SLOVENSKI STANDARD
oSIST prEN ISO 4074:2012

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Kondomi iz naravnega kavčuka - Zahteve in preskusne metode (ISO/DIS 4074:2012)

Natural latex rubber condoms - Requirements and test methods (ISO/DIS 4074:2012)

Kondome aus Naturkautschuklatex - Anforderungen und Prüfverfahren (ISO/DIS 4074:2012)

Préservatifs masculins en latex de caoutchouc naturel - Exigences et méthodes d'essai (ISO/DIS 4074:2012)

Ta slovenski standard je istoveten z: **prEN ISO 4074**

ICS:

11.200	Načrtovanje družine. Mehanski kontracepcijski pripomočki	Birth control. Mechanical contraceptives

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Natural latex rubber condoms - Requirements and test methods (ISO/DIS 4074:2012)

Préservatifs masculins en latex de caoutchouc naturel - Exigences et méthodes d'essai (ISO/DIS 4074:2012)

Kondome aus Naturkautschuklatex - Anforderungen und Prüfverfahren (ISO/DIS 4074:2012)

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-CENELEC 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
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (prEN ISO 4074:2012) has been prepared by Technical Committee ISO/TC 157 "Non-systemic contraceptives and STI barrier prophylactics" 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 EU Directive(s).

Endorsement notice

The text of ISO/DIS 4074:2012 has been approved by CEN as a prEN ISO 4074:2012 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 4074

ISO/TC **157** Secretariat: **DSM**

Voting begins on **2012-05-17** Voting terminates on **2012-10-17**

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

Natural rubber latex male condoms — Requirements and test methods

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

[Revision of first edition (ISO 4074:2002), ISO 4074:2002/Cor.1:2003 and ISO 4074:2002/Cor.2:2008]

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, *Non-systemic contraceptives and STI barrier prophylactics*.

This second edition cancels and replaces the first edition (ISO 4074:2002, ISO 4074:2002/Cor.1:2003, ISO 4074:2002/Cor.2:2008), which has been technically revised. The modifications are as follows:

a) the maximum lot size has been limited to 500 000;

b) specific requirements for biocompatibility assessments, as defined in ISO 10993-1, have been added;

c) manufacturers are required to establish procedures for the periodic monitoring of microbial contamination (bioburden) as part of their quality management system including requirements for the absence of specific pathogens and limits for total viable counts on finished condoms; methods of determining bioburden levels on condoms are given in Annex G;

d) specific requirements for extra strength condoms have been deleted but there is now a general requirement for manufacturers to justify any additional claims made for their products; claims relating to improved efficacy or safety have to be substantiated by clinical investigation;

e) requirements for an expanded range of condom sizes have been introduced in informative Annex P to provide guidance to regulatory authorities, Notified Bodies and other interested parties when assessing condoms that fall outside of the size range covered in the normative parts of the standard;

f) amendments have been made to the methods for determining the shelf life of condoms including a simplified procedure for determining the shelf life by accelerated stability studies based on fixed ageing periods at 50 °C;

g) the procedure for determining the thickness of a condom by the micrometer method is described in detail;

h) the radius of the clamping collar used in the inflation test described in Annex H has been increased to a minimum of 2 mm;

i) the volume of electrolyte used in the electrical test for determining freedom from holes described in Annex M has been brought into line with the volume used for the water leak test;

j) the ASTM “hang and squeeze” procedure has been integrated into the water leak test for freedom from holes.

Introduction

Condoms made from intact latex film have 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. Numerous clinical studies have confirmed that male latex condoms are effective in helping to prevent pregnancy and reduce the risk of transmission of most STIs including HIV.

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. To ensure high quality product, it is essential that condoms produced under a good quality management system. Reference can be made, for example, to ISO 13485 and the ISO 9000-series of standards for quality management requirements and ISO 14971 for risk management requirements.

Condoms are non-sterile medical devices but manufacturers are advised to take appropriate precautions to minimize microbiological contamination of the product throughout the manufacturing and packaging processes. Requirements for manufacturers to periodically monitor microbial contamination during production are included in this edition of ISO 4074.

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 11. 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 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 has been published by ISO/TC 157. The guideline includes additional information on the test methods and requirements specified in this International Standard.

Natural rubber latex male condoms — Requirements and test methods

1 Scope

This International Standard specifies requirements and the test methods for male condoms made from natural rubber latex.

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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 skin sensitization*

ISO 15223-2, *Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation*

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

EN 1041, *Information supplied by the manufacturer of medical devices*

2 Terms and definitions

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

3.1
acceptance quality limit
AQL
quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling

[ISO 2859-1]

3.2
male condom
medical device used by consumers, which is intended to cover and be retained on the penis during sexual activity, for purposes of contraception and prevention of sexually transmitted infections