SLOVENSKI STANDARD
SIST EN ISO 4074:2002

01-november-2002

Nadomeģ a:
SIST EN 600:2000

Kondomi iz naravnega kavļ uka - Zahteve in preskusne metode (ISO 4074:2002)

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

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

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

Ta slovenski standard je istoveten z: EN ISO 4074:2002

ICS:

11.200	Naļ rtovanje druģine. Mehanski kontracepcijski pripomoļ ki	Birth control. Mechanical contraceptives

SIST EN ISO 4074:2002 **en**

EUROPEAN STANDARD

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EN ISO 4074

February 2002

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Supersedes EN 600:1996

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 4074

First edition
2002-02-15

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2002-12-01

Natural latex rubber condoms — Requirements and test methods

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

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Annexes

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 acceptance 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

3.4
expiry date
stated date after which a condom should not be used

3.5
identification number
number, or combination of numerals, symbols or letters used by a manufacturer on consumer packages to identify uniquely the lot numbers of individual condoms contained in that package, and from which it is possible to trace those lots through all stages of packaging and distribution

NOTE When the consumer package contains only one kind of condom, then the identification number may be the same as the lot number. But if the consumer package contains several different types of condom, for instance condoms of different shapes or colours, then the identification number will be different from the lot number.

3.6
individual container
immediate wrapping of a single condom

3.7
inspection level
relationship between lot size and sample size.

NOTE For description, see ISO 2859-1:1999, 10.1.

3.8
lot
collection of condoms of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, raw materials of the same specifications, common equipment and packed with the same lubricant and any other additive or dressing in the same type of individual container

NOTE This International Standard does not specify the size of a lot, but it is possible for a purchaser to do so as part of the purchasing contract. Attention is drawn to the difficulties that can be associated with the distribution and control of very large lots. The recommended maximum individual lot size for production is 500 000.

3.9
lot number
number or combination of numerals, symbols or letters used by the manufacturer to identify a lot of individually packaged condoms, and from which it is possible to trace that lot through all stages of manufacture up to packaging

NOTE For testing purposes, sampling is conducted by lot number, not identification number. See requirements in clause 4.

3.10
lot test
test to assess the compliance of a lot

NOTE A lot test may be limited to include only those parameters which may change from lot to lot.

3.11
non-visible hole
hole in the condom that is not visible under normal or corrected vision but is detected by leakage when rolling on absorbant paper

3.12
sampling plan
specific plan which indicates the number of units of product from each lot which are to be inspected (sample size or series of sample sizes) and the associated criteria for determining the acceptability of the lot (acceptance and rejection numbers)

3.13
shelf life
time from date of manufacture to the claimed expiry date

3.14
visible hole
hole or tear in the condom that is visible under normal or corrected vision

4 Quality verification

Condoms are mass-produced articles manufactured in very large quantities. Inevitably there will be some variation between individual condoms, and a small proportion of condoms in each production run may not meet the requirements in this International Standard. Further, the majority of the test methods described in this International standard are destructive. For these reasons the only practicable method of assessing compliance with this International Standard is by testing a representative sample from a lot or series of lots. Basic sampling plans are given in ISO 2859-1. Reference should be made to ISO/TR 8550 for guidance on the selection of an acceptance sampling system, scheme or plan for the inspection of discrete items in a lot.

When on-going verification is required of the quality of condoms, it is suggested that, instead of concentrating solely on evaluation of the final product, the party concerned also directs his attention to the manufacturer's quality system. In this connection it should be noted that the ISO 9000 series (see Bibliography) covers the provision of an integrated quality system.

Sampling plans shall be selected to provide an acceptable level of consumer protection. Suitable sampling plans are given in annexes A and B.

a) Annex A describes sampling plans based on ISO 2859-1 and is most applicable to manufacturers or purchasers assessing the compliance of a continuing series of lots. The full level of consumer protection available depends upon the switch to tightened inspection if a deterioration in quality is detected. The switching rules cannot offer full protection for the first two lots tested, but become progressively more effective as the number of lots in a series increases. The sampling plans in annex A are recommended when five or more lots are being tested.

b) Annex B describes sampling plans, based on ISO 2859-1, that are recommended for the assessment of isolated lots. The sampling plans in annex B provide approximately the same level of consumer protection as those given in annex A when used with the switching rules. It is recommended that these sampling plans be used for the assessment of fewer than five lots, for example in cases of dispute, for referee purposes, for type testing, for qualification purposes or for short runs of continuing lots.

c) Handling and storage conditions shall be documented before drawing the samples.

It is necessary to know the lot size in order to derive from ISO 2859-1 the number of condoms to be tested. The lot size will vary between manufacturers and is regarded as part of the process and quality controls used by the manufacturer.

5 Design

5.1 Integral bead

The open end of the condom shall terminate in an integral bead and shall comply with clause 9.

5.2 Lubrication

If the amount of lubricant in the package is specified, then this amount shall be determined by the method described in annex C.

The method in annex C also recovers part of the dressing powder on the condom. (See rationale, in P.7.) An allowance should be made for this when manufacturers or purchasers specify lubricant levels.

