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Second edition
2014-08-15

Natural rubber latex male condoms — Requirements and test methods

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



Reference number
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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.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

This second edition cancels and replaces the first edition (ISO 4074:2002), which has been technically revised. It also incorporates the Technical Corrigenda ISO 4074:2002/Cor.1:2003 and ISO 4074:2002/Cor.2:2008. The modifications are as follows:

- a) The maximum lot size has been limited to 500 000.
- b) Specific requirements for biocompatibility assessments, as defined in ISO 10993-1, have been added.
- c) It is recommended that manufacturers establish procedures for the periodic monitoring of microbial contamination (bioburden) as part of their quality management system including requirements for the absence of specific pathogens and limits for total viable counts on finished condoms; methods of determining bioburden levels on condoms are given in [Annex G](#).
- d) Specific requirements for extra strength condoms have been deleted but there is now a general requirement for manufacturers to justify any additional claims made for their products; claims relating to improved efficacy or safety have to be substantiated by clinical investigation.
- e) A minimum airburst volume of 28,0 dm³ has been introduced for condoms with mid-body widths that are greater than or equal to 65,0 mm and not more than 75,0 mm.
- f) The radius of the inner edge of the clamping collar wherever it contacts the inflated condom has to be a minimum of 2 mm ([Annex H](#)).
- g) The volumes of electrolyte used in the electrical test for determining freedom from holes described in [Annex M](#) have been brought into line with the volumes used for the water leak test.
- h) The volumes of water or electrolyte specified in the freedom from holes test have been increased for condoms that have mid-body widths greater than or equal to 56 mm and/or are longer than 210 mm.
- i) When conducting the electrical test for freedom from holes, the voltage is now measured from the time that the condom is first immersed and for up to 10 s after full immersion.

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- j) The method of testing for freedom from holes specified in ASTM D3492^[8] has been included by reference.
- k) A limit has been introduced for the number of individual containers with visibly open seals, to be evaluated when the containers are inspected during the freedom from holes test described in [Annex M](#).
- l) Recommended requirements for minimum airburst properties and freedom from holes testing for condoms narrower than 45 mm and/or shorter than 160 mm have been introduced in informative [Annex P](#) to provide guidance to regulatory authorities, Notified Bodies and other interested parties when assessing condoms that fall outside of the normative size range specified in the standard.
- m) Amendments have been made to the methods for determining the shelf life of condoms including a simplified procedure for determining the shelf life by accelerated stability studies based on fixed ageing periods at 50 °C.
- n) Testing for freedom from holes, airburst properties and package integrity are required when conducting stability studies to establish that condoms meet the minimum stability requirements specified in the standard and when determining condom shelf lives.
- o) The procedure for determining the thickness of a condom by the micrometer method is described in detail.
- p) An alternative method of removing the lubricant from the condom using an aqueous surfactant solution has been introduced into the method for determining the amount of lubricant on the condom.
- q) Revisions have been made to labelling requirements including the additional information supplied with the condom.

Regulatory agencies, Notified Bodies and purchasers should consider the need for a transition period when implementing the requirements of this International Standard to allow manufacturers to make the changes required to maintain compliance. This applies particularly to the changes in packaging and labelling specified in [Clause 15](#).

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Introduction

Condoms made from intact latex film have 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. Numerous clinical studies have confirmed that male latex condoms are effective in helping to prevent pregnancy and reduce the risk of transmission of most STIs including HIV.

In order to help ensure that condoms are effective for contraceptive purposes and in 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.

Condoms are medical devices. To ensure high quality product, it is essential that condoms are produced under a good quality management system. See ISO 13485^[4] for quality management requirements and ISO 14971^[5] for risk management requirements.

Condoms are non-sterile medical devices but manufacturers are advised to take appropriate precautions to minimize microbiological contamination of the product throughout the manufacturing and packaging processes. Recommendations for manufacturers to periodically monitor microbial contamination during production are included in this International Standard. Methods that can be used to determine bioburden levels are included in [Annex G](#).

This International Standard 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 11](#). The real-time stability test may be considered as part of the manufacturers' 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.

Condoms might be subject to specific local requirements as required by national regulatory bodies in addition to those specified in this International Standard.

ISO 16038^[6] provides guidance for the application of this International Standard. It includes additional information on the test methods and requirements specified in this International Standard.