

## **Looduslikust latekskummist kondoomid. Nõuded ja katsemeetodid**

Natural latex rubber condoms - Requirements and  
test methods

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 4074:2002 sisaldab Euroopa standardi EN ISO 4074:2002+AC:2004 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 06.08.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 4074:2002 consists of the English text of the European standard EN ISO 4074:2002+AC:2004.</p> <p>This document is endorsed on 06.08.2002 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p><b>Käsitlusala:</b></p> <p>This International Standard specifies the minimum requirements and the test methods to be used for condoms made from natural rubber latex which are supplied to consumers for contraceptive purposes and to assist in the prevention of sexually transmitted infections.</p>	<p><b>Scope:</b></p> <p>This International Standard specifies the minimum requirements and the test methods to be used for condoms made from natural rubber latex which are supplied to consumers for contraceptive purposes and to assist in the prevention of sexually transmitted infections.</p>
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**ICS 11.200**

**Võtmesõnad:** contraceptive agents, contraceptive sheaths, latices, leak tests, natural rubber, natural rubber latex, rubber, specification (approval), specifications, tear strength, testing

English version

**Natural latex rubber condoms - Requirements and test methods  
(ISO 4074:2002)**

Préservatifs masculins en latex de caoutchouc naturel -  
Exigences et méthodes d'essai (ISO 4074:2002)

Kondome aus Naturkautschuklatex - Anforderungen und  
Prüfverfahren (ISO 4074:2002)

This European Standard was approved by CEN on 2 February 2002.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## Foreword

This document (ISO 4074:2002) has been prepared by Technical Committee ISO/TC 157 "Mechanical contraceptives" in collaboration with Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

This document supersedes EN 600:1996.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2002, and conflicting national standards shall be withdrawn at the latest by August 2002.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

## Endorsement notice

The text of the International Standard ISO 4074:2002 has been approved by CEN as a European Standard without any modifications.

## Annex ZA (informative)

### Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard are likely to support requirements of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

**Table ZA.1 - Correspondence between this European Standard and EU Directives**

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
4 (Quality verification)	1, 6	
5 (Design)	1, 2, 3, 4, 5	
6 (Burst)	3, 4, 5, 7.3	
6.3 (Extra strength)	3	
7 (Stability and shelf life)	4, 5	
8 (Holes)	3, 4, 5, 7.5, 7.6	
9 (Visible defects)	3, 4	
10 (Package Integrity)	3, 5, 7.2, 8.1	
11.1 (Packaging)	5, 7.2, 7.3, 7.5, 7.6, 8.1	
11.2 (Labelling)	13.1, 13.2, 13.3 a), b), d), e), f), i), j), k), 13.4, 13.6 a), d), l), n), o)	
11.3 (Inspection)	3, 4, 5	
Annexes, verifying of requirements, not included as they have the requirements in the text above.		

# INTERNATIONAL STANDARD

**ISO  
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2002-12-01

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## **Natural latex rubber condoms — Requirements and test methods**

*Préservatifs masculins en latex de caoutchouc naturel — Exigences et  
méthodes d'essai*



Reference number  
ISO 4074:2002(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 4074 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives*.

This first edition of ISO 4074 cancels and replaces ISO 4074-1:1996, ISO 4074-2:1994, ISO 4074-3:1994, ISO 4074-4:1980, ISO 4074-5:1996, ISO 4074-6:1996, ISO 4074-7:1996, ISO 4074-8:1984, ISO 4074-9:1996, ISO 4074-10:1990 and ISO 4074-12:1980.

Annexes A, C, D, E, F, G, H, I, J, L, M and N form a normative part of this International Standard. Annexes B, K, O and P are for information only.

This corrected version of ISO 4074:2002 incorporates correction in the Foreword, where the years of publication of the parts of ISO 4074 being replaced by the new edition were erroneously omitted.

## 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 infections (STIs) and to spermatozoa. In order to help ensure that condoms are effective for contraceptive purposes and for assisting in the prevention of transmission of STIs, it is essential that condoms fit the penis 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 this International Standard.

The condom and any lubricant, additive, dressing, individual packaging 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 storage or use. Reference should be made to ISO 10993 for test methods to evaluate the safety of condoms particularly in respect of the risk of local irritation and sensitization.

Condoms are medical devices. Therefore they should be produced under a good quality management system. Reference should be made, for example to the ISO 9000-series, ISO 14971-1 and one of the relevant standards: ISO 13485 or ISO 13488.

Condoms are non-sterile medical devices but manufacturers should take appropriate precautions to minimize microbiological contamination of the product during manufacture and packaging.

This first edition of ISO 4074 requires manufacturers to conduct stability tests to estimate the shelf life of any new or modified condom before the product is placed on the market and to initiate real-time stability studies. These requirements are described in clause 7. The real-time stability test can be considered as part of the manufacturer's requirement to conduct post-marketing surveillance on their products. These requirements are intended to ensure that manufacturers have adequate data to support shelf-life claims before products are placed on the market and that these data are available for review by regulatory authorities, third-party test laboratories and purchasers. They are also intended to limit the need for third parties to conduct long-term stability studies.

A guideline (ISO 16038) for the application of this International Standard is under development by ISO/TC 157/WG 14.

This International Standard contains requirements for tensile properties (force at break) when a manufacturer makes a claim for "extra strength". Annex I contains the test method for determination of force and elongation at break, as it may be useful in the quality system of a manufacturer and in very special cases in a purchaser's contract.

Background information including technical explanations relating to certain clauses of this International Standard is given in annex P. Where this is relevant, the appropriate clause in annex P is referenced in the text.



# Natural latex rubber condoms — Requirements and test methods

## 1 Scope

This International Standard specifies the minimum requirements and the test methods to be used for condoms made from natural rubber latex which are supplied to consumers for contraceptive purposes and to assist in the prevention of sexually transmitted infections.

## 2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 188, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests*

ISO 2859-1:1999, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptable quality limit (AQL) for lot-by-lot inspection*

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

EN 980, *Graphical symbols for use in the labelling of medical devices*

## 3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 2859-1 and the following apply.

### 3.1

#### **acceptable quality limit**

##### **AQL**

When a continuous series of lots is considered, the quality level which for the purposes of sampling inspection is the limit of a satisfactory process mean (according to ISO 2859-1)

### 3.2

#### **condom**

medical device used by consumers, which is intended to be retained on the penis during sexual activity, for purposes of contraception and prevention of sexually transmitted infections

NOTE If a consumer could responsibly consider a device to be a condom (due to its shape, packaging, etc.), it is considered a condom for the purpose of this International Standard.

### 3.3

#### **consumer package**

package, intended for distribution to a consumer, containing one or more individual containers