



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

ILNAS-EN ISO 4074:2002

Natural latex rubber condoms - Requirements and test methods (ISO 4074:2002)

Kondome aus Naturkautschuklatex -
Anforderungen und Prüfverfahren (ISO
4074:2002)

Préservatifs masculins en latex de
caoutchouc naturel - Exigences et
méthodes d'essai (ISO 4074:2002)

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National Foreword

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EUROPEAN STANDARD ^{ILNAS-EN ISO 4074:2002} **EN ISO 4074**
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English version

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This European Standard was approved by CEN on 2 February 2002.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (ISO 4074:2002) 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 BSI.

This document supersedes EN 600:1996.

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 standard.

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 August 2002, and conflicting national standards shall be withdrawn at the latest by August 2002.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 4074:2002 has been approved by CEN as a European Standard without any modifications.

Annex ZA (informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard 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 93/42/EEC.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard are likely to support requirements of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 - Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
4 (Quality verification)	1, 6	
5 (Design)	1, 2, 3, 4, 5	
6 (Burst)	3, 4, 5, 7.3	
6.3 (Extra strength)	3	
7 (Stability and shelf life)	4, 5	
8 (Holes)	3, 4, 5, 7.5, 7.6	
9 (Visible defects)	3, 4	
10 (Package Integrity)	3, 5, 7.2, 8.1	
11.1 (Packaging)	5, 7.2, 7.3, 7.5, 7.6, 8.1	
11.2 (Labelling)	13.1, 13.2, 13.3 a), b), d), e), f), i), j), k), 13.4, 13.6 a), d), l), n), o)	
11.3 (Inspection)	3, 4, 5	
Annexes, verifying of requirements, not included as they have the requirements in the text above.		

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Natural latex rubber condoms — Requirements and test methods

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



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