SLOVENSKI STANDARD
oSIST prEN ISO 4074:2009

01-september-2009

Kondomi iz naravnega kavļuka - Zahteve in preskusne metode (ISO/DIS 4074:2009)

Natural rubber latex condoms - Requirements and test methods (ISO/DIS 4074:2009)

Kondome aus Naturkautschuklatex - Anforderungen und Prüfverfahren (ISO/DIS 4074:2009)

Préservatifs masculins en latex de caoutchouc naturel - Exigences et méthodes d'essai (ISO/DIS 4074:2009)

Ta slovenski standard je istoveten z: prEN ISO 4074

ICS:

11.200	Naļrtovanje druģine. Mehanski kontracepcijski pripomoļki	Birth control. Mechanical contraceptives

oSIST prEN ISO 4074:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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ICS 11.200

Will supersede EN ISO 4074:2002

English Version

Natural rubber latex condoms - Requirements and test methods (ISO/DIS 4074:2009)

Préservatifs masculins en latex de caoutchouc naturel - Exigences et méthodes d'essai (ISO/DIS 4074:2009)

Kondome aus Naturkautschuklatex - Anforderungen und Prüfverfahren (ISO/DIS 4074:2009)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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 CEN Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (prEN ISO 4074:2009) 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 DIN.

This document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 4074:2002.

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 EC Directive(s).

Endorsement notice

The text of ISO/DIS 4074:2009 has been approved by CEN as a prEN ISO 4074:2009 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 4074

ISO/TC **157**

Secretariat: **DSM**

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

Natural rubber latex condoms — Requirements and test methods

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

(Revision of first edition ISO 4074:2002 and ISO 4074:2002/Cor 1:2003)

ICS 11.200

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 4074 was prepared by Technical Committee ISO/TC 157, *Mechanical Contraceptives*.

This second edition cancels and replaces the first edition (ISO 4074:2002), of which has been technically revised.

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 in 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.

Condoms are medical devices. Therefore they should be produced under a good quality management system. Reference should be made, for example, to ISO 13485, the ISO 9000-series and ISO 14971.

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

This 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 10. The real time stability test can be considered as part of the manufacturers' requirement to conduct post-marketing surveillance on their products. These requirements are intended to ensure that manufactures have adequate data to support shelf life claims before products are placed on the market and that this data is 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 has been published by ISO/TC 157.

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 male 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 referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity*

ISO 2859-1, 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 document, the terms and definitions given in ISO 2859-1 and the following apply.

3.1
acceptable quality limit
AQL
quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling (according to ISO 2859-1)

3.2
male 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 reasonably 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 of condoms

3.4
expiry date
date at the end of the shelf life

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 manufacturing, packaging and distribution

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

3.6
individual container
primary package containing 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

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

3.10
lot test
test to assess the conformity 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 a condom that is not visible under normal or corrected vision but is detected by the water leak test or the electrical test described in this International Standard

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
period from date of manufacture, during which condoms are required to conform to the requirements of Clauses 9, 11 and Clause 13

3.14
visible hole
hole in the condom that is visible under normal or corrected vision before the condom is filled with water or electrolyte during the freedom from holes test

3.15
date of manufacture
the date of dipping or the date the condoms are packed in their individual containers provided that, in the latter case, a maximum period of bulk storage is specified and shelf life studies have been conducted on condoms that have been subjected to the maximum bulk storage period

3.16
visible defects (other than holes and tears)
broken, missing or severely distorted rim and permanent creases with adhesion of the film

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 might 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 conformity 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 use of acceptance sampling system, scheme or plan for the inspection of discrete items in lots. For testing purposes, sampling shall be conducted by lot number, not by identification number.

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 and, in particular, ISO 13485 [10] cover 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 conformity of a continuing series of lots. The full level of consumer protection available depends upon the switch to tightened inspection if deterioration in quality is detected. The switching rules cannot offer their 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 are 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 are to 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.