

INTERNATIONAL STANDARD

ISO
4074-10

Second edition
1990-08-15

Rubber condoms —

Part 10:

**Packaging and labelling — Condoms in
consumer packages**

Préservatifs masculins en caoutchouc —

*Partie 10: Emballage et étiquetage — Préservatifs masculins en
emballages collectifs*



Reference number
ISO 4074-10:1990(E)

Contents

	Page
1 Scope	1
2 Definition	1
3 Packaging	1
4 Labelling	1

STANDARDSISO.COM : Click to view the full PDF of ISO 4074-10:1990

© ISO 1990

All rights reserved. No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

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

Printed in Switzerland

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 4074-10 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives*.

This second edition cancels and replaces the first edition (ISO 4074-10:1980), of which it constitutes a technical revision.

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*

This page intentionally left blank

STANDARDSISO.COM : Click to view the full PDF of ISO 4074-10:1990

Rubber condoms —

Part 10:

Packaging and labelling — Condoms in consumer packages

1 Scope

This part of ISO 4074 specifies requirements for the packaging and labelling of rubber condoms supplied in consumer packages.

2 Definition

For the purposes of this part of ISO 4074, the following definition applies.

batch number: Number, or combination of numerals, symbols or letters given by a manufacturer to each batch of goods, to identify uniquely that batch, and from which it is possible to trace that batch through all stages of manufacture, packaging and distribution.

3 Packaging

Each condom shall be packaged in an individual sealed container. One or more individual containers shall be packaged in a consumer package. Except where condoms of different colours are packaged together, all condoms shall be of the same batch number. The individual sealed container, or the consumer package, or both shall be opaque to light.

NOTES

1 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.

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

3 Individual containers and consumer packages should be such that the condom does not suffer mechanical damage when the container and package are opened. In-

dividual containers should have a feature to facilitate easy opening of the container and to help ensure that the container opens at the point intended.

4 Labelling

4.1 Individual containers

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

- the identity of the manufacturer or distributor (e.g. trade-mark, name, abbreviated name);
- the manufacturer's identifying reference for traceability (e.g. the batch number).

4.2 Consumer package

4.2.1 The outside of the consumer package shall bear at least the following information:

- a description of the condom, e.g. colour, tip type, ribbing;
- the number of condoms contained;
- the nominal width of the condom;
- the name of the manufacturer, re-packer or distributor;
- the expiry date (month and year) and/or the date of manufacture (month and year), stating which date is marked;
- instructions for storage, based on annex C of ISO 4074-1;
- whether the condom is lubricated or dry, and if lubricated, whether the lubricant is spermicidal.

NOTE 4 In some countries, there may be national regulations covering spermicidal materials.

4.2.2 The outside or the inside of the consumer package, or a leaflet contained within the consumer package, shall bear at least the following information:

- a) the address of the manufacturer, re-packager or distributor;
- b) instructions for use of the condom, including
 - 1) the need to remove the condom from the package carefully so as to avoid damage to the condom,
 - 2) how to put on the condom,

NOTE 5 Mention could be made that the condom should be placed on the erect penis before any contact occurs between the penis and the partner's body in order to assist in the prevention of sexually transmitted diseases.

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

- 4) the need to avoid the use of oil-based lubricants such as petroleum jelly and baby oil,
- 5) the need, if an additional lubricant is desired, to use the correct type of lubricant,
- 6) the need to consult a doctor or pharmacist about the compatibility with condoms of prescription or over-the-counter topical medicines that are applied to the penis or vagina;

NOTES

6 Mention should also be made of the advantage of the concomitant use of a spermicidal preparation for contraception.

7 The instructions should be expressed in simple language and it is recommended that they be supplemented by pictorial representations of the major steps involved.

- c) instructions on how to dispose of the used condom;
- d) a statement that the condom is for single use.

STANDARDSISO.COM : Click to view the full PDF of ISO 4074-10:1990