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Rubber condoms — Guidance on the use of ISO 4074 in the quality management of natural rubber latex condoms

Préservatifs en caoutchouc — Directives sur l'utilisation de l'ISO 4074 dans le management de la qualité des préservatifs en latex de caoutchouc naturel

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 16038 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives*.

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. It is a reference document for standardised end-product quality test protocols and a baseline specification for critical attributes that affect condom safety and effectiveness. It is applied by manufacturers, procurement agencies, regulatory bodies and testing laboratories.

The use of ISO 4074 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 assured at every point in the design, planning, production and procurement processes. This International Standard 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, as ISO 4074 is general by design, and will not cover completely all circumstances.

This International Standard is a guidance document providing manufacturers, buyers, and third-party test laboratories guidance to implement and apply ISO 4074 in the manufacture of condoms and for purchasers to apply ISO 4074 as a technical specification and to verify that condoms delivered, comply with the specification.

In order to be acceptable, condoms need to meet or exceed the minimum requirements specified in ISO 4074.

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 GMP validation requirements and the validation requirements of ISO 9001; these are not currently covered by ISO 4074, 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.

ISO 4074 is mainly concerned with finished product testing carried out to monitor or to verify that the condoms have been manufactured with 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 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 lack of controlled studies, the absence of practical and economical tests, and the need for different specifications to suit different users. ISO 4074 is 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 International Standard also addresses how to deal with other important issues not covered by ISO 4074. It is meant to help the user of ISO 4074 to understand any risks that may be associated with the use of condoms. It also helps in deciding whether such risks are acceptable when weighed against the benefits to the user. ISO 4074 also helps 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, thereby minimizing compliance testing costs.

It should also be noted that in many countries condoms being medical devices are subject to appropriate regulations.

Information about standards can be obtained through catalogues issued by ISO, IEC, national standards bodies and regulatory agencies. List of projects under development by various ISO technical committees can be found in the ISO technical programme of each committee. Additional useful information can also be found by searching in the work program documents for a specific technical committee or its working groups. The catalogues and abstracts are issued yearly to the member bodies.

Modern technology opens up the opportunity for new ways to disseminate information about standards. Many national member bodies issue information on CD-ROM. Information also can be found on the World Wide Web by searching for quality-related subjects or under ISO. It is possible to search for information by committees, by published standards, and in a standards catalogue. It is also possible to obtain information on the revision status of a standard and the expected time of publication. This information is updated regularly, and it is therefore an extremely useful tool to search for standards in a given field and the stage of development.

— ISO on-line has the address http://www.iso.org;

— IEC on-line has the address http://www.iec.ch.

On both of these servers, links to member bodies which also have additional services are available, sometimes by subscription.

Other useful documents are given in the Bibliography.

Rubber condoms — Guidance on the use of ISO 4074 in the quality management of natural rubber latex condoms

1 Scope

This International Standard provides guidance on using ISO 4074 and addresses quality issues to be considered during the development, manufacture, quality verification and procurement of condoms. It encompasses the aspects of quality management systems in design, manufacture and delivery of condoms with emphasis on performance, safety and reliability of condoms.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 31-0:1992, *Quantities and units — Part 0: General principles*

ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 4074:2002, *Natural latex rubber condoms — Requirements and test methods*

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4074 and ISO 9000 apply.

4 Quality of design

4.1 General

The condom is a single-use medical device, the performance and safety of which depends upon the design and the manufacturing process. New designs of condoms may require clinical testing, several other tests and analysis ‘on a limited basis' for validation purposes such as shelf-life determination (type testing) and risk assessment. These requirements are generally prescribed by licensing authorities and the data generated become part of the master file for the product. Guidelines are available in ISO 9000 and the GMP requirements. When new products are developed, their design should conform to the requirements of design control as laid down in ISO 9001 and GMP requirements.