



# INTERNATIONAL STANDARD ISO 4074:2002 TECHNICAL CORRIGENDUM 1

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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*

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

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#### 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.

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### **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:

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### **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.

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

Replace the second paragraph by the following text:

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".

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### **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".

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

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

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#### Subclause F.3.8, NOTE

Add the following sentence to the end of the note:

This is not the referee method.

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#### Figure G.1

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

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#### 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:

$$\text{Tensile strength (MPa)} = \rho \cdot F_b \cdot w \cdot m^{-1}$$

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.

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#### 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  $\left(30 \pm \frac{5}{2}\right) ^\circ\text{C}$ .

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#### **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,".

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#### **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:

Another method has been published as the P&K method [27].

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#### **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 ( $8,314 \text{ J mol}^{-1} \text{ K}^{-1}$ )

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#### **Subclause M.2.1.1**

Delete the reference to Annex P.

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#### **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...

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**Clause P.10    Annex L**

Delete item a) L. 2 Based on ASTM D 3078-94 [19].

Renumber the remaining list items.