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

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.

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.

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 whith 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 $\pm$ 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 (0,005 55 $\times$ w^2) dm^3 (rounded off to the nearest 0,5 dm^3), 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 %