

INTERNATIONAL STANDARD

ISO
4074-1

First edition
1990-08-15

Rubber condoms —

Part 1:

**Requirements — Condoms in consumer
packages**

Préservatifs masculins en caoutchouc —

Partie 1: Exigences — Préservatifs masculins en emballages collectifs



Reference number
ISO 4074-1:1990(E)

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International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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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*.

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

- *Part 1: Requirements — Condoms in consumer packages*
- *Part 2: Determination of length*
- *Part 3: Determination of width*
- *Part 4: Determination of colour fastness*
- *Part 5: Testing for holes*
- *Part 6: Determination of bursting volume and pressure*
- *Part 7: Determination of resistance to deterioration during storage*
- *Part 8: Determination of mass*
- *Part 9: Determination of tensile properties*
- *Part 10: Packaging and labelling — Condoms in consumer packages*
- *Part 11: Requirements — Condoms in individual packages*
- *Part 12: Storage*

Annexes A, B, C, D and E of this part of ISO 4074 are for information only.

Annexes A and B, however, can be referred to for lack of other stipulations.

Rubber condoms —

Part 1:

Requirements — Condoms in consumer packages

EXAMPLE 1

4 Recommendations on the storage of packaged condoms are given in annex C, which does not form a normative part of this part of ISO 4074.

1 Scope

This part of ISO 4074 specifies requirements for condoms, made from compounded natural rubber latex, supplied in consumer packages, designed to be worn over the erect penis during sexual intercourse to prevent semen from entering the vagina and to assist in the prevention of sexually transmitted diseases. It does not apply to condoms supplied unpackaged or in individual packages. Requirements for condoms in individual packages will be given in ISO 4074-11.

NOTES

1 The efficacy of spermicidal and other active lubricants or dressing materials is not within the scope of ISO 4074. 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. A manufacturer may be required by a certification or inspection authority or by a purchaser to provide a certificate of composition and/or other properties.

2 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 that may be used in cases of dispute and to assess compliance with the standard of a batch of condoms or for reasons cited in A.1.2 in annex A, are given in annex A, which does not form a normative part of this part of ISO 4074.

3 Guidance on the determination of properties of condoms that have been stored after purchase is given in annex B, which does not form a normative part of this part of ISO 4074.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 4074. At the time of publication, the editions indicated were valid. 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 4074-2:1980, *Rubber condoms — Part 2: Determination of length.*

ISO 4074-3:1980, *Rubber condoms — Part 3: Determination of width.*

ISO 4074-4:1980, *Rubber condoms — Part 4: Determination of colour fastness.*

ISO 4074-5:1984, *Rubber condoms — Part 5: Testing for holes.*

ISO 4074-6:1984, *Rubber condoms — Part 6: Determination of bursting volume and pressure.*

ISO 4074-7:1986, *Rubber condoms — Part 7: Determination of resistance to deterioration during storage.*

ISO 4074-9:1980, *Rubber condoms — Part 9: Determination of tensile properties.*

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

3 Definitions

For the purposes of this part of ISO 4074, the following definitions apply.

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

NOTE 5 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 percent non-conforming: Percentage of condoms in a batch that fails in one or more respects to comply with the requirements of this part of ISO 4074.

4 Design

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

NOTE 6 Condoms may be of the designs given in the following list, which is not intended to be exhaustive: smooth, textured, parallel-sided, non-parallel-sided, plain-ended, reservoir-ended, dry, lubricated, transparent, translucent, opaque or coloured, form-fitting.

5 Dimensions

When tested by the methods given in ISO 4074-2 and ISO 4074-3 respectively, the length of the condom shall be not less than 160 mm, and the width shall equal the nominal width stated by the manufacturer (see ISO 4074-10) within a tolerance of ± 2 mm. The nominal width shall be in the range of 44 mm to 56 mm.

The percent non-conforming for each parameter shall be not greater than 4 %.

6 Bursting volume and pressure

6.1 Untreated condoms

When tested as described in ISO 4074-6, the bursting pressure shall be not less than 0,9 kPa and the bursting volume shall be not less than $(0,00555 \times$

$w^2)$ dm³ (rounded off to the nearest 0,5 dm³), where w is the nominal width of the condom in millimetres.

The percent non-conforming shall be not greater than 1,5 %.

NOTES

7 Derivation of the formula is given in annex D which does not form a normative part of this part of ISO 4074.

8 See table 1 for bursting volume equating to common nominal widths.

Table 1 — Bursting volume

Nominal width, w mm	Minimum bursting volume dm ³
47	12,5
49	13,5
50	14,0
52	15,0
53	15,5
54	16,0

6.2 Oven-treated condoms

When oven-treated and tested as described in ISO 4074-7, the bursting volume and pressure shall be as specified in 6.1.

The percent non-conforming shall be not greater than 1,5 %.

7 Tensile properties

7.1 Untreated condoms

When tested as described in ISO 4074-9, the tensile properties shall be not less than the values given in table 2, except for fully textured condoms for which no tensile strength requirements are specified.

The percent non-conforming shall be not greater than 2,5 %.

Table 2 — Tensile properties

Property	Full-textured condoms	Other condoms
Force at break	30 N	30 N
Tensile strength	No requirement	17 MPa
Elongation at break	650 %	650 %

7.2 Oven-treated condoms

When oven-treated and tested as described in ISO 4074-7, the tensile properties shall be as specified in 7.1.

The percent non-conforming shall be not greater than 1,5 %.

8 Freedom from holes

When tested as described in ISO 4074-5, there shall be no leakage through the wall of the condom and the percent non-conforming condoms shall be not greater than 0,4 %.

9 Colour fastness

When tested as described in ISO 4074-4, there shall be no staining of the absorbent paper and the percent non-conforming shall be not greater than 1,0 %.

10 Packaging and labelling

The condom shall be packaged and labelled as specified in ISO 4074-10.

When examined visually the percent of packages non-conforming shall be not greater than 1,0 %.

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Annex A (informative)

Rubber condoms — Assessment of compliance with Standard — Sampling plans and compliance levels

A.1 Quality verification

A.1.1 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 E) covers the provision of an integrated quality system.

A.1.2 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 clause A.2 to clause A.9 may be applied. For example:

- a) for type-testing of product;
- b) for on-going production testing and quality control by a manufacturer;
- c) for contractual purposes by a purchaser;
- d) by a national inspection 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, unambiguous procedures are necessary to validate claims of conformity with this part of ISO 4074, and for this purpose the sampling plans and compliance levels given in clause A.2 are to be used as reference procedures.

NOTES

9 If, in particular circumstances, different compliance levels are required, reference should be made to ISO 2859-1.

10 Sampling plans and compliance levels are given in annex B to give guidance on the determination of condom properties for purposes other than checking claims of conformity with this part of ISO 4074, e.g. inspection by a bulk purchaser of stocks of stored condoms prior to re-

lease for retail supply, or investigation of condoms purchased in the market place.

A.2 Sampling

Sampling and establishment of the sampling plan shall be carried out as described in ISO 2859-1. The definitions given in ISO 2859-1 apply together with those in clause 3 of this part of ISO 4074.

NOTE 11 It is necessary to know the batch size in order to derive from ISO 2859-1 the number of samples 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.

A.3 Unit of product

The unit of product shall be as given in clause A.4 to clause A.9 (i.e. individually packaged condoms except for the inspection of packaging, in which case the unit of product shall be the filled consumer package). The batch size shall be the number of individually packaged condoms, except for clause A.9 where it shall be the number of consumer packages.

A.4 Dimensions (length and width) (clause 5)

Unit of product:	individually packaged condom
Sampling plan:	ISO 2859-1, special inspection level S-2
Compliance level:	AQL of 4,0 (Individual for each parameter)

A.5 Bursting volume and pressure (clause 6)

Unit of product:	individually packaged condom
Sampling plan:	ISO 2859-1, general inspection level 1
Compliance level:	AQL of 1,5 (Individual for each parameter)

A.6 Tensile properties (clause 7)

Unit of product: individually packaged condom
Sampling plan: ISO 2859-1, special inspection level S-2
Compliance level: AQL of 2,5 (Individual for each parameter)

A.7 Freedom from holes (clause 8)

Unit of product: individually packaged condom
Sampling plan: ISO 2859-1, general inspection level 1
Compliance level: AQL of 0,4

A.8 Colour fastness (clause 9)

Unit of product: individually packaged condom
Sampling plan: ISO 2859-1, special inspection level S-2
Compliance level: AQL of 1,0

A.9 Packing and labelling (clause 10)

Unit of product: filled consumer package
Sampling plan: ISO 2859-1, special inspection level S-2
Compliance level: AQL of 1,0

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Annex B (informative)

Rubber condoms — Sampling plans for determination of properties of 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.

NOTE 12 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 6 and 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 after the time of supply should not include the oven-treatment procedure.

Annex C

(informative)

Rubber condoms — Storage recommendation

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. They 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. As soon as any condom shows deteri-

oration (for example, tackiness, brittleness) of the rubber, it should be destroyed.

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

For more information on storage, see ISO 2230.

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Annex D (informative)

Rubber condoms — Derivation of inflation volume formula

Let

w = flat width of condom;

r = radius of condom;

l = initial testing length of condom.

Assuming all condoms are cylindrical in shape and that dimension l is the same for all widths of condoms, the volume of air (V) in a condom is proportional to

$$\pi r^2 l$$

Now

$$w = \frac{2\pi r}{2}$$

$$r = \frac{w}{\pi}$$

Hence

$$V = K(w)^2$$

Basing the calculations on the minimum bursting volume of 15 dm³ for a 52 mm width condom, we have

$$K = 15/(52 \times 52) = 0.00555$$

By inserting this value for K in the above formula, the bursting volumes for other nominal widths are obtained.

NOTE 13 This is a simplistic approach.