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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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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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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.

i) The impact of new test for visibly open seals as given in ISO 4074 and potential rework has been addressed.

j) The control of maximum storage period of naked condoms before packing them in individual sealed containers has been incorporated in accordance with ISO 4074.

Introduction

Condoms are medical devices used for contraception and for prevention of sexually transmitted infections.

ISO 4074 is a quality standard for natural rubber latex condoms and ISO 23409 for condoms made from synthetic materials. They are reference documents for standardized end product quality test protocols and a baseline specification for critical attributes that affect condom safety and effectiveness. They are applied by manufacturers, procurement agencies, regulatory bodies and testing laboratories.

The use of ISO 4074 and or ISO 23409 does not by itself ensure consistency in quality; consistent high quality at the lowest possible cost is attained only through a regime termed quality management, through which, quality is built into the product and ensured at every point in the design, planning, production and procurement processes. This document should lead to continuous improvement in manufacturing, procurement and testing processes. The special requirements of buyers and consumers should also be given due consideration when applying ISO 4074 or ISO 23409, as ISO 4074 and ISO 23409 are general by design, and will not cover all circumstances completely.

This document provides guidance to manufacturers, buyers and third-party test laboratories on implementing and applying ISO 4074 in the manufacture of condoms, and to purchasers on applying ISO 4074 or ISO 23409 and verifying that the condoms delivered conform to the specification, as appropriate.

Acceptable condoms meet or exceed the minimum requirements specified in ISO 4074 or ISO 23409, as applicable.

It is not possible, nor is it required, to subject condoms to user trials on a batch-by-batch basis. For this reason, certain evaluations are carried out only in the case of a pre-market validation; for example for new or significantly modified designs.

Design validation requirements normally include all the good manufacturing practice (GMP) validation requirements and the validation requirements of ISO 9001 and ISO 13485; these are not currently covered by ISO 4074 and ISO 23409, but are generally included by regulatory authorities as prerequisites for registering new designs of medical devices. Design considerations such as stability testing, etc., are, however, covered in ISO 4074 and evaluation of barrier properties by clinical trials and determination of burst properties are covered in ISO 23409.

ISO 4074 and ISO 23409 are mainly concerned with finished product testing carried out to monitor or to verify that the condoms have been manufactured with an adequate level of consistency in quality. For this purpose, tests have been designed that can be carried out rapidly and economically. The requirements in ISO 4074 and ISO 23409 are based on those properties which, based upon current knowledge, are believed to be relevant to the performance of condoms in normal use.

Some important properties of condoms are nevertheless difficult to define in quantitative terms because of a lack of controlled studies, the absence of practical and economical tests, and the need for different specifications to suit different users. ISO 4074 and ISO 23409 are, therefore, focused on the essential properties where limits can be clearly defined. Other properties are addressed only in general terms and are meant to be augmented through appropriate manufacturing records, certification by the manufacturer or by buyers' specifications.

This document also addresses how to deal with other related important issues not covered by ISO 4074 and ISO 23409.

It is meant to help the user of ISO 4074 and ISO 23409 to understand any risks that can be associated with the use of condoms. It also helps in deciding whether such risks are acceptable when weighed against the benefits to the condom user. ISO 4074 and ISO 23409 also help in assessing whether the products are demonstrably safe and offer protection to health. Good communication between the

buyer and the manufacturer will result in the delivery of satisfactory and safe products, thus avoiding unnecessary testing or inappropriate specifications, and thereby minimizing conformity testing costs.

NOTE In many countries, condoms, being medical devices, are subject to regulations.

The requirements for quality management are given in standards such as ISO 9001 and ISO 13485. ISO 9001 is based on the approach of achieving business excellence through quality management. For condoms, being a medical device, it is appropriate that ISO 13485 is applied for quality management as part of compliance to regulatory requirements.