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Natural latex rubber condoms — Requirements and test methods

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

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

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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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 4074 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives*.

This first edition of ISO 4074 cancels and replaces ISO 4074-1:1996, ISO 4074-2:1994, ISO 4074-3:1994, ISO 4074-4:1980, ISO 4074-5:1996, ISO 4074-6:1996, ISO 4074-7:1996, ISO 4074-8:1984, ISO 4074-9:1996, ISO 4074-10:1990 and ISO 4074-12:1980.

Annexes A, C, D, E, F, G, H, I, J, L, M and N form a normative part of this International Standard. Annexes B, K, O and P are for information only.

This corrected version of ISO 4074:2002 incorporates correction in the Foreword, where the years of publication of the parts of ISO 4074 being replaced by the new edition were erroneously omitted.

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 for 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.

The condom and any lubricant, additive, dressing, individual packaging material or powder applied to it should neither contain nor liberate substances in amounts that are toxic, sensitizing, locally irritating or otherwise harmful under normal conditions of storage or use. Reference should be made to ISO 10993 for test methods to evaluate the safety of condoms particularly in respect of the risk of local irritation and sensitization.

Condoms are medical devices. Therefore they should be produced under a good quality management system. Reference should be made, for example to the ISO 9000-series, ISO 14971-1 and one of the relevant standards: ISO 13485 or ISO 13488.

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

This first 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 7. The real-time stability test can be considered as part of the manufacturer's 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.

A guideline (ISO 16038) for the application of this International Standard is under development by ISO/TC 157/WG 14.

This International Standard contains requirements for tensile properties (force at break) when a manufacturer makes a claim for "extra strength". Annex I contains the test method for determination of force and elongation at break, as it may be useful in the quality system of a manufacturer and in very special cases in a purchaser's contract.

Background information including technical explanations relating to certain clauses of this International Standard is given in annex P. Where this is relevant, the appropriate clause in annex P is referenced in the text.

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 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 normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 188, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests*

ISO 2859-1:1999, *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 International Standard, the terms and definitions given in ISO 2859-1 and the following apply.

3.1
acceptable quality limit
AQL
When a continuous series of lots is considered, the quality level which for the purposes of sampling inspection is the limit of a satisfactory process mean (according to ISO 2859-1)

3.2
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 responsibly 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

3.4
expiry date
stated date after which a 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 packaging and distribution

NOTE When the consumer package contains only one kind of condom, then the identification number may be the same as the lot number. But if the consumer package contains several different types of condom, for instance condoms of different shapes or colours, then the identification number will be different from the lot number.

3.6
individual container
immediate wrapping of 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

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. Attention is drawn to the difficulties that can be associated with the distribution and control of very large lots. The recommended maximum individual lot size for production is 500 000.

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

NOTE For testing purposes, sampling is conducted by lot number, not identification number. See requirements in clause 4.

3.10
lot test
test to assess the compliance 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 the condom that is not visible under normal or corrected vision but is detected by leakage when rolling on absorbant paper

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
time from date of manufacture to the claimed expiry date

3.14
visible hole
hole or tear in the condom that is visible under normal or corrected vision

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 may 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 compliance 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 selection of an acceptance sampling system, scheme or plan for the inspection of discrete items in a lot.

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 (see Bibliography) covers 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 compliance of a continuing series of lots. The full level of consumer protection available depends upon the switch to tightened inspection if a deterioration in quality is detected. The switching rules cannot offer 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 be 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 shall 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 Design

5.1 Integral bead

The open end of the condom shall terminate in an integral bead and shall comply with clause 9.

5.2 Lubrication

If the amount of lubricant in the package is specified, then this amount shall be determined by the method described in annex C.

The method in annex C also recovers part of the dressing powder on the condom. (See rationale, in P.7.) An allowance should be made for this when manufacturers or purchasers specify lubricant levels.

5.3 Dimensions

5.3.1 Length

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

5.3.2 Width

When tested by the method given in annex E, taking 13 condoms from each lot, no width measurement shall deviate from the nominal width stated by the manufacturer by more than $\pm$ 2 mm.

The width shall be measured at the narrowest part of the condom within 35 mm from the open end, or at a point specified by the manufacturer within the same area.

NOTE The width for determination of the requirements for burst volume as in 6.1 may be measured at the same time.

5.3.3 Thickness

If the thickness of the condom is specified, then it shall be determined by the method in annex F.

6 Burst volume and pressure

6.1 Untreated condoms

When tested in accordance with annex G, the bursting pressure shall be not less than 1,0 kPa and the bursting volume (rounded to the nearest 0,5 dm^3) shall be not less than:

— 16,0 dm^3 for condoms with a width less than 50,0 mm, or

— 18,0 dm^3 for condoms with a width greater than or equal to 50,0 mm and up to 56,0 mm, or

— 22,0 dm^3 for condoms with a width greater than or equal to 56,0 mm

The width is defined as the mean flat width of 13 condoms measured in accordance with annex E at a point (75 ± 5) mm from the closed end. (See rationale in annex P.)

The compliance level for each lot shall be an AQL of 1,5 for non-conforming condoms.

A non-conforming condom is defined as a condom that fails the requirement for volume, pressure, or both, or any condom that exhibits any leakage.

6.2 Lot testing for oven-treated condoms

The purpose of this test is to check for major formulation or vulcanization errors. When oven-treated as described in annex H for (168 ± 2) h at (70 ± 2) °C and tested according to annex G, the condoms shall meet the requirements of 6.1. This test does not provide information about the shelf life of the product.

This test is applicable only to condoms that are less than one year old from the date of manufacture.

6.3 Extra strength

6.3.1 General

If a manufacturer makes a claim that a particular brand of condoms is stronger or implies that a particular brand of condoms provides extra protection or safety in use because the condoms are stronger than regular condoms, then the additional requirements for “Extra Strength” condoms defined in this section shall apply. (See annex P.)

6.3.2 Requirements for mechanical properties

When tested according to annex G, the minimum bursting pressure shall be not less than 2,0 kPa and the bursting volume shall conform to the requirements of 6.1.

When tested according to annex I, the minimum mean force at break shall be 100 N based on the mean of 13 condoms selected at random from each lot of condoms.

6.3.3 Requirements for clinical data

Manufacturers shall substantiate the extra-strength claims with clinical data or prominently display on the pack the statement given in 11.2.3.2.

The clinical data shall substantiate a statistically significant reduction in breakage rate for the extra strong condom when compared in a random, double blind trial to a reference, marketed condom from normal production produced by the same manufacturer. The reference condom shall comply with the requirements of ISO 4074 and shall exceed 0,060 mm single wall thickness at the mid body.

Useful references are ISO 14155 or EN 540 and ISO 16037 (in preparation).

7 Tests for stability and shelf life

7.1 General

Manufacturers shall verify that the condoms comply with the requirements of 6.1 of this International Standard until the end of the labelled shelf life. Shelf-life claims shall not exceed five years (see annex P).

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 a new or modified condom design is placed on the market, the following requirements shall be met.

— The condom shall be tested for the minimum stability requirements as described in 7.2.

— A real-time study as described in 7.3 to determine shelf life shall have commenced.

— Pending completion of the real-time study, shelf life shall be estimated as described in 7.4.

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

Shelf-life estimates (7.4) shall be based on a mean kinetic temperature of 30 °C for all climatic conditions and may be carried out on condoms from the same production lots as used for real-time determination of shelf life (7.3).

For existing designs on the market at the date of publication of this International Standard, real-time data in a form consistent with annex J, and at temperatures consistent with local regulatory requirements prevailing at the time the product was introduced, shall be acceptable, to verify the shelf-life claims.

7.2 Minimum stability requirements

Test three lots of condoms for compliance with ISO 4074, except 11.2 and 11.3, using the sampling plans given in annex B.

Only lots meeting all of the requirements of ISO 4074, except 11.2 and 11.3, shall be used for this test.

Incubate samples in their individual sealed containers according to annex H, one set for (168 ± 5) 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 6.1.

The test report shall include the requirements of annexes G and N.

NOTE Data to verify compliance with 7.2 can be extracted from studies for estimates of shelf life (7.4).

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

After testing according to annex J the condoms shall meet the requirements in 6.1.

If the real-time data indicate a shorter shelf life than that claimed on the basis of accelerated ageing (7.4), 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. In no case shall shelf life exceed five years. For condoms placed on the market, real-time stability studies shall be completed for the full period of the shelf-life claim.

7.4 Estimating shelf life based upon accelerated stability studies

Pending the completion of real-time studies, accelerated stability studies shall be used to estimate the shelf life.

At the date of publication, no single method of analysis was sufficiently validated or widely used to justify its designation as a standard method. Several approaches to the analysis of accelerated-ageing data have been explored. It is anticipated that as manufacturers and regulatory agencies accumulate real-time data, a consensus method for the next revision of this International Standard will be developed. Meanwhile, the results of accelerated-ageing data may be analysed by a number of methods or as stipulated by the manufacturer's regulatory authority.

Examples of methods for accelerated studies and data analysis are provided in annex K. Data generated from such studies shall support the claim that the condoms fulfil the requirements in 6.1 for the duration of the labelled shelf life at 30 °C.

8 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.

9 Visible defects

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

10 Package integrity

When requested by a customer or a regulatory body, the manufacturer or supplier shall provide information on package integrity based upon the test method given in annex M. The compliance level for each lot shall be an AQL of 2,5.

11 Packaging and labelling

11.1 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. However packaged, the packaging shall protect the condom from light even if only the individual package is provided to the consumer.

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 during 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. (See rationale in annex P.)

11.2 Labelling

11.2.1 Symbols

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

11.2.2 Individual container

Each individual container shall bear at least the following information:

a) the identity of the manufacturer or distributor. (See rationale in annex P);

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. (See rationale in annex P.)

11.2.3 Consumer package

11.2.3.1 General

The outside of the consumer package shall bear at least the following information in at least one of the official language(s) of the country of destination or as stipulated differently by that country:

a) a description of the condom, including whether or not it has a reservoir. If the condom is coloured or textured this shall be stated;

b) the number of condoms contained;

c) the nominal width of the condom;

d) the name or trade name and address of the manufacturer and/or distributor, depending on national and regional requirements. (See rationale in annex P);

e) the expiry date (year and month). The format of the year shall be in four digits and the format of the month shall be in letters or two digits. If a consumer package includes condoms from different lots, the earliest expiry date shall apply to all condoms;

f) a statement to store the condom in a cool dry place away from direct sunlight;

g) a statement that individual containers, if not opaque to light, should not be stored outside the opaque consumer package;

h) whether the condom is lubricated or dry. When a medicinal ingredient is added, it shall be identified and its purpose indicated (e.g. spermicidal). If the condom or lubricant is fragranced or flavoured, this shall be stated;

i) the manufacturer's identifying reference for traceability (e.g. the identification number/lot number). If different types of condoms, e.g. different colours, are packaged together in the same consumer package, the identification number on the consumer package shall allow the manufacturer to identify uniquely the lot numbers of the individual condoms contained in that package, so that it is possible to trace those lots through all stages of manufacture up to packaging;

j) a statement that the condom is made of natural rubber latex.

11.2.3.2 Labelling of extra-strong condoms

A claim such as “extra strong” implies that the condoms have a lower level of breakage than a “regular” condom. Such claims shall be supported by clinical investigations. (See 6.3.3.)

If the manufacturer wishes to use the claim “extra strong” pending the completion of a clinical study, the labelling shall state:

“This extra-strong condom has not been shown to be safer in use than regular condoms.”

11.2.4 Additional information on the consumer package

The outside or the inside of the consumer package, or a leaflet contained within the consumer package, shall bear at least the following information expressed in simple terms, and in at least one of the official language(s) of the country of destination, if possible supplemented by pictorial representations of the major steps involved or as stipulated differently by that country.

a) Instructions for use of the condom, including

1) the need to handle the condom carefully, including removal from the package so as to avoid damage to the condom by fingernails, jewellery etc.;

2) how and when to put on the condom; mention should be made that the condom should be placed on the erect penis before any contact occurs between the penis and the partner's body to assist in the prevention of sexually transmitted infections and pregnancy;

3) the need to withdraw the penis soon after ejaculation, while holding the condom firmly in place at the base of the penis;

4) the need, if an additional lubricant is desired, to use the correct type of lubricant which is recommended for use with condoms and the need to avoid the use of oil-based lubricants such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine etc. as these are deleterious to the integrity of the condom;

5) the need to consult a doctor or pharmacist about the compatibility of topical medicines that may come in contact with the condom.

b) Instructions on how to dispose of the used condom.

c) A statement that the condom is for single use.

d) The number of this International Standard, i.e. ISO 4074. (See rationale in annex P.)

11.3 Inspection

From each lot, 13 consumer packages and 13 individual containers shall be inspected for compliance. All inspected containers shall comply with the requirements.

Under certain conditions it may be permissible for the manufacturer/distributor to correct faults associated with packaging and labelling requirements and resubmit the lot for further conformity testing. Examples include insertion

of missing instruction leaflets or re-packaging of individual containers into new complete consumer packages before placing on the market.

If condoms from the same lot are packed into different consumer packages, then at least one consumer package of each variant should be inspected. The number of packages inspected should not exceed 13 unless the number of variants exceeds 13.

12 Test report

Test reports shall contain at least the information as described in annex N.