, K, M and N, and Clause 16.

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 International Standard, except for 15.2 and 15.3.

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

Further information on accelerated studies is provided in Annex L. Data generated from such studies shall support the claim that the condoms fulfil the requirements in Clauses 10, 12 and 14 for the duration of the labelled shelf life at $\left(30^{+5}_{-2}\right)$ °C.

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

12 Freedom from holes

When tested by either method described in Annex M, the compliance level, for each lot, for the sum of condoms with visible and non-visible holes and tears shall be an AQL of 0,25.

The method for testing for freedom from holes specified in ASTM D3492 may also be used.

Condoms that have a mid-body width less than 45 mm and/or are shorter than 160 mm excluding the reservoir tip cannot be claimed to meet ISO 4074. Guidelines for the volume of water or electrolyte to be used in the freedom from holes test for these condoms are given in Annex P. Marketing of these products is at the discretion of the appropriate regulatory authorities or Notified Bodies.

13 Visible defects

For visible defects specified in M.2.3.4 and M.3.3.5, the compliance level for each lot shall be an AQL of 0,4.