

**SLOVENSKI STANDARD  
SIST EN ISO 4074:2002/AC:2004  
01-november-2004**

---

?cbXca J]n'bUfUj bY[ U\_Uj i \_U!NU hYj Y]b'dfYg\_i gbY'a YfcXYE'DcdfUj Y\_fhGC  
(\$+( .8\$\$&#7 cf "%&\$\$' £

Natural latex rubber condoms - Requirements and test methods (ISO 4074:2002/Cor.1:2003)

Kondome aus Naturkautschuklatex - Anforderungen und Prüfverfahren (ISO 4074:2002/Cor.1:2003)

**iTeh STANDARD PREVIEW**

**(standards.iteh.ai)**

Préservatifs masculins en latex de caoutchouc naturel - Exigences et méthodes d'essai (ISO 4074:2002/Cor.1:2003)

[SIST EN ISO 4074:2002/AC:2004](#)

<https://standards.iteh.ai/catalog/standards/sist/120e1ec4-08c7-42e9-8b08-07fdb79b19cf/sist-en-iso-4074-2002-ac-2004>

**Ta slovenski standard je istoveten z: EN ISO 4074:2002/AC:2004**

---

**ICS:**

11.200	þælçæþ Ál' 0ð^È T^@•\Ã[ } ðæ&^] &þ\ã ] þ[ { [ \ã	Birth control. Mechanical contraceptives
--------	--	--

**SIST EN ISO 4074:2002/AC:2004**

**en,fr,de**

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 4074:2002/AC:2004](#)

<https://standards.iteh.ai/catalog/standards/sist/120e1ec4-08c7-42e9-8b08-07fdb79b19cf/sist-en-iso-4074-2002-ac-2004>

EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

EN ISO 4074:2002/AC

September 2004  
Septembre 2004  
September 2004

ICS 11.200

English version  
Version Française  
Deutsche Fassung

Natural latex rubber condoms - Requirements and test methods (ISO  
4074:2002/Cor.1:2003)

Préservatifs masculins en latex de  
caoutchouc naturel - Exigences et  
méthodes d'essai (ISO  
4074:2002/Cor.1:2003)

Kondome aus Naturkautschuklatex -  
Anforderungen und Prüfverfahren (ISO  
4074:2002/Cor.1:2003)

This corrigendum becomes effective on 22 September 2004 for incorporation in the three official language versions of the EN.

iTeh STANDARD PREVIEW

Ce corrigendum prendra effet le 22 septembre 2004 pour incorporation dans les trois versions linguistiques officielles de la EN.[\(standards.iteh.ai\)](https://standards.iteh.ai)

Die Berichtigung tritt am 22. September 2004 zur Einarbeitung in die drei offiziellen Sprachfassungen der EN in Kraft. <https://standards.iteh.ai/catalog/standards/sist/120e1ec4-08c7-42e9-8b08-07fdb79b19cf/sist-en-iso-4074-2002-ac-2004>



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

Management Centre: rue de Stassart, 36 B-1050 Brussels

**English version**

**Endorsement notice**

The text of ISO 4074:2002/Cor.1:2003 has been approved by CEN as a European Corrigendum without any modifications.

**Version française**

**Notice d'entérinement**

Le texte de l'ISO 4074:2002/Cor.1:2003 a été approuvé par le CEN comme Corrigendum européen sans aucune modification.

**Deutsche Fassung**

**Anerkennungsnotiz**

Der Text von ISO 4074:2002/Cor.1:2003 wurde vom CEN als Europäisches Corrigendum ohne irgendeine Abänderung genehmigt.

**(standards.iteh.ai)**

**SIST EN ISO 4074:2002/AC:2004**

<https://standards.iteh.ai/catalog/standards/sist/120e1ec4-08c7-42e9-8b08-07fdb79b19cf/sist-en-iso-4074-2002-ac-2004>



# INTERNATIONAL STANDARD ISO 4074:2002

## TECHNICAL CORRIGENDUM 1

Published 2003-11-01

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

## Natural latex rubber condoms — Requirements and test methods —

### TECHNICAL CORRIGENDUM 1

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

*RECTIFICATIF TECHNIQUE 1*

## iTeh STANDARD PREVIEW

Technical Corrigendum 1 to ISO 4074:2002 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives*.

[SIST EN ISO 4074:2002/AC:2004](#)

<https://standards.iteh.ai/catalog/standards/sist/120e1ec4-08c7-42e9-8b08-07fdb79b19cf/sist-en-iso-4074-2002-ac-2004>

---

Page 1

### Clause 3 Terms and definitions

Replace term and definition 3.1 with the following:

**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 2859-1:1999, definition 3.1.26]

NOTE Process average is also defined in ISO 2859-1.

Page 4

### **Subclause 5.3.3 Thickness**

Replace the text of this subclause with the following:

If the thickness of the condom is specified, then the referee method for determination of thickness shall be as given in Annex F.

### **Subclause 6.1 Untreated condoms**

Replace the first paragraph by the following text:

When tested in accordance with Annex G, the bursting pressure shall be not less than 1,0 kPa (2,0 kPa for extra-strength condoms, see 6.3.2) and the bursting volume shall be not less than:

Page 5

### **Subclause 6.3.2 Requirements for mechanical properties**

Replace the first paragraph by the following text:

When tested in accordance with Annex G, the bursting pressure specified in 6.1 shall be increased to 2,0 kPa.

## **iTeh STANDARD PREVIEW (standards.iteh.ai)**

### **Subclause 6.3.3 Requirements for clinical data**

[SIST EN ISO 4074:2002/AC:2004](#)

Replace the second paragraph by the following text:  
<https://standards.iteh.ai/catalog/standards/sist/120e1ec4-08c7-42e9-8b08-07fdb79b19cf/sist-en-iso-4074-2002-ac-2004>

The clinical data shall substantiate a statistically significant reduction in breakage rate for the extra-strength condom when compared to a reference, marketed condom from normal production produced by the same manufacturer. The reference condom shall comply with the requirements of this International Standard (ISO 4074) and single-wall thickness at the mid-body shall exceed 0,060 mm.

In the third paragraph, delete the words "(in preparation)" after "ISO 16037".

Page 6

### **Subclause 7.2 Minimum stability requirements**

Replace the second paragraph by the following:

Only lots meeting the requirements of Clause 5, Subclauses 6.1, 6.2, 6.3.2, and Clauses 8, 9 and 10 shall be used for this test.

In the third paragraph, replace "(168 ± 5) h" by "(168 ± 2) h".

Page 17

### **Clause F.1 Principle**

In the second paragraph, replace "0,933 g/cm<sup>2</sup>" by "0,933 g/cm<sup>3</sup>"

*Page 18*

**Subclause F.3.8, NOTE**

Add the following sentence to the end of the note:

This is not the referee method.

*Page 20*

**Figure G.1**

In detail X, replace "R 5" with "R 0,5"

*Page 24*

**Subclause I.5.2, NOTE**

Replace the text of the existing Note by the following:

NOTE The tensile strength, in megapascals, can be calculated from the following formula:

Tensile strength (MPa) =  $\rho \cdot F_b \cdot w \cdot m^{-1}$   
**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

where  
 $\rho$  is the density of rubber (0,933 g/cm<sup>3</sup>);  
 $F_b$  is the force at break, in newtons;  
 $w$  is the mean flat width, in millimetres;  
 $m$  is the mass, in milligrams, of the test piece.

and round to the nearest 0,1 MPa.

*Page 25*

**Subclause J.2.1 General**

Replace the first paragraph by the following text:

After determining compliance with Clause 5, Subclauses 6.1, 6.2, 6.3.2 and Clauses 8, 9 and 10, sufficient condoms shall be placed in a controlled environment and conditioned to

**Subclause J.2.2, item b)**

Replace the text of b) by the following:

Conditioning according to Annex H or in a controlled environment shall be carried out at  $(30^{+5}_{-2})$  °C.

Page 26

**Clause J.4 Test report**

Replace the first paragraph by the following text:

The test report shall include the requirements of Annex G in the form specified by Annex N and:

**Item J.4 b)**

Delete the words "and distribution curves,".

Page 27

**Clause K.2 Procedure for conducting accelerated ageing studies**

Add the following new paragraph at the beginning of the clause:

Only lots meeting the requirements of Clause 5, Subclauses 6.1, 6.2, 6.3.2, Clauses 8, 9 and 10 shall be used for this test.

**Clause K.3 Analysis of accelerated ageing data to estimate provisional shelf-life**

In the second paragraph, delete the following sentence:

**iTeh STANDARD PREVIEW**  
Another method has been published as the P&K method [27].  
**(standards.iteh.ai)**

SIST EN ISO 4074:2002/AC:2004

Page 28

<https://standards.iteh.ai/catalog/standards/sist/120e1ec4-08c7-42e9-8b08-07fdb79b19cf/sist-en-iso-4074-2002-ac-2004>

**Subclause K.5.1 Background to applying the time-temperature superposition method**

Substitute the following for the explanation of  $R$  after Equation (K.1):

$R$  is the gas constant ( $8,314 \text{ J mol}^{-1} \text{ K}^{-1}$ )

Page 35

**Subclause M.2.1.1**

Delete the reference to Annex P.

Page 41

**Clause P.3 6.3 Requirements for products proclaiming “extra strength”**

In the second paragraph, replace the first phrase "The force at break, as measured..." with the following:

The mean force at break, as measured...