LOODUSLIKUST LATEKSKUMMIST MEESTE KONDOOMID. NÕUDED JA KATSEMEETODID

Natural rubber latex male condoms - Requirements and test methods (ISO 4074:2015)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 4074:2015 sisaldab Euroopa standardi EN ISO 4074:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 4074:2015 consists of the English text of the European standard EN ISO 4074:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 11.11.2015.	Date of Availability of the European standard is 11.11.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.200

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 4074

November 2015

ICS 11.200

Supersedes EN ISO 4074:2002

English Version

Natural rubber latex male condoms - Requirements and test methods (ISO 4074:2015)

Préservatifs masculins en latex de caoutchouc naturel - Exigences et méthodes d'essai (ISO 4074:2015)

Kondome aus Naturkautschuklatex - Anforderungen und Prüfverfahren (ISO 4074:2015)

This European Standard was approved by CEN on 16 July 2015.

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 CEN-CENELEC 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 4074:2015 E

European foreword

This document (EN ISO 4074:2015) 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 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 May 2016, and conflicting national standards shall be withdrawn at the latest by November 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes 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).

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

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table 1 — Correlation between normative references and dated EN and ISO or IEC standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 2859-1	---	ISO 2859-1:1999 + Cor1:2001
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 10993-5	EN ISO 10993-5:2009	ISO 10993-5:2009
ISO 10993-10	EN ISO 10993-1:2013	ISO 10993-1:2010
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012
ISO 15223-2	---	ISO 15223-2:2010
ISO/IEC 17025	EN ISO/IEC 17025:2005	ISO/IEC 17025:2005

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 4074:2015 has been approved by CEN as EN ISO 4074:2015 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Medical Devices Directive 93/42/EEC.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1— Correspondence between this European Standard and the Essential Requirements of EU Directive 93/42/EEC as amended for medical devices

Clause(s)/sub-clause(s) of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
6, 7, 14, 15	7.2	Clauses 6, 7, 14 and 15 provide a presumption of conformity with the Essential Requirements relating to the risk posed by contaminants and residues to persons involved in the transport, storage and use of the devices.
6, 15.2.4.2	7.3	Clause 15.2.4.2 includes requirements for information to users regarding use of additional lubricants with condoms.
6, 15.2.4.2	7.4	This standard does not consider the systemic safety and usefulness of any ancillary medicinal substance that could be incorporated into the condom.
6	7.5	
7	8.1	Condoms are not sterile devices but manufacturers should take steps to control microbial contamination.
14, 15.1	8.6	
15.2	13.1	
15.2.2,15.2.4.1, 15.2.4.2,	13.2	
15.2.3, 15.2.4.1, 15.2.4.2, 15.2.5	13.3	
15.2.4.1, 15.2.4.2	13.4	
15.2.3, 15.2.4.1	13.5	

15.2.4.2, 15.2.5	13.6	
Annexes, which provide details of test methods, have not been included as the all the requirements are included above.		

WARNING — Other requirements and other EU Directives may be applicable to the products falling within the scope of this European Standard.

Contents

Page

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

This third edition cancels and replaces the second edition (ISO 4074:2014), 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) It is recommended that manufacturers 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) A minimum airburst volume of 28,0 dm^3 has been introduced for condoms with mid-body widths that are greater than or equal to 65,0 mm and not more than 75,0 mm.

f) The radius of the inner edge of the clamping collar wherever it contacts the inflated condom has to be a minimum of 2 mm (Annex H).

g) The volumes of electrolyte used in the electrical test for determining freedom from holes described in Annex M have been brought into line with the volumes used for the water leak test.

h) The volumes of water or electrolyte specified in the freedom from holes test have been increased for condoms that have mid-body widths greater than or equal to 56 mm and/or are longer that 210 mm.

i) When conducting the electrical test for freedom from holes, the voltage is now measured from the time that the condom is first immersed and for up to 10 s after full immersion.

j) The method of testing for freedom from holes specified in ASTM D3492[8] has been included by reference.

k) A limit has been introduced for the number of individual containers with visibly open seals, to be evaluated when the containers are inspected during the freedom from holes test described in Annex M.

l) Recommended requirements for minimum airburst properties and freedom from holes testing for condoms narrower than 45 mm and/or shorter than 160 mm 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 normative size range specified in this International Standard.

m) 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.

n) Testing for freedom from holes, airburst properties, and package integrity are required when conducting stability studies to establish that condoms meet the minimum stability requirements specified in this International Standard and when determining condom shelf lives.

o) The procedure for determining the thickness of a condom by the micrometer method is described in detail.

p) An alternative method of removing the lubricant from the condom using an aqueous surfactant solution has been introduced into the method for determining the amount of lubricant on the condom.

q) Revisions have been made to labelling requirements including the additional information supplied with the condom.

Regulatory agencies, notified bodies, and purchasers should consider the need for a transition period when implementing the requirements of this International Standard to allow manufacturers to make the changes required to maintain compliance. This applies particularly to the changes in packaging and labelling specified in Clause 15.