
Male condoms — Guidance on the use of ISO 4074 and ISO 23409 in the quality management of condoms

*Préservatifs masculins — Lignes directrices sur l'utilisation de la
norme ISO 4074 et ISO 23409 sur le management de la qualité
des préservatifs en latex de caoutchouc naturel et en matériau
synthétiques*





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Foreword

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This document was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

This second edition cancels and replaces the first edition (ISO 16038:2005), which has been technically revised, considering the revisions to ISO 4074 and the publication of ISO 23409. The modifications are as follows.

- a) The title and Scope have been expanded to include ISO 23409 and the relevant aspects of synthetic male condoms have been added in this edition. The major points incorporated are with respect to design, determination of limits for burst properties, stability studies and clinical trials.
- b) The revision to ISO 4074 and points arising out of the publication of ISO 4074:2015 have been incorporated in the guidance document.
- c) An explanation regarding the application of switching rules in sampling in accordance with ISO 2859-1 has been incorporated.
- d) The section on design has been expanded to explain significant changes to condoms, which warrant validation.
- e) The principle of estimating shelf life of natural rubber latex condoms has been revised to reflect the principles of shelf determination as given in ISO 4074:2015.
- f) The section on testing has been revised to include the modifications to test methods for determining freedom for holes.
- g) The section on dimensions has been revised to include the aspects of tolerances for thinner condoms.
- h) The aspects of condoms of smaller and larger sizes than those specified in ISO 4074 have been incorporated.