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Natural rubber latex condoms — Requirements and test methods

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

(Revision of first edition ISO 4074:2002 and ISO 4074:2002/Cor 1:2003)

ICS 11.200

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 4074 was prepared by Technical Committee ISO/TC 157, *Mechanical Contraceptives*.

This second edition cancels and replaces the first edition (ISO 4074:2002), of which has been technically revised.

Introduction

The intact latex film has 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. 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. Therefore they should be produced under a good quality management system. Reference should be made, for example, to ISO 13485, the ISO 9000-series and ISO 14971.

Condoms are non-sterile medical devices but manufacturers should take appropriate precautions to minimise microbiological contamination of the product during manufacture and packaging.

This edition of ISO 4074 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 10. 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 manufactures have adequate data to support shelf life claims before products are placed on the market and that this data is 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.

A guideline ISO 16038 for the application of this International Standard has been published by ISO/TC 157.

Natural latex rubber condoms — Requirements and test methods

1 Scope

This International Standard specifies the minimum requirements and the test methods to be used for male condoms made from natural rubber latex which are supplied to consumers for contraceptive purposes and to assist in the prevention of sexually transmitted infections.

2 Normative references

The following referenced documents are indispensable for the application 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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

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 delayed-type hypersensitivity*

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

EN 980, *Graphical symbols for use in the labelling of 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
acceptable quality limit
AQL
quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling (according to ISO 2859-1)

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

NOTE If a consumer could reasonably consider a device to be a condom (due to its shape, packaging, etc.), it is considered a condom for the purpose of this International Standard.

3.3
consumer package
package, intended for distribution to a consumer, containing one or more individual containers of condoms

3.4
expiry date
date at the end of the shelf life

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 When the consumer package contains only one kind of condoms 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
relationship between lot size and sample size

NOTE For description see ISO 2859-1:1999, 10.1.

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
lot test
test to assess the conformity of a lot

NOTE A lot test may be limited to include only those parameters which may change from lot to lot.

3.11
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

3.12
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)

3.13
shelf life
period from date of manufacture, during which condoms are required to conform to the requirements of Clauses 9, 11 and Clause 13

3.14
visible hole
hole in the condom that is visible under normal or corrected vision before the condom is filled with water or electrolyte during the freedom from holes test

3.15
date of manufacture
the date of dipping or the date the condoms are packed in their individual containers provided that, in the latter case, a maximum period of bulk storage is specified and shelf life studies have been conducted on condoms that have been subjected to the maximum bulk storage period

3.16
visible defects (other than holes and tears)
broken, missing or severely distorted rim 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 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, the party concerned also directs his attention to the manufacturer's quality system. In this connection it should be noted that the ISO 9000 series and, in particular, ISO 13485 [10] cover the provision of an integrated quality system.

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 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.

c) Handling and storage conditions are to be documented before drawing the samples.

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.

5 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. Testing 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 tested. Regulatory bodies may also specify specific local requirements. Accredited laboratories shall be used for the testing. Regulatory bodies may require the results to be interpreted by a qualified toxicologist. The biological assessment report shall justify that the product is safe under normal conditions of use.

6 Lot size

The maximum individual lot size for production is 500 000.

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.

7 Product claims

Condoms meeting the requirements of this International Standard can be used for contraceptive purposes and 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 clinical investigation.

8 Design

8.1 Integral bead

The open end of the condom shall terminate in an integral bead and shall conform to Clause 12.

8.2 Lubrication

If verification is required of the quantity of lubricant in a package, the method given in Annex C shall be used. The criteria of compliance shall be as agreed between the parties concerned.

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

8.3 Dimensions

8.3.1 Length

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

8.3.2 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.

Where the design of the condom is such that this measurement cannot be made reliably or the narrowest point within the first 50 mm from the open end of the condom is at the bead, the method of measurement shall be provided by the manufacturer.

8.3.3 Thickness

If verification is required of the thickness of a condom, the thickness, determined in accordance with one of the methods given in Annex F shall be equal to the claimed thickness, subject to a tolerance of ± 0.01 mm.

9 Burst volume and pressure

When determined in accordance with Annex G, 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 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.

For the purpose of this test, take the mid-body width to be the mean flat width of 13 condoms measured in accordance with Annex E at a point (75 ± 5) mm from the closed end.

The compliance level for each lot shall be an AQL of 1,5 for condoms that fail the requirement for volume, or pressure or both, or any condom that exhibits obvious leakage.

10 Stability and shelf life

10.1 General

Manufacturers shall verify that the condoms comply with the requirements of Clauses 9, 11 and 13 of this International Standard until the end of the labelled shelf life. Shelf life claims shall not exceed five years.

Data supporting the shelf life claims made by the manufacturer shall be made available to the appropriate regulatory authorities and direct purchasers upon request.

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 be tested for the minimum stability requirements as described in 10.2;

— a real-time study as described in 10.3 to determine shelf life shall have commenced;

— pending completion of the real-time study manufacturers shall substantiate shelf-life claims as described in 10.4.

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 10.2 does not imply that the shelf life of the product has been determined.

Shelf life estimates (10.4) shall be based on a mean kinetic temperature of (30^{+5}_{-2}) °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 (10.3).

10.2 Minimum stability requirements

Test three lots of condoms for conformity with this International Standard, except 14.2 and 14.3, using the sampling plans given in Annex B.

Only lots meeting all of the requirements of Clauses 8, 9, 11, 12 and 13 shall be used for this test.

Incubate samples in their individual sealed containers according to Annex H, 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 airburst properties according to Annex G and the requirements of Clauses 9, 11 and 13.

The test report shall include the requirements of Annex G and Clause 15.

NOTE 1 Data to verify compliance with 10.2 can be extracted from studies for estimates of shelf life (10.4).

NOTE 2 This test ensures that the condoms have adequate stability to be placed on the marked pending verification of shelf life claims. It is not predictive of shelf life. Purchasers, test laboratories and other interested parties can use this test to confirm that condoms meet the minimum stability requirements.

10.3 Procedure for determining shelf life by real time stability studies

After testing according to Annex J the condoms shall meet the requirements in Clauses 9, 11 and 13.

If the real-time data indicates a shorter shelf life than that claimed on the basis of accelerated ageing (10.4) the manufacturer shall notify the relevant regulatory authorities and direct purchasers. The manufacturer shall change the shelf life claims for the product to one based upon the real time study. In no case shall shelf life exceed 5 years.

For condoms placed on the market based upon accelerated stability studies, real time stability studies shall be completed for the full period of the shelf life claim.

10.4 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.

Further information on accelerated studies is provided in Annex K. Data generated from such studies shall support the claim that the condoms fulfil the requirements in Clauses 9, 11 and 13 for the duration of the labelled shelf life at (30^{+5}_{-2}) °C.

11 Freedom from holes

When tested by either method described in Annex L, 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.

12 Visible defects

For visible defects (L.2.3.3, L.3.3.4), the compliance level for each lot shall be an AQL of 0,4.

13 Package integrity of individual container

When an individual container comprising one or more laminar strips sealed together is tested in accordance with Annex M, it shall pass the test. The compliance level for each test shall be an AQL of 2,5.

For other designs of individual container, the manufacturer shall apply a suitable pack integrity test of equivalent sensitivity to Annex M and each container shall pass. The compliance level for each test shall be an AQL of 2,5.

14 Packaging and labelling

14.1 Packaging

Each condom shall be packed in an individual container. One or more individual containers may be packed in other packaging such as a consumer package. The individual container, or consumer package or both shall be opaque to light. If condoms are intended to be supplied only in individual containers, the individual containers shall be opaque.

If a marking medium, such as ink, is used on a condom or on any part of a package directly in contact with a condom, it shall not have any deleterious effect on the condom or be harmful to the user.

Individual containers and any other packaging shall protect the condom from damage or loss of lubricant during normal transport and storage.

Individual containers and any other packaging shall be designed in such a way that the pack can be opened without damaging the condom. The design of the individual container should facilitate easy opening.

14.2 Labelling

NOTE National regulations might apply in relation to labelling especially for latex allergy etc.

14.2.1 Symbols

If symbols are used on packaging, information and marketing materials, the symbols shall meet the requirements in ISO 15223 or EN 980.

14.2.2 Individual container

Each individual container shall be indelibly marked with at least the following information:

a) the identity of the manufacturer or distributor or, if permitted by local regulations the registered brand or trade mark;

b) the manufacturer's identifying reference for traceability (e.g. the lot number);

c) the expiry date (year, month). The format of the year shall be in four digits; the format of the month shall be in letters or two digits.

14.2.3 Consumer package

Where products are supplied for distribution in consumer packages, the packages shall conform to 14.2.3.1 and 14.2.3.2.