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AMENDMENT 1
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Rubber condoms for clinical trials — Measurement of physical properties —

AMENDMENT 1

Préservatifs masculins en caoutchouc destinés aux essais cliniques — Mesurage des propriétés physiques —
AMENDEMENT 1

Reference number
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Foreword

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Amendment 1 to ISO 16037:2002 was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

Rubber condoms for clinical trials — Measurement of physical properties —

AMENDMENT 1

Page 2, 6.2

Replace the text with the following:

> Measure at least 13 condoms, using a flat-footed micrometer, dial- or digital-type, measurement intervals of not larger than 0,001 mm, with a foot pressure set at (22 ± 5) kPa. The recommended foot diameter is (5 ± 2) mm. The procedure is as described in ISO 4074.

Page 2, 6.3

In the first paragraph, replace “using the weighing method” with “using the mass method”.

Page 2, 6.3

Replace the second paragraph, including the equation and the note, with “The procedure for determining the thickness is as described in ISO 4074.”

Page 2, Clause 8

In the first paragraph, replace “at least 315 condoms” with “at least 500 condoms”.

Delete “(but preferably 500)”.

Page 2, Clause 8

Replace the second paragraph with the following note:

> NOTE Data can be summarized as histograms (or stem-and-leaf diagrams). The aim of the test is not only to determine whether the lot(s) of products being used in the investigation comply with ISO 4074, but also to reliably estimate the mean, range, standard deviation, and number of non-compliers. For a more reliable estimate of lot defectiveness, it is advisable that at least 2 000 condoms be tested.

Page 3, Clause 12

At the end of the clause, replace “allergenicity, etc.” with “allergenicity, date of manufacture, etc.”.

Page 4, Clause 13

At the end of the clause, add the following explanatory note concerning retesting:

> NOTE If the clinical trial is examining the relationship between performance or acceptance against the physical properties of the condom, then it is important to keep track of changes in these properties during the course of the trial, and to take appropriate action if necessary. If the trial relies on continuing compliance with ISO 4074, it is important to verify that the physical properties have not dropped to the extent that compliance is at risk.

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