SLOVENSKI STANDARD
SIST EN ISO 4074:2026

01-junij-2026

Nadomešča:
SIST EN ISO 4074:2016

Kondomi iz naravnega kavčuka - Zahteve in preskusne metode (ISO 4074:2026)

Natural rubber latex male condoms - Requirements and test methods (ISO 4074:2026)

Kondome aus Naturkautschuklatex für Männer- Anforderungen und Prüfverfahren (ISO 4074:2026)

Préservatifs masculins en latex de caoutchouc naturel - Exigences et méthodes d'essai (ISO 4074:2026)

Ta slovenski standard je istoveten z: **EN ISO 4074:2026**

ICS:

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

SIST EN ISO 4074:2026 **en,fr,de**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 4074

April 2026

ICS 11.200

Supersedes EN ISO 4074:2015

English Version

Natural rubber latex male condoms - Requirements and test methods (ISO 4074:2026)

Préservatifs externes en latex de caoutchouc naturel - Exigences et méthodes d'essai (ISO 4074:2026)

Kondome aus Naturkautschuklatex für Männer - Anforderungen und Prüfverfahren (ISO 4074:2026)

This European Standard was approved by CEN on 22 February 2026.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 4074:2026 E

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European foreword

This document (EN ISO 4074:2026) 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 October 2026, and conflicting national standards shall be withdrawn at the latest by April 2029.

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

This document supersedes EN ISO 4074:2015.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 4074:2026 has been approved by CEN as EN ISO 4074:2026 without any modification.

Annex ZA
(informative)

Relationship between this International Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in 0 and application of the edition of the normatively referenced standards as given in 0 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this harmonised standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in the Annex ZA. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this document can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region the standard can only support European regulatory requirements to the extent of the scope of the European Regulation for medical devices ((EU) 2017/745).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in 0, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / subclause(s) of this Standard	Remarks / Notes
I.4., 2nd paragraph	15.2.4.1 15.2.4.2	Partially covered. The GSPR is covered in respect to the risk of allergic reactions (15.2.4.1). The GSPR is covered in respect to the risk of reuse (15.2.4.2). The GSPR is covered in respect of the user causing damage to the device or misusing the deice in a manner that increases the risk of failing during use (15.2.4.2).
I.6	11.2, 11.3, 11.4	Partially covered Covered in respect to: a) compliance to the same test limits as in the original tests after production after artificial ageing (stability test, 11.2); b) determination of shelf life by real time stability studies (11.3); c) estimating shelf life based upon accelerated stability studies (11.4).
I.7	Clause 14, Clause 15	Partially covered Clause 14 describes a test method to assure the integrity of the primary package while clause 15 describes requirements for packaging and also labelling information that assure that there cannot be an adverse effect by temperature and humidity.
II.10.1 f) and h)	Clause 10, Clause 11, Clause 12, Clause 14	Fully covered The requirements in these clauses ensure the products meet the physical performance levels required to provide acceptable levels of protection. — 10.1 f) airburst test clause 10; — 10.1 h) requirements for tests in clause 10, clause 11, clause 12 and clause 14.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / subclause(s) of this Standard	Remarks / Notes
III.23.1 (g)	15.2.4.1 k) 15.2.4.2 a), e)	Partially covered. The GSPR is covered in respect to the risk of allergic reactions only [15.2.4.1 k)]. The GSPR is covered in respect to the risk of allergic reactions and reuse only [15.2.4.1 a) and e)].
III.23.2 a), e), g), i), k), m)	15.2.3 b), c) 15.2.4.1 e), f), g), h), i), j), k), m) 15.2.4.2 a) - e)	Partially covered The clauses of GSPR 23.2 are covered by the following clauses of the document:
		— III.23.2 a): 15.2.4.1 e) — III.23.2 e): 15.2.4.1 i) — III.23.2 g): 15.2.3 b) and 15.2.4.1 j) — III.23.2 i): 15.2.3 c) and 15.2.4.1 f) — III.23.2 k): 15.2.4.1 g), h) — III.23.2 m): 15.2.4.1 k) and m) and 15.2.4.2 a)-e)
III 23.4 a), g), h), p), q), s), w)	15.2.4.1 c), d), e), g), h), i), j), k), m) 15.2.4.2 a), b), e)	Partially covered The clauses of GSPR 23.4 are covered by the following clauses of the document:
		— III.23.4 a): 15.2.4.1 e), g)-h), j) and m) — III.23.4 g): 15.2.4.1 k) and 15.2.4.2 b) a)-b) and e) — III.23.4 h): 15.2.4.1 c) and d) — III.23.4 p): 15.2.4.2 a) — III.23.4 q): 15.2.4.2 b) 6) — III.23.4 s): 15.2.4.1 and 15.2.4.2 div. sub points — III.23.4 w): 15.2.4.2. b) 7)

Table ZA.2 — Normative references from Clause 2 of this document and their corresponding European publications

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 2859-1	ISO 2859-1:1999 ISO 2859-1:1999/Cor 1:2001 ISO 2859-1:1999/Amd 1:2011	Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	None For applicable standard edition see Column 2
ISO 10993-1	ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
ISO 14971	ISO 14971:2019	Medical devices — Application of risk management to medical devices	EN ISO 14971:2019 EN ISO 14971:2019/A11:2021
ISO 15223-1	ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	EN ISO 15223-1:2021
ISO/IEC 17025	ISO/IEC 17025:2017	General requirements for the competence of testing and calibration laboratories	EN ISO/IEC 17025:2017

The documents listed in the Column 1 of 0, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of 0.

WARNING 1 Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

International Standard

ISO 4074

Natural rubber latex male condoms — Requirements and test methods

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

Fourth edition
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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.

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 4074:2015), which has been technically revised.

The main changes are as follows.

— The Scope (Clause 1) has been amended because this document now covers all condom sizes including those with dimensions specified in Annex P, which has been made normative.

— A statement has been added to Annex A regarding the sample sizes used for reduced inspection.

— The use of technical grade propan-2-ol is permitted for removing lubricant from condoms when determining the lubricant quantity according to Annex C.

— In Annex G, it has been made clear that a Stomacher® is a specific type of mixer that can be used along with other types of mixers when preparing samples for microbiological testing of condoms. Some amendments to the test procedures have been made based on current best practices.

— Improvements have been made to inflation test procedure specified in Annex H.

— The condom handling procedures described in ISO/TR 19969:2018 have been integrated into Annex H, testing for burst properties, and Annex M, testing for freedom from holes.

— Annex K has been updated to provide clearer and more detailed information about conducting real time stability tests.

— Annex L has been updated to include a more rapid accelerated stability test to assess the effect of process and formulation changes on the stability of a product and provide a stress test for condoms that might be stored in high temperature environments.