

International Standard ISO 4074/10



INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Rubber condoms — Part 10 : Packaging and labelling

Préservatifs masculins en caoutchouc — Partie 10 : Emballage et étiquetage

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been set up 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

International Standard ISO 4074/10 was developed by Technical Committee ISO/TC 157, *Mechanical contraceptives*, and was circulated to the member bodies in July 1979.

It has been approved by the member bodies of the following countries :

Brazil	Italy	South Africa, Rep. of
Canada	Korea, Rep. of	Sri Lanka
Denmark	Mexico	Sweden
Egypt, Arab Rep. of	Netherlands	United Kingdom
France	Poland	USSR
India	Romania	

The member bodies of the following countries expressed disapproval of the document on technical grounds :

Australia
Czechoslovakia
USA

Rubber condoms — Part 10 : Packaging and labelling

1 Scope and field of application

Part 10 of ISO 4074 specifies requirements for the packaging and labelling of rubber condoms.

2 Packaging

Each condom shall be packed in an individual sealed container in hygienically satisfactory conditions. Several individual containers may be packed together in a consumer package.

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

Individual containers or consumer packages shall be so designed, and made from such materials, that the condoms are fully protected during transport and storage and do not suffer any mechanical damage when the container and package is opened.

When consumer packages are filled by other than the manufacturer, it is desirable that the packer maintains adequate records for product traceability.

The packaging material shall not mildew in tropical climates and shall not attract insects.

3 Labelling

Each condom or individual container shall carry the following information :

a) the manufacturer's or distributor's recognizable identification, for example trade mark, name, abbreviated name;

b) the manufacturer's identification reference for traceability, for example the batch number;

additionally, each consumer package shall carry the following information :

c) the manufacturer's or distributor's name;

d) the number of contained condoms;

e) the registered certification mark of the third party certification body, where applicable;

f) instructions for use;

NOTE — Alternatively these may be given on a separate leaflet within the package.

furthermore, if required by the purchaser, standardizing body, regulating authority or manufacturer, each consumer package shall also carry the following information :

g) the batch number;

h) the expiry date (month and year) i.e. the date after which the contained condom should not be used;

j) instructions for storage, for example "Store in a cool, dry place away from direct sunlight or ozone".