ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 4074:2015

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 für Männer — Anforderungen und Prüfverfahren (ISO 4074:2015)

11/2015

National Foreword

This European Standard EN ISO 4074:2015 was adopted as Luxembourgish Standard ILNAS-EN ISO 4074:2015.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

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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

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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.

INTERNATIONAL STANDARD

ISO 4074

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

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