First edition
2002-02-15

Corrected version
2002-12-01

Natural latex rubber condoms — Requirements and test methods

Préservatifs masculins en latex de caoutchouc naturel — Exigences et méthodes d'essai

Reference number
ISO 4074:2002(E)

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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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 4074 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives*.

This first edition of ISO 4074 cancels and replaces ISO 4074-1:1996, ISO 4074-2:1994, ISO 4074-3:1994, ISO 4074-4:1980, ISO 4074-5:1996, ISO 4074-6:1996, ISO 4074-7:1996, ISO 4074-8:1984, ISO 4074-9:1996, ISO 4074-10:1990 and ISO 4074-12:1980.

Annexes A, C, D, E, F, G, H, I, J, L, M and N form a normative part of this International Standard. Annexes B, K, O and P are for information only.

This corrected version of ISO 4074:2002 incorporates correction in the Foreword, where the years of publication of the parts of ISO 4074 being replaced by the new edition were erroneously omitted.

Introduction

The intact latex film has been shown to be a barrier to human immunodeficiency virus (HIV), other infectious agents responsible for the transmission of sexually transmitted infections (STIs) and to spermatozoa. In order to help ensure that condoms are effective for contraceptive purposes and for assisting in the prevention of transmission of STIs, it is essential that condoms fit the penis properly, are free from holes, have adequate physical strength so as not to break during use, are correctly packaged to protect them during storage and are correctly labelled to facilitate their use. All these issues are addressed in this International Standard.

The condom and any lubricant, additive, dressing, individual packaging material or powder applied to it should neither contain nor liberate substances in amounts that are toxic, sensitizing, locally irritating or otherwise harmful under normal conditions of storage or use. Reference should be made to ISO 10993 for test methods to evaluate the safety of condoms particularly in respect of the risk of local irritation and sensitization.

Condoms are medical devices. Therefore they should be produced under a good quality management system. Reference should be made, for example to the ISO 9000-series, ISO 14971-1 and one of the relevant standards: ISO 13485 or ISO 13488.

Condoms are non-sterile medical devices but manufacturers should take appropriate precautions to minimize microbiological contamination of the product during manufacture and packaging.

This first edition of ISO 4074 requires manufacturers to conduct stability tests to estimate the shelf life of any new or modified condom before the product is placed on the market and to initiate real-time stability studies. These requirements are described in clause 7. The real-time stability test can be considered as part of the manufacturer's requirement to conduct post-marketing surveillance on their products. These requirements are intended to ensure that manufacturers have adequate data to support shelf-life claims before products are placed on the market and that these data are available for review by regulatory authorities, third-party test laboratories and purchasers. They are also intended to limit the need for third parties to conduct long-term stability studies.

A guideline (ISO 16038) for the application of this International Standard is under development by ISO/TC 157/WG 14.

This International Standard contains requirements for tensile properties (force at break) when a manufacturer makes a claim for "extra strength". Annex I contains the test method for determination of force and elongation at break, as it may be useful in the quality system of a manufacturer and in very special cases in a purchaser's contract.

Background information including technical explanations relating to certain clauses of this International Standard is given in annex P. Where this is relevant, the appropriate clause in annex P is referenced in the text.