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Rubber condoms —

Part 1: Requirements

*Préservatifs masculins en caoutchouc —
Partie 1: Exigences*



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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.*

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)