



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*.

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.

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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:

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.

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".

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".

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Clause F.1 Principle

In the second paragraph, replace "0,933 g/cm²" by "0,933 g/cm³"

Page 18

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"

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:

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

where

- ρ is the density of rubber (0,933 g/cm³);
- 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].

Page 28

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.

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...