INTERNATIONAL STANDARD

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Male condoms — Requirements and test methods for condoms made from synthetic materials

Préservatifs masculins — Exigences et méthodes d'essai pour les préservatifs fabriqués en matières synthétiques

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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 23409 was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

Introduction

Synthetic condoms can be made from 100 % synthetic materials or a blend of synthetic materials and natural rubber latex. The material(s) used in synthetic condoms should be validated as constituting a barrier to human immunodeficiency virus (HIV), to other infectious agents responsible for the transmission of sexually transmitted infections (STIs), and to spermatozoa. It is essential that the condoms fit the penis properly, remain on the penis during use, are free from holes and have adequate physical strength so as not to break or tear during use so that the condoms can be deemed to be effective for contraceptive purposes and in order to help prevent the transmission of STIs. It is also important that they be correctly packaged so that they are protected during storage and suitably labelled. All of these issues are addressed in this International Standard.

To be safe, it is essential that the condom and any lubricant, additive, marking materials, dressing, individual packaging material or powder applied to it neither contain nor liberate substances in amounts that are toxic, likely to produce allergies (sensitization), locally irritating or otherwise harmful under normal conditions of storage and use.

Condoms are medical devices. To ensure high quality product, it is essential that condoms be produced under a quality management system using design controls. Reference can be made, for example, to ISO 9001[4], to ISO 14971, and to ISO 13485[8]. Additional guidance can be found in ISO 16038[9].

Condoms are non-sterile medical devices; however, a clean environment is essential to minimize microbiological contamination of the product during manufacturing and packaging.

Condoms can be of the designs given in the following terms, which are not intended to be exhaustive: smooth, textured, parallel-sided, non-parallel-sided, plain-ended, reservoir-ended, dry, lubricated, transparent, translucent, opaque, coloured, preshaped, welded or non-welded.

This International Standard specifies preclinical, clinical, and lot-by-lot physical requirement testing for condoms made from synthetic materials, including condoms made from a blend of synthetic materials and natural rubber latex. Application of lot-by-lot testing requirements becomes relevant only after the preclinical and clinical requirements of this International Standard have been met.

Male condoms — Requirements and test methods for condoms made from synthetic materials

1 Scope

This International Standard specifies the minimum requirements and the test methods applicable to male condoms produced from synthetic materials or blends of synthetic materials and natural rubber latex which are used for contraceptive purposes and to aid in the prevention of sexually transmitted infections.

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 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, *Natural latex rubber condoms — Requirements and test methods*

ISO/TR 8550 (all parts), *Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for* in vitro *cytotoxicity*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223 (all parts), *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied*

ISO 16037, *Rubber condoms for clinical trials — Measurement of physical properties*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 2859-1 and the following apply.

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, 3.1.26]