INTERNATIONAL STANDARD

ISO 4074-1

Second edition
1996-12-01

Rubber condoms —

Part 1: Requirements

Préservatifs masculins en caoutchouc —

Partie 1: Exigences

Reference number
ISO 4074-1:1996(E)

Contents

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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.

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.

International Standard ISO 4074-1 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives.*

This second edition cancels and replaces the first edition (ISO 4074-1:1990), which has been technically revised.

ISO 4074 consists of the following parts, under the general title *Rubber condoms:*

– *Part 1: Requirements*

– *Part 2: Determination of length*

– *Part 3: Determination of width*

– *Part 5: Testing for holes – Water leakage test*

– *Part 6: Determination of bursting volume and pressure*

– *Part 7: Oven conditioning*

– *Part 9: Determination of tensile properties*

– *Part 10: Packaging and labelling – Condoms in consumer packages*

Annexes A, B, C and D of this part of ISO 4074 are for information only. Annex B, however, can be referred to in the absence of other stipulations.

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 diseases (STDs) and spermatozoa. In order to help ensure that condoms are effective for contraceptive purposes and in assisting in the prevention of transmission of STDs, it is essential that condoms fit 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 ISO 4074.

The sampling plans and acceptable quality levels (AQLs) given in this part of ISO 4074 are intended for referee testing. Manufacturers may devise and apply other quality control measures during production. These measures will be specific to production methods and plants, and may differ between manufacturers.

Condoms are not sterile medical devices, but manufacturers should take appropriate precautions to minimize microbiological contamination of the product during manufacture and packaging. Reference to the ISO 9000 series and associated guides is recommended to meet this requirement.

The condom and any lubricant, dressing 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 use. Reference should be made to ISO 10993-10.

Rubber condoms – Part 1: Requirements

1 Scope

This part of ISO 4074 specifies requirements for male condoms made from compounded natural rubber latex, supplied to consumers and designed for contraceptive purposes and to assist in the prevention of sexually transmitted diseases.

This part of ISO 4074 does not contain requirements for tensile properties of condoms. If determination of tensile properties is desired, the test method given in ISO 4074-9 can be used.

NOTE 1 Condoms are mass-produced articles. Inevitably there will be some variation between individual condoms, and a small proportion of condoms in each production run may contain defects. Information regarding the verification of quality of condoms and sampling plans to assess compliance of a batch of condoms with this part of ISO 4074 are given in annex A.

NOTE 2 Guidance on the determination of properties of condoms that have been stored after purchase is given in annex B.

NOTE 3 Recommendations on the storage of packaged condoms are given in annex C.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 4074. All standards are subject to revision, and parties to agreements based on this part of ISO 4074 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 2859-1:–[1], *Sampling procedures for inspection by attributes – Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection.*

ISO 4074-2:1994, *Rubber condoms – Part 2: Determination of length.*

ISO 4074-3:1994, *Rubber condoms – Part 3: Determination of width.*

ISO 4074-5:–[2], *Rubber condoms – Part 5: Testing for holes – Water leakage test.*

ISO 4074-6:–[3], *Rubber condoms – Part 6: Determination of bursting volume and pressure.*

ISO 4074-7:–[4], *Rubber condoms – Part 7: Oven conditioning.*

ISO 4074-10:1990, *Rubber condoms – Part 10: Packaging and labelling – Condoms in consumer packages.*

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1) To be published. (Revision of ISO 2859-1:1989)

2) To be published. (Revision of ISO 4074-5:1984)

3) To be published. (Revision of ISO 4074-6:1984)

4) To be published. (Revision of ISO 4074-7:1986)

3 Definitions

For the purposes of this part of ISO 4074, the definitions given in ISO 2859-1 and the following definitions apply.

3.1 batch: Number of condoms of the same design, colour, shape, size and latex formulation, manufactured continuously at essentially the same time, using the same process, the same raw materials, applying to the same specification, common equipment and the same personnel.

NOTE – This standard does not specify the size of a batch, but it may be 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 control of very large batches.

Batches normally range in size from 50 000 to 500 000 condoms, the most usual size in current and past practice being approximately 150 000.

3.2 acceptable quality level (AQL): When a continous series of batches are considered, the quality level which, for the purposes of sampling inspection, is the limit of a satisfactory process average.

4 Sampling

Sampling and establishment of the sampling plan shall be carried out in accordance with ISO 2859-1.

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

5 Design

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

Condoms may be of the designs given in the following list, which is not intended to be exhaustive: smooth, textured, parallel-sided, nonparallel-sided, plain-ended, reservoir-ended, dry, lubricated, flavoured, transparent, translucent, opaque or coloured, form-fitting.

6 Dimensions

When tested by the method given in ISO 4074-2, the length of the condom shall be not less than 160 mm. The width shall equal the nominal width stated by the manufacturer (see ISO 4074-10), within a tolerance of ± 2 mm, measured 30 mm ± 5 mm from the open end, determined in accordance with ISO 4074-3.

NOTE – Measurement of width is also required in clause 7. To save time, the measurements can be performed at the same occasion.

Each batch shall be sampled in accordance with ISO 2859-1, special inspection level S-2. When tested in accordance with ISO 4074-2 and ISO 4074-3, the compliance level shall be an AQL of 4,0 for each individual parameter.

7 Bursting volume and pressure

7.1 Untreated condoms

When tested in accordance with ISO 4074-6, the bursting pressure shall be not less than 1,0 kPa and the bursting volume shall be not less than 0,005 92 × $\overline{w}^2$ dm^3 (rounded off to the nearest 0,5 dm^3), where $\overline{w}$ is the average width of 13 condoms, expressed in millimetres of the shank portion of the condom, measured 70 mm ± 5 mm from the open end, determined in accordance with ISO 4074-3.

NOTE – Measurement of width is also required in clause 6. To save time, the measurements can be performed at the same occasion.

Each batch shall be sampled in accordance with ISO 2859-1, general inspection level 1. When tested in accordance with ISO 4074-6, the compliance level shall be an AQL of 1,0 for each individual property.

See table 1 for bursting volumes equating to common average widths.

Table 1 — Bursting volume

Average width $\overline{w}$ mm	Minimum bursting volume dm^3
47,0	13,0
47,5	13,5
48,0	13,5
48,5	14,0
49,0	14,0
49,5	14,5
50,0	15,0
50,5	15,0
51,0	15,5
51,5	15,5
52,0	16,0
52,5	16,5
53,0	16,5
53,5	17,0
54,0	17,5
54,5	17,5
55,0	18,0
55,5	18,0
56,0	18,5

7.2 Oven-treated condoms

When oven-treated in accordance with ISO 4074-7 and tested in accordance with ISO 4074-6, the bursting volume and pressure shall be as specified in 7.1.

Each batch shall be sampled in accordance with ISO 2859-1, at least special inspection level S-4. When tested in accordance with ISO 4074-6, the compliance level shall be an AQL of 1,0 for each individual property.

8 Freedom from holes

When tested in accordance with ISO 4074-5, there shall be no leakage through the wall of the condom.

Each batch shall be sampled in accordance with ISO 2859-1, general inspection level 1, but at least code letter M. When tested in accordance with ISO 4074-5 the compliance level shall be an AQL of 0,25.

9 Packaging and labelling

Condoms in consumer packages shall be packaged and labelled as specified in ISO 4074-10.

Individually packaged condoms shall meet the requirements in 9.1 and 9.2

9.1 Packaging

Each condom shall be packaged in an individual sealed container. The container shall be opaque to light.

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 should not be deleterious to the condom or harmful to the user.

Individual containers should protect the condom during transport and storage, should not mildew and should not attract insects.

Individual containers should be such that the condom does not suffer mechanical damage when the container is opened. Individual containers should have a feature to facilitate easy opening of the container.

9.2 Labelling

Each individual container or condom shall bear at least the following information:

a) the identity of the manufacture or distributor (e.g. trademark, name, abbreviated name);

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

c) the expiry date (year and month) or the expiry date and the date of manufacture (year and month).

Each batch shall be sampled in accordance with ISO 2859-1, special inspection level S-2. When examined visually, the compliance level shall be an AQL of 4,0 for the consumer package and the individual sealed containers.

Annex A
(informative)
Rubber condoms – Assessment of compliance

A.1 Quality verification

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 ISO 9002 (see annex D) covers the provision of an integrated quality system.

A.2 Sampling plans and compliance levels

If a party wishes to establish, by inspection and testing of samples of the final product, whether a batch of condoms produced to this part of ISO 4074 complies with its requirements, the sampling plans given in clauses 6, 7, 8 and 9, or higher levels of inspection, shall be applied.

The procedure may include:

a) on-going production testing and quality control by a manufacture;

b) testing, for contractual purposes, by a purchaser;

c) inspection by a national authority.

It is acknowledged that a manufacturer may devise and apply quality control measures specific to his production method and plant, and that these measures will differ between manufacturers.

However, for referee test, unambiguous procedures are necessary to validate claims of conformity with this part of ISO 4074.

Annex B
(informative)
Sampling plans for determination of properties of rubber condoms that have been stored after purchase

B.1 General

It is sometimes necessary or desirable to determine the properties of condoms that have been stored after purchase. The most usual instances are:

a) the wish of a purchaser to ensure that condoms which were purchased some time previously and which he has stored since then are suitable for release and use; or

b) to establish the properties of condoms purchased in small numbers, usually "over-the-counter", in order to compare their properties with those given in this part of ISO 4074 or in some other set of requirements.

The sampling can only apply to condoms from one and the same batch.

For third-party certification, sampling plans form part of the rules of a certification scheme and may vary, depending upon the details of the approved manufacturer's quality system. In order to allow the necessary flexibility for certification bodies to devise rules appropriate to each scheme, this part of ISO 4074 does not specify sampling plans for certification schemes.

B.2 Selection of sample size

If the batch size is known, the sampling plans given in annex A should be used, and the relevant acceptance and rejection numbers given in ISO 2859-1 should be used to assess the properties of the condoms. If the batch size is less than 10 001, 10 001 should be assumed to be the batch size.

If the size of the batch from which the condoms in question were derived is unknown, it should be assumed that the batch size is between 10 001 and 35 000.

B.3 Oven treatment of condoms tested after time of supply

The test and requirements given in this part of ISO 4074 for mechanical properties (see clause 7) are intended to be applied to condoms at the time of supply. Therefore they include an oven-treatment procedure intended to simulate the effect of normal storage, which together with requirements for untreated and oven-treated condoms, should ensure that the mechanical properties of the condom will remain satisfactory upon normal storage.

When testing the mechanical properties of condoms that have been held in store for some time, the application of the oven-treatment procedure is considered to be inappropriate, since the effects of the simulated ageing will already have been brought about naturally. For this reason, tests on condoms conducted more than 12 months from the date of manufacture (or date of purchase if manufacturing date is not known) should not include the oven-treatment procedure.

Annex C
(informative)
Rubber condoms – Storage recommendations

Rubber tends to deteriorate with age. Condoms are packed in a way which normally protects them during storage. Nevertheless, they should not be kept in stock longer than is necessary, especially in warm climates.

Condoms should be stored in a cool, dry place and should be kept in containers such that the contents will not be subject to mechanical damage or sunlight.

The condom, even in the package, should not be allowed to come into contact with oil-based antiseptic, phenols and their derivatives, petroleum-based grease, petroleum spirit, paraffin oil and other related organic products.

For more information on storage, see ISO 2230.

Annex D
(informative)
Bibliography

[1] ISO/IEC Guide 7:1994, *Guidelines for drafting of standards suitable for use for conformity assessment.*

[2] ISO 2230:1973, *Vulcanized rubber – Guide to storage.*

[3] ISO 4074-9:–[5], *Rubber condoms – Part 9: Determination of tensile properties.*

[4] ISO 9002:1994, *Quality systems – Model for quality assurance in production, installation and servicing.*

[5] ISO 10993-10:1995, *Biological evaluation of medical devices – Part 10: Tests for irritation and sensitization.*

5) To be published.