INTERNATIONAL STANDARD

**ISO 4074**

Second edition
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# Natural rubber latex male condoms — Requirements and test methods

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



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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).

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 $dm^3$ 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 that 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.

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.

# 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.

# Natural rubber latex male condoms — Requirements and test methods



## 1 Scope

This International Standard specifies requirements and test methods for male condoms made from natural rubber latex.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 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 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

## 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

[SOURCE: ISO 2859-1:1999, 3.1.26]

**3.2**
**male condom**
medical device used by consumers, which is intended to cover and be retained on the penis during sexual activity, for purposes of contraception and prevention of sexually transmitted infections

**3.3**
**consumer package**
package, intended for distribution to a consumer, containing one or more individual containers of condoms