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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

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 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

3.4
expiry date
date after which the condom should not be used

3.5
identification number
number, or combination of numerals, symbols or letters, used by a manufacturer on consumer packages to identify uniquely the lot numbers of individual condoms contained in that package, and from which it is possible to trace those lots through all stages of manufacturing, packaging and distribution

Note 1 to entry: When the consumer package contains only one type of condom then the identification number may be the same as the lot number; but if the consumer package contains several different types of condoms, for instance condoms of different shapes or colours, then the identification number will be different from the lot numbers.

3.6
individual container
primary package containing a single condom

3.7
inspection level
index of the relative amount of inspection of an acceptance sampling scheme, chosen in advance, and relating the sample size to the lot size

[SOURCE: ISO 3534-2:2006, 4.3.5]

3.8
lot
collection of condoms of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, raw materials of the same specifications, common equipment and packed with the same lubricant and any other additive or dressing in the same type of individual container

3.9
lot number
number, or combination of numerals, symbols or letters, used by the manufacturer to identify a lot of individually packaged condoms, and from which it is possible to trace that lot through all stages of manufacture up to packaging

3.10
non-visible hole
hole in a condom that is not visible under normal or corrected vision but is detected by the water leak test or the electrical test described in this International Standard

3.11
sampling plan
specific plan which indicates the number of units of product from each lot which are to be inspected (sample size or series of sample sizes) and the associated criteria for determining the acceptability of the lot (acceptance and rejection numbers)

3.12
shelf life
period from date of manufacture during which condoms are required to conform to the requirements for bursting pressure, bursting volume, freedom from holes and pack integrity specified in this International Standard

3.13
visible hole
hole in the condom that is visible under normal or corrected vision before the condom is filled with water or electrolyte during testing for freedom from holes

3.14
date of manufacture
date specified by the manufacturer when the product was made subject to the requirements specified in 11.1

3.15
visible defects (other than holes and tears)
broken, missing or severely distorted bead and permanent creases with adhesion of the film

4 Quality verification

Condoms are mass produced articles manufactured in very large quantities. Inevitably there will be some variation between individual condoms, and a small proportion of condoms in each production run might not meet the requirements in this International Standard. Further, the majority of the test methods described in this International Standard are destructive. For these reasons the only practicable method of assessing conformity with this International Standard is by testing a representative sample from a lot or series of lots. Basic sampling plans are given in ISO 2859-1. Reference should be made to ISO/TR 8550[2] for guidance on the use of acceptance sampling system, scheme or plan for the inspection of discrete items in lots. For testing purposes, sampling shall be conducted by lot number, not by identification number.

When on-going verification is required of the quality of condoms, it is suggested that, instead of concentrating solely on evaluation of the final product, attention is also directed at the manufacturer's quality system. In this connection it should be noted that ISO 13485[4] covers the provision of an integrated quality system for the manufacture of medical devices.

Sampling plans shall be selected to provide an acceptable level of consumer protection. Suitable sampling plans are given in Annexes A and B.

a) Annex A describes sampling plans based on ISO 2859-1 and is most applicable to manufacturers or purchasers assessing the conformity of a continuing series of lots. The full level of consumer protection available depends upon the switch to tightened inspection if deterioration in quality is detected. The switching rules, described in ISO 2859-1:1999, Clause 9, cannot offer their full protection for the first two lots tested but become progressively more effective as the number of lots in a series increases. The sampling plans in Annex A are recommended when five or more lots are being tested.

b) Annex B describes sampling plans, based on ISO 2859-1, that are recommended for the assessment of isolated lots. The sampling plans in Annex B provide approximately the same level of consumer protection as those given in Annex A when used with the switching rules. It is recommended that these sampling plans are used for the assessment of fewer than five lots, for example in cases of dispute, for referee purposes, for type testing, for qualification purposes or for short runs of continuing lots.

It is necessary to know the lot size in order to derive from ISO 2859-1 the number of condoms to be tested. The lot size will vary between manufacturers and is regarded as part of the process and quality controls used by the manufacturer.

If the lot size is not known or cannot be confirmed by the manufacturer then a lot size of 500 000 condoms shall be assumed for determining the sample sizes for testing.

5 Lot size

The maximum individual lot size for production shall be 500 000 condoms.

NOTE This International Standard does not specify the size of a lot, but it is possible for a purchaser to do so as part of the purchasing contract. Purchasers are encouraged to specify a lot size compatible with the manufacturer's quality management system.

6 Biocompatibility

For any new product or following a significant change to the formulation or manufacturing process, biocompatibility assessments shall be conducted in accordance with ISO 10993-1. Evaluation for cytotoxicity according to ISO 10993-5, irritation according to ISO 10993-10 and sensitization (delayed contact hypersensitivity) according to ISO 10993-10 shall be conducted. The condom together with any lubricant, additive, dressing material, or powder applied to it shall be evaluated.

The laboratory used for any testing shall comply with the requirements contained in ISO/IEC 17025. The results shall be interpreted by a qualified toxicologist or any other appropriately qualified expert. The biological assessment report shall justify that the product is safe for its intended use.

NOTE Many latex products that have been established as safe including condoms and medical gloves can exhibit a positive cytotoxic response when tested according to ISO 10993-5. While any cytotoxic effect can be of concern, it is primarily an indication of potential for *in vivo* toxicity and a condom cannot necessarily be determined to be unsuitable for use based solely on cytotoxicity data.

7 Microbial contamination

Manufacturers are recommended to establish procedures for the control and periodic monitoring of microbial contamination (bioburden) as part of their quality management system. *Staphylococcus aureus, Pseudomonas aeruginosa* and *Enterobacteriaceae,* including *Escherichia coli*, are pathogenic organisms that can potentially be found on condoms and can cause urinary tract or other infections. It is recommended that these organisms are absent from condoms. The procedures should include requirements for 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.

NOTE 1 General methods for determining microbial contamination on sterile medical devices are given in ISO 11737-1. The standard includes methods for validating testing (ISO 11737-1:2006, Annex C). The methods described in Annex G of this International Standard have been found to be suitable for use with condoms taking into account specific issues associated with testing these products. These issues include the residual antimicrobial activity of some of compounds used in latex formulations which can interfere with the assays.

NOTE 2 To control microbial contamination on the finished product manufacturers need to control the manufacturing environment to reduce the risk of contaminating the product, establish general cleaning and sanitizing procedures throughout the operation, and monitor bioburden levels on raw materials and equipment.

8 Product claims

Condoms meeting the requirements of this International Standard may be used for contraceptive purposes and to help protect against sexually transmitted infections. Manufacturers shall justify any additional claims made for their products. If a manufacturer makes a claim relating to improved efficacy or safety then the claim shall be substantiated by appropriate clinical investigation to demonstrate superiority. Information supporting such claims shall be made available on request to interested parties including regulatory authorities and Notified Bodies.

9 Design

9.1 Integral bead

The open end of the condom shall terminate in an integral bead.

9.2 Lubrication

If verification is required of the quantity of lubricant on a condom (and in the package), either of the methods given in Annex C shall be used. The criteria of compliance shall be as agreed between the parties concerned.

The methods in Annex C also recover part of the dressing powder on the condom. An allowance should be made for this when manufacturers or purchasers specify lubricant levels.

9.3 Dimensions

9.3.1 Length

When tested by the method given in Annex D, taking 13 condoms from each lot, no individual measurement shall be below 160 mm.

Condoms that do not comply with the limit specified above cannot be claimed to meet ISO 4074.

9.3.2 Width

When tested by the method given in Annex E measuring at the narrowest part of the condom in the range of 20 mm to 50 mm from the open end, taking 13 condoms from each lot, no measurement of the width shall deviate from the nominal width stated by the manufacturer by more than ± 2 mm.

9.3.3 Thickness

If verification is required of the thickness of a condom, the average thickness, determined in accordance with one of the methods given in Annex F, shall be equal to the claimed nominal thickness, subject to a tolerance of:

— ± 0,008 mm for condoms with nominal claimed thickness less than 0,05 mm;

— ± 0,01 mm for condoms with nominal claimed thickness equal to or greater than 0,05 mm;

10 Bursting volume and pressure

When determined in accordance with Annex H, the bursting pressure shall not be less than 1,0 kPa and the bursting volume shall be not less than:

— 16,0 dm^3 for condoms with a mid-body width greater than or equal to 45,0 mm and less than 50,0 mm; or

— 18,0 dm^3 for condoms with a mid-body width greater than or equal to 50,0 mm and less than 56,0 mm; or

— 22,0 dm^3 for condoms with a mid-body width greater than or equal to 56,0 mm and less than 65,0 mm: or

— 28,0 dm^3 for condoms with a mid-body width greater than or equal to 65,0 mm and not more than 75,0 mm.

For the purpose of this test, the mid-body width is the mean flat width rounded to the nearest 0,5 mm of 13 condoms measured in accordance with Annex E at a point (75 ± 5) mm from the closed end excluding the reservoir tip.

The compliance level for each lot shall be an AQL of 1,5 for condoms that fail the requirement for bursting volume, or bursting pressure or both.

Condoms that do not comply with the limits specified above cannot be claimed to meet ISO 4074.

For condoms that have a mid-body width less than 45,0 mm and/or are shorter than 160 mm excluding the reservoir tip, guidelines for bursting pressures and volumes are given in Annex P. Marketing of these products is at the discretion of the appropriate regulatory authorities or Notified Bodies.

11 Stability and shelf life

11.1 General

Manufacturers shall verify that the condoms comply with the requirements of Clauses 10, 12 and 14 until the end of the labelled shelf life. Products on the market at the time of publication of this International Standard whose shelf lives have been established according to the procedures specified in ISO 4074:2002 shall be deemed to comply with the shelf life claims of this International Standard unless the manufacturer has made significant changes to the process, formulation or packaging type. Shelf life claims shall not exceed 5 years from the date of manufacture.

The date of manufacture can be the date of dipping or the date of packaging in individual sealed containers depending upon the procedures specified by the manufacturer. The date of manufacture shall not exceed 2 years from the date of dipping. Unpackaged condoms shall be stored under controlled conditions as specified by the manufacturer between dipping and packaging. Manufacturers shall have documented procedures for validating the storage conditions and maximum storage period. The stored condoms shall be protected from exposure to excessive temperatures, light, ozone and any other factor that could affect the shelf life of the packaged condoms.

Assessment for minimum stability and shelf life claims shall be verified on condoms that have been stored in bulk for the maximum permitted period between dipping and packaging, and under the conditions specified by the manufacturer.

Data supporting the shelf life claims made by the manufacturer shall be made available on request to interested parties including regulatory authorities, Notified Bodies and testing laboratories.

Before compliance with this International Standard may be claimed for a new or modified condom design, the manufacturer shall provide evidence that the following requirements have been met:

— the condom shall comply with the minimum stability requirements as described in 11.2;

— a real-time study as described in 11.3 to determine shelf life shall have commenced;

— pending completion of the real-time study manufacturers shall substantiate shelf-life claims as described in 11.4.

NOTE 1 A modified condom design is one in which there have been significant changes to the formulation, manufacturing process or individual sealed containers.

NOTE 2 Compliance with the requirements of 11.2 does not imply that the shelf life of the product has been determined.

NOTE 3 A practical limit of 5 years has been set for the shelf life because manufacturers have no control over storage conditions once condoms have been distributed.

Shelf life estimates (11.4) shall be based on a mean kinetic temperature of $\left(30^{+5}_{-2}\right)$ °C for all climatic conditions and should be carried out on condoms from the same production lots as used for real-time determination of shelf life (11.3).

11.2 Minimum stability requirements

Test three lots of condoms for conformity with this International Standard, except for 15.2 and 15.3.

Only lots meeting all of the requirements of Clauses 9, 10, 12, 13 and 14 shall be used for this test.

Condition samples in their individual sealed containers according to Annex I, one set for (168 ± 2) h (1 week) at (70 ± 2) °C and the other set for (90 ± 1) days at (50 ± 2) °C. At the end of the incubation periods withdraw the condoms and test for compliance with the requirements of Clauses 10, 12 and 14 using as a minimum the sampling plans specified in Annex A or preferably the sampling plans in Annex B.

The test report shall include the requirements of Annexes H, K, M and N, and Clause 16.

NOTE 1 Data to verify compliance with 11.2 may be extracted from studies for estimates of shelf life (11.4).

NOTE 2 This test ensures that the condoms have adequate stability to be placed on the market pending verification of shelf life claims. It is not predictive of shelf life. Purchasers, test laboratories and other interested parties may use this test to confirm that condoms meet the minimum stability requirements.

11.3 Procedure for determining shelf life by real-time stability studies

Real-time stability testing shall be conducted on three lots of condoms meeting all of the requirements of Clauses 9, 10, 12, 13 and 14. Real-time stability studies shall continue for the full period of the shelf life claim. In no case shall shelf life claim exceed 5 years.

For condoms placed on the market based upon accelerated stability studies, if the real-time data indicates a shorter shelf life than that claimed on the basis of accelerated ageing (11.4), the manufacturer shall notify the relevant regulatory authorities and direct purchasers. The manufacturer shall change the shelf life claim for the product to one based upon the real-time study.

Test three lots of condoms for conformity with this International Standard, except for 15.2 and 15.3.

After testing according to Annex K using the sampling plans specified in Annex A or preferably the sampling plans in Annex B, the condoms shall meet the requirements specified in Clauses 10, 12 and 14.

The test report shall include the requirements of Annexes H, K, M and N, and Clause 16.

11.4 Estimating shelf life based upon accelerated stability studies

Pending the completion of real-time studies, manufacturers shall substantiate provisional shelf life claims. Accelerated stability studies may be used for this purpose.

Test three lots of condoms for conformity with this International Standard, except for 15.2 and 15.3.

Only lots meeting all of the requirements of Clauses 9, 10, 12, 13 and 14 shall be used for accelerated stability testing.

Further information on accelerated studies is provided in Annex L. Data generated from such studies shall support the claim that the condoms fulfil the requirements in Clauses 10, 12 and 14 for the duration of the labelled shelf life at $\left(30^{+5}_{-2}\right)$ °C.

The test report shall include the requirements of Annexes H, L, M and N, and Clause 16.

12 Freedom from holes

When tested by either method described in Annex M, the compliance level, for each lot, for the sum of condoms with visible and non-visible holes and tears shall be an AQL of 0,25.

The method for testing for freedom from holes specified in ASTM D3492 may also be used.

Condoms that have a mid-body width less than 45 mm and/or are shorter than 160 mm excluding the reservoir tip cannot be claimed to meet ISO 4074. Guidelines for the volume of water or electrolyte to be used in the freedom from holes test for these condoms are given in Annex P. Marketing of these products is at the discretion of the appropriate regulatory authorities or Notified Bodies.

13 Visible defects

For visible defects specified in M.2.3.4 and M.3.3.5, the compliance level for each lot shall be an AQL of 0,4.

14 Package integrity of individual container

When individual containers comprising one or more flexible laminated films sealed together are tested in accordance with Annex N, the compliance level for each lot shall be an AQL of 2,5.

When condoms are tested for freedom from holes, the individual containers shall be inspected for visibly open seals. The compliance level for individual containers having visibly open seals shall be an AQL of 0,4.

For designs of individual container other than flexible laminated films, the manufacturer shall apply a suitable pack integrity test. The compliance level for each test shall be an AQL of 2,5. The method given in Annex N may be used with suitable adjustment to the level of vacuum applied. Details of the test method shall be provided to regulatory authorities, testing laboratories and purchasers on request.

15 Packaging and labelling

15.1 Packaging

Each condom shall be packed in an individual container. One or more individual containers may be packed in other packaging such as a consumer package. The individual container, or consumer package or both shall be opaque to light. If condoms are intended to be supplied only in individual containers, the individual containers shall be opaque.

If a marking medium, such as ink, is used on a condom or on any part of a package directly in contact with a condom, it shall not have any deleterious effect on the condom or be harmful to the user.

Individual containers and any other packaging shall protect the condom from damage or loss of lubricant during normal transport and storage.

Individual containers and any other packaging shall be designed in such a way that the package can be opened without damaging the condom. The design of the individual container should facilitate easy opening, for example by having a notch to help initiate tearing.

15.2 Labelling

15.2.1 General

Where national regulations apply in relation to labelling they take precedence over the requirements in this International Standard. When there is no contradiction with national regulations, the requirements of this International Standard shall apply.

15.2.2 Symbols

If symbols are used on packaging, information and marketing materials, the symbols shall meet the requirements in ISO 15223. If symbols are used on the outside of the consumer packaging their meaning should be explained in the additional information on the inside of the consumer package or a leaflet contained within the consumer package.

15.2.3 Individual container

Each individual container shall be indelibly and legibly marked with at least the following information.

a) The identity of the manufacturer or distributor or, if permitted by local regulations, the registered brand or trade mark.

b) The manufacturer's identifying reference for traceability (e.g. the lot number).

c) The expiry date (year, month). The format of the year shall be in four digits; the format of the month shall be in letters or two digits.

d) Any additional marking required by local regulations.

NOTE For condoms intended for distribution within the European Union additional marking includes the CE Mark. Refer to EN 1041[7] for additional requirements for condoms intended for distribution within the European Union.

15.2.4 Consumer package

15.2.4.1 General

The outside of the consumer package shall bear at least the following information in at least one of the official language(s) of the country of destination or as stipulated by the national authority.

a) A full description of the condom, for example whether or not it has a reservoir tip, is parallel sided or shaped, is coloured or natural, textured or plain, has a flavour or fragrance, and is lubricated or not. A diagram may be used to convey some of this information.

b) The number of condoms contained.

c) The nominal width of the condom.

d) The name or trade name and full postal address of the manufacturer and/or distributor and/or manufacturer's authorized representative, depending on national and regional requirements. A PO Box number is not an acceptable address.

NOTE For condoms intended for distribution within the European Union the name or trade name and address of the manufacturer is required. Where the manufacturer does not have a registered place of business in the European Union the name and address of the European Authorized Representative is also required.

e) The expiry date (year and month). The format of the year shall be in four digits and the format of the month shall be in letters or two digits. If a consumer package includes condoms from different lots, the earliest expiry date shall apply to all condoms.

f) A statement to store the condom in a cool dry place away from direct sunlight. Accepted symbols may be used as an alternative.

g) If the individual containers are not opaque to light a statement that individual containers should not be stored outside the opaque consumer package.

h) Whether the condom is lubricated or dry. When a medicinal ingredient is added, it shall be identified and its purpose indicated (e.g. spermicidal). If the condom or lubricant is fragranced or flavoured, this shall be stated.

i) The manufacturer's identifying reference for traceability (e.g. the identification number/lot number). If different types of condoms, e.g. different colours, are packaged together in the same consumer package, the identification number on the consumer package shall allow the manufacturer to identify uniquely the lot numbers of the individual condoms contained in that package, so that it is possible to trace those lots through all stages of manufacture up to packaging.

j) A statement that the condom is made of natural rubber latex, which might cause allergic reactions including anaphylactic shock. An accepted symbol for natural rubber latex may be used as an alternative. If a symbol is used the additional information on the inside of the consumer package or a leaflet contained within the consumer packaging shall include a statement warning about the risk of allergic reactions including anaphylactic shock.

k) For condoms intended for distribution within the European Union, the CE Mark.

l) A statement that the condom is for single use only. An accepted symbol may be used as an alternative.

m) A statement to read the instructions for use. An accepted symbol may be used as an alternative.

15.2.4.2 Additional information

The outside or the inside of the consumer package, or a leaflet contained within the consumer package, shall bear at least the following information expressed in simple terms, and in at least one of the official language(s) of the country of destination, if possible supplemented by pictorial representations of the major steps involved or as stipulated differently by that country.

a) Instructions for use of the condom, including

   1) the need to handle the condom carefully, including removal from the package so as to avoid damage to the condom by fingernails, jewellery, etc.,

   2) how and when to put on the condom; mention should be made that the condom should be placed on the erect penis before any contact occurs between the penis and the partner's body to assist in the prevention of sexually transmitted infections and pregnancy,

   3) the need to stop and check if the user feels the condom slipping off or tightening excessively onto the penis because this might lead to breakage,

   4) the need to withdraw the penis soon after ejaculation, while holding the condom firmly in place at the base of the penis,

   5) the need, if an additional lubricant is desired, to use the correct type of lubricant which is recommended for use with condoms and the need to avoid the use of oil-based lubricants such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine, etc. as these are deleterious to the integrity of the condom,

   6) the need to consult a doctor or pharmacist about the compatibility of topical medicines that might come in contact with the condom,

   7) advice to seek medical assistance as soon as possible, at least within 72 h should a condom leak or burst during use,

   8) advice that if the individual container is obviously damaged to discard that condom and use a new one from an undamaged package.

b) Instructions on how to dispose of the used condom.

c) A statement that the condom is for single use and that if reused there might be an increased risk of failure or infection.

d) An explanation of any symbol used on the packaging.

e) A statement that the condom is made of natural rubber latex, which might cause allergic reactions including anaphylactic shock if a symbol for latex is used on the packaging.

f) The date of issue or the date of latest revision of the instructions for use.

g) The number of this International Standard, i.e. ISO 4074.

h) For condoms intended for distribution within the European Union, the CE Mark.

15.2.5 Condoms not distributed in consumer packages

For condoms that are distributed without a consumer package (e.g. in single foils or strips of foils), complete information should be made available in accordance with local regulations.

NOTE 1 In the European Union the labelling must comply with the European Medical Device Directives 93/42/EEC as amended.

NOTE 2 In countries outside of Europe, information can be in the form of leaflets, training sessions, posters, or additional packing added in the distribution chain, subject to local regulations. For guidance on the content, see 15.2.4.1 and 15.2.4.2.

15.3 Inspection

When tested for conformity for labelling requirements, 13 consumer packages and 13 individual containers from each lot shall be inspected. All inspected containers shall conform to the requirements.

Under certain conditions it is permissible for the manufacturer to correct faults associated with packaging and labelling requirements and resubmit the lot for further conformity testing. Examples include insertion of missing instruction leaflets or re-packaging of individual containers into new complete consumer packages before placing on the market.

If condoms from the same lot are packed into different consumer packages, then at least one consumer package of each variant should be inspected. The number of packages inspected should not exceed 13 unless the number of variants exceeds 13.

16 Test report

Test reports to demonstrate conformity to one or more of the requirements of this International Standard shall contain at least the following information:

a) name and address of the test laboratory;

b) name and address of the client;

c) identification of the test report;

d) the identity of the sample (brand or name, sample size, lot number and lot size);

e) origin of the sample, date of the sample's arrival at the laboratory;

f) a reference to this International Standard and the relevant annexes;

g) a description of all deviations from this International Standard;

h) the test results according to relevant annexes; summary results may be substituted by agreement with the client but the full results shall be provided on request to relevant interested parties;

i) the uncertainty in the test result, if available;

j) date of the test report and the signature and title of the person(s) responsible for the report.

Annex A
(normative)

Sampling plans intended for assessing compliance of a continuing series of lots of sufficient number to allow the switching rules to be applied

A.1 Quality verification

When on-going verification is required of the quality of condoms, it is suggested that, instead of concentrating solely on evaluation of the final product, the party concerned also directs his attention to the manufacturer's quality system. In this connection it should be noted that ISO 9000[17] series and, in particular, ISO 13485,[4] covers the provision of an integrated quality system.

A.2 Sampling plans and compliance levels

If a party wishes to establish, by inspection and testing of samples of the final product, whether a continuing series of lots are in compliance with the requirements of this International Standard, the sampling plans and acceptance criteria given in Table A.1 shall be applied.

Manufacturers may use the schemes in Table A.1 or may devise and implement validated alternative quality control methods that result in at least equivalent consumer protection.

When tests are being conducted on fewer than five lots of condoms the additional protection of the switching rules in ISO 2859-1 is not available and it is recommended that the sampling plans given in Annex B are used to maintain the level of consumer protection.

Table A.1 — Sampling plans and acceptance criteria for a continuing series of lots

Attributes	Inspection level[a]	Acceptance criteria
Length and width	13 condoms	All samples shall meet the criteria of length ≥ 160 mm and width ± 2 mm of stated nominal width
Bursting volume and pressure	General Inspection Level I	AQL of 1,5
Freedom from holes	General Inspection Level I but at least code letter M	AQL of 0,25
Visible defects	General Inspection Level I but at least code letter M	AQL of 0,4
Individual containers with visibly open seals	General Inspection Level I but at least code letter M	AQL of 0,4
Package integrity	Special Inspection Level S-3	AQL of 2,5
Packaging and labelling	13 consumer packages and 13 individual containers	All shall comply
Quantity of lubricant	13 condoms	As agreed (see 9.2)
Thickness	13 condoms	As agreed (see 9.3.3)

[a] See ISO 2859-1 where relevant.

Applications for these sampling plans include the following:

a) on-going production testing and quality control by a manufacturer;

b) on-going testing by a purchaser for contractual purposes;

c) on-going inspection by a national authority.

Annex B
(informative)

Sampling plans intended for assessing compliance of isolated lots

Use of the sampling plans given in Annex A for small numbers of lots, i.e. fewer than five, will result in a higher level of consumer risk because the switching rules are not available. In such circumstances the use of larger sample sizes is recommended in order to maintain an acceptable level of consumer protection. The choice of a suitable sampling plan will be governed by cost considerations. Larger sample sizes will give better discrimination but at increased cost. Purchasers may, for example, rely upon their experience with a particular supplier when assessing the sample sizes to use for small numbers of lots.

The sampling plans given in Table B.1 when applied to isolated lots, provide approximately the same level of consumer protection as those given in Annex A when used in conjunction with the switching rules. Attention is drawn to the possibility of using Double or Multiple Sampling Plans which can reduce the total number of condoms that need to be tested to demonstrate compliance when quality is significantly better than the AQLs.

The producers' and consumers' risk associated with these sampling plans can be obtained by reference to the relevant tables and operating characteristic curves given in ISO 2859-1.

NOTE There is no simple mathematical formula for computing the sample size solely as a function of the lot size. Sample sizes may be increased independently of the lot size to achieve a more reliable estimate of lot quality.

Table B.1 — Sampling plans and acceptance criteria for isolated lots

Attributes	Inspection level[a]	Acceptance criteria
Length and width	13 condoms	All samples shall meet the criteria of length ≥ 160 mm and width ± 2 mm of stated nominal width
Bursting volume and pressure	General Inspection Level I but at least code letter M	AQL of 1,5
Freedom from holes	General Inspection Level I but at least code letter N	AQL of 0,25
Visible defects	General Inspection Level I but at least code letter N	AQL of 0,4
Individual containers with visibly open seals	General Inspection Level I but at least code letter N	AQL of 0,4
Package integrity	Special Inspection Level S-3 but at least code letter H	AQL of 2,5
Packaging and labelling	13 consumer packages and 13 individual containers	All shall comply
Quantity of lubricant	13 condoms	As agreed (see 9.2)
Thickness	13 condoms	As agreed (see 9.3.3)

[a] See ISO 2859-1 where relevant.

These sampling plans should be used for the following:

a) type testing as part of a certification procedure;

b) in cases where the total number of lots being assessed is insufficient to allow the switching rules to be effective;

c) in cases of dispute involving isolated lots, e.g. for referee testing.

Annex C
(normative)

Determination of total lubricant for condoms in individual containers

C.1 General

This annex specifies two alternative methods of equal validity for determining the amount of lubricant on a condom. The methods differ in the choice of medium used to remove the lubricant. In the first method propan-2-ol is used. In the second an aqueous solution of surfactant is used.

If other solvents, surfactants or surfactant concentrations are used, different results might be obtained. Any changes to the solvent, surfactant or drying procedures necessary to meet local needs shall be fully validated to demonstrate equivalence with the procedures specified in this International Standard.

C.2 Propan-2-ol method

C.2.1 Principle

The mass loss is determined by removing the lubricant from the pack and condom by washing with a solvent. Washing is carried out either in an ultrasonic bath or by manual agitation. A minimum sample size of 13 condoms shall be used.

C.2.2 Apparatus

C.2.2.1 **Ultrasonic cleaning bath(s)** or suitable container, e.g. **beaker**, and **stirrer**.

C.2.2.2 **Balance,** accurate to 1 mg.

C.2.2.3 **Propan-2-ol,** laboratory reagent grade.

C.2.2.4 **Scissors**

C.2.2.5 **Indelible marker pen**

C.2.2.6 **Soft industrial roll tissue**

C.2.2.7 **Drying oven**

C.2.3 Procedure

C.2.3.1 Weigh each sealed individual container to the nearest 1 mg and record the results.

C.2.3.2 Slit the individual container carefully around three edges or tear the containers along one edge. Carefully remove the condom from the individual container, leaving the individual container in one piece. Split the individual container on two sides of the pocket, using scissors if needed. Label each condom and respective individual container using an indelible marker pen, allowing sufficient time for the markings to dry thoroughly.

C.2.3.3 Using a pair of scissors, carefully make a cut across from side to the centre point of the rolled condom. Unroll the condom to a sheet to expose fully all surfaces.

C.2.3.4 When using the ultrasonic bath, immerse the condom and individual container in propan-2-ol in an ultrasonic bath and wash for 2 min to 10 min. Repeat the washing in clean propan-2-ol as many times as necessary until two consecutive weighings differ by less than 10 mg after drying as below in C.2.3.6 to C.2.3.7.

C.2.3.5 When washing the condoms manually, immerse the condom and individual container in propan-2-ol in a bath and wash with manual agitation. Repeat the washing in clean propan-2-ol as many times as necessary until two consecutive weighings differ by less than 10 mg after drying as below in C.2.3.6 to C.2.3.7.

C.2.3.6 Remove the condom and individual container from the propan-2-ol and wipe to remove excess propan-2-ol.

C.2.3.7 Dry the condom and individual container at a temperature not exceeding 55 °C until two consecutive weighings at least 15 min apart differ by less than 10 mg.

C.2.3.8 Weigh each dry condom and individual container to the nearest 1 mg and subtract this result from that found in C.2.3.1 to give the total quantity of lubricant.

C.2.4 Accuracy of lubricant recovery

In an inter-laboratory study, this method was shown to recover about 85 mg more "lubricant" than the amount that was added when the test samples were made. This excess "lubricant" is partly dressing powder, which is also removed by the method.

C.3 Aqueous surfactant method

C.3.1 Principle

The mass loss is determined by removing the lubricant from the individual container and condom by washing with an aqueous surfactant solution. Washing is carried out by manual agitation. A minimum sample size of 13 condoms shall be used.

C.3.2 Apparatus

C.3.2.1 Suitable containers, e.g. **beakers**, and **stirrer**.

C.3.2.2 **Balance**, accurate to 1 mg.

C.3.2.3 **Potassium laurate**, technical grade.

C.3.2.4 **De-ionised water**

C.3.2.5 **Scissors**

C.3.2.6 **Indelible marker pen**

C.3.2.7 **Soft industrial roll tissue**

C.3.2.8 **Drying oven**

C.3.3 Procedure

C.3.3.1 Weigh each sealed individual container to the nearest 1 mg and record the results.

C.3.3.2 Slit the individual container carefully around three edges or tear the individual containers along one edge. Carefully remove the condom from the individual container, leaving the individual container in one piece. Split the individual container on two sides of the pocket, using scissors if needed. Label each condom and respective individual container using an indelible marker pen, allowing sufficient time for the markings to dry thoroughly.

C.3.3.3 Using a pair of scissors, carefully make a cut across from side to the centre point of the rolled condom. Unroll the condom to a sheet to expose fully all surfaces.

C.3.3.4 Wipe the condom and individual container with soft industrial roll tissue until the lubricant and oily feel are removed as far as possible.

C.3.3.5 Fill beakers of 250 cm^3 capacity with 150 cm^3 of wash material (a mass fraction of 5 % potassium laurate dissolved in deionised water, avoiding foaming). Prepare two beakers per condom for a total of two wash cycles per sample.

C.3.3.6 Place each condom (cut and wiped as above) into a separate beaker containing the wash material. Stir the content with a glass rod agitating periodically for 5 min. Next transfer each condom into a second unused beaker containing fresh wash material and repeat the wash cycle procedure for another 5 min. Meanwhile, place the respective individual container into the first wash beaker and wash for 5 min using the same leftover wash material. Next transfer the individual container into respective second wash cycle beaker and repeat wash for another 5 min using the wash material left over after the second condom wash is completed.

C.3.3.7 Check that the pen markings on the individual condoms are still legible. Bulk all 13 condoms together into a large wash container and rinse with 10 dm^3 of deionised water. Agitate content with glass rod. Repeat the rinse one more time. If the pen markings are becoming difficult to read (due to fading) wash the condoms individually.

C.3.3.8 Fasten the wet condoms onto drying lines in an oven using pegs (or other devices). Leave the condoms to dry fully in the oven at (55 ± 5) °C until two consecutive weighings differ by less than 10 mg (this should take around 30 min).

C.3.3.9 Check that the pen markings on the individual containers are still legible. Bulk all 13 individual containers together into a large wash container and rinse with 10 l of deionised water. Agitate content with glass rod. Repeat the rinse one more time. If the pen markings are becoming difficult to read (due to fading) wash the individual containers individually. Dry the individual containers in a similar manner to the condoms.

C.3.3.10 Weigh the dried condoms and respective individual containers accordingly to 1 mg and record the results.

C.3.3.11 Subtract the final weight (washed and dried condom and respective individual container) from its original weight (condom in individual container); the difference is measured as the amount of lubricant recovered from a condom.

C.3.4 Accuracy of lubricant recovery

In an inter-laboratory study, this method was shown to be equivalent to a solvent recovery method which recovered about 85 mg more “lubricant” than the amount that was added when the test samples were made. This excess “lubricant” was partly dressing powder, which is also removed by the method.

C.4 Expression of results

Report the amount of lubricant recovered to the nearest 10 mg for each condom and the information specified in Clause 16.

Annex D
(normative)

Determination of length

D.1 Principle

The unrolled condom is allowed to hang freely over a mandrel and its length, excluding the reservoir tip, is observed and recorded.

D.2 Apparatus

D.2.1 Mandrel, having a rounded end with a diameter of (25 ± 2) mm with a scale divided into millimetres and dimensions shown in Figure D.1, with the zero beginning at the rounded end or other suitable validated device having the dimensions shown in Figure D.1 capable of measuring the length of the condom from the rounded end.

D.3 Procedure

D.3.1 Move the condom inside the individual container such that it is away from the area where the container is to be torn. Tear the container and remove the condom.

In no circumstances, use scissors or other sharp instruments to open the package.

D.3.2 Unroll the condom, stretch it slightly twice but by no more than 20 mm to smooth out the wrinkles caused by the condom having been rolled up. Lubricants may be removed by washing with a suitable solvent such as propan-2-ol and suitable powders may be added to avoid sticking. Alternatively a suitable powder may be used to absorb the lubricant. If a solvent is used to remove the lubricant an adequate period of drying should be allowed before testing.

D.3.3 Put the condom over the mandrel (D.2.1) and let it hang freely, stretched only by its own mass.

D.3.4 Note, to the nearest millimetre, the smallest value of the length of the condom that can be read on the scale outside the open end of the condom.

D.3.5 Condoms subjected to this test may also be used for determination of width.

D.4 Expression of results

The test report shall include the information specified in Clause 16 and the length of each tested condom.

Dimensions in millimetres

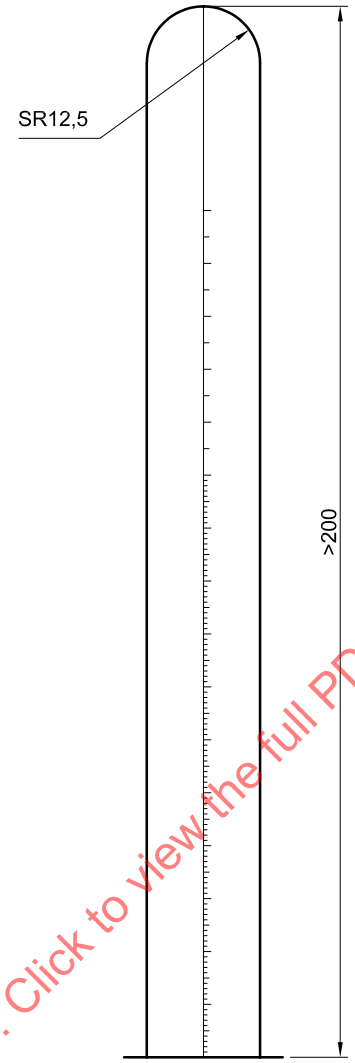

Figure D.1 — Mandrel for determining length of condom

Annex E
(normative)

Method for the determination of width

E.1 Principle

The unrolled condom is allowed to hang freely over the edge of a ruler and its width is observed and recorded.

E.2 Apparatus

E.2.1 **Ruler,** with a scale divided into millimetres or other suitably validated measuring device.

E.3 Procedure

E.3.1 Move the condom inside the individual container such that it is away from the area where the container is to be torn. Tear the container and remove the condom.

In no circumstances, use scissors or other sharp instruments to open the package.

E.3.2 Unroll the condom and lay it flat over the edge of the ruler (E.2.1), perpendicular to the condom's axis, allowing it to hang freely. If a lubricated condom does not hang freely, then the lubricant may be removed by washing with a suitable solvent such as propan-2-ol and suitable powders may be added to avoid sticking. If a solvent is used to remove the lubricant an adequate period of drying should be allowed before testing.

Measure to the nearest 0,5 mm, the width of the condom at a point specified in the relevant clauses of this International Standard.

E.3.3 Condoms subjected to this test may also be used for determination of length.

E.4 Expression of results

The test report shall include the information specified in Clause 16 and the width of each tested condom, including the point along the condom at which the measurement was made.

Annex F
(normative)

Determination of thickness

F.1 General

This annex describes two test methods for determining the thickness of latex rubber condoms. The mass method is recommended for measuring the thickness of textured condoms when the region specified for thickness measurement is textured. When using the micrometer method the latex film is compressed slightly.

F.2 Mass method

F.2.1 Principle

A condom laid flat and test specimen is die cut from it and weighed. Using the mass, the size of the die-cut specimen, and a density of 0,92 g/cm^3, the thickness is calculated.

F.2.2 Apparatus

F.2.2.1 **Laboratory scale**, accurate to 0,1 mg.

F.2.2.2 **Cutting die**, in accordance with I.2.1.

F.2.2.3 **Hydraulic, pneumatic**, or **mechanical press**, suitable for die cutting.

F.2.2.4 **Ruler,** graduated in 1 mm.

F.2.2.5 **Scissors.**

F.2.3 Procedure

F.2.3.1 Move the condom inside the individual container such that it is away from the area where the container is to be torn. Tear the container and remove the condom.

Do not use scissors or other sharp instruments to open the package.

F.2.3.2 Unroll the condom ensuring that it is not excessively stretched in any direction and powder the condom.

F.2.3.3 Lay the condom flat with its length at right angles to the cutting edge of the die. Obtain the test piece by cutting the condom with one stroke of the press when the die is positioned with its centre (30 ± 5) mm from the open end of the condom.

F.2.3.4 Cut the ring open using scissors and measure the length of one edge to the nearest 0,5 mm with the ruler. If the condom is not parallel sided, measure both edges and calculate the mean. Calculate the area as the obtained length, in millimetres, × 20 mm.

F.2.3.5 Repeat F.2.3.3 and F.2.3.4 at (30 ± 5) mm from the closed end and within ± 5 mm of the mid point between the open and closed ends of the condom excluding the reservoir tip.

F.2.3.6 Wash the samples in propan-2-ol and dry until two consecutive weighings at least 15 min apart differ by less than 1 mg.

F.2.3.7 Weigh the specimen to the nearest 0,1 mg and record the individual values.

F.2.3.8 Calculate the thickness of each specimen as follows:

$$t = \frac{1}{\rho} \times \frac{1}{A} \times m$$

where

t is the thickness of the test specimen, in millimetres;

ρ is the density of the rubber made from natural rubber latex (see Bibliography[14]) = 0,92 g/cm^3;

A is the area of the test specimen, in square millimetres;

m is the mass of the test specimen, in milligrams.

F.3 Micrometer method

F.3.1 Principle

The thickness of the condom is measured directly using a micrometer gauge.

F.3.2 Apparatus

F.3.2.1 A **flat footed micrometer**, dial or digital type, measurement intervals of not larger than 0,001 mm, with a foot pressure set at (22 ± 5) kPa. The recommended foot diameter is between 3 mm and 10 mm.

F.3.2.2 Scissors.

F.3.3 Procedure

F.3.3.1 Move the condom inside the individual container such that it is away from the area where the individual container is to be torn. Tear the individual container and remove the condom.

Under no circumstances, use scissors or other sharp instruments to open the package.

F.3.3.2 Unroll the condom ensuring that it is not excessively stretched in any direction and wash the condom in propan-2-ol or other suitable solvent to remove lubricants. Dry the condom to a constant mass (±10 mg).

F.3.3.3 Cut the condom along its length using scissors and open it out to allow the single wall thickness to be measured.

F.3.3.4 Zero the micrometer, place the test specimen on the micrometer and take the measurement at ± 5 mm from the mid-point between the open and closed ends of the condom, excluding the reservoir

tip. Read and record the single wall thickness from the micrometer to the nearest 0,001 mm. Repeat the measurement at two more locations around the circumference of the condom maintaining the same distance between the open and closed ends of the condom; and then record and average the results.

F.3.3.5 Repeat F.3.3.4 at (30 ± 5) mm from the open end of the condom and at (30 ± 5) mm from the closed end, excluding the reservoir tip.

F.4 Expression of results

The test report shall include the information specified in Clause 16 and the following particulars:

a) the calculated thickness of each die-cut specimen when using the mass method or the individual thickness measurements and average for each condom when using the micrometer method;

b) the average thickness at each of the three locations along the length of the condom (i.e. at (30 ± 5) mm from the closed end, (30 ± 5) mm from the open and at ± 5 mm from the midpoint between the open and closed ends);

c) the average calculated thickness of all the condoms measured.

Annex G
(informative)

Determination of microbial contamination

G.1 General

This annex gives three methods for determining microbial contamination (bioburden) on latex condoms. Although these methods have been shown to work effectively with condoms, any methods used need to be validated by the user.

The first method allows the total viable count to be estimated on a condom. The second method also allows the total viable count to be determined but also allows the specified organisms to be identified. The third is based on methods described in the European Pharmacopoeia[9] for counting the total number of viable, aerobic bacteria on Agar plates (direct plating method).

These methods, which are given as examples, are known to work with condoms. Other methods may be used. Methods for determining microbial contamination on sterile medical devices are given in ISO 11737-1.

Residual compounding ingredients in condoms can inhibit bacterial growth and interfere with the assays. It is recommended that culture media used contain additives, such as lecithin and polysorbate (Tween 80), that will neutralize these antimicrobial effects. It is essential that the amounts of lecithin and polysorbate (Tween 80) used are validated with any specific condom type to ensure that any residual inhibitory effects from the condom are neutralized without any direct inhibitory action on bacterial growth due to the additives themselves. Methods for validating test methods are given in ISO 11737-1:2006[3], Annex C. Routine confirmatory testing using spiked samples is strongly recommended, for example using the methods described in USP 62[11] - Suitability of the test method. Further information on determining the effectiveness of the culture medium and the validity of the counting method is given in G.4.3.

It is recommended that a preliminary identification of any organisms found is conducted irrespective of the test method used for enumeration. A gram stain, coagulase test and oxidase test will indicate whether species identification is required. Biochemical profiles may be used to identify organisms to species level.

G.2 Enumeration of total population of aerobic microorganisms on foiled condoms

G.2.1 A random sample of 10 to 13 condoms should be taken from the lot. Each condom is tested individually.

G.2.2 Using sterile forceps and scissors, aseptically remove a condom from the foil, cut the bead in two places, unroll the condom with sterile forceps and place in 10 cm^3 of peptone water with added 0.3 % lecithin and 3 % polysorbate (Tween 80). Lecithin and polysorbate are added to neutralize any residual inhibitory effects from the condoms. It is essential that the amount of lecithin and polysorbate (Tween 80) used is validated with any specific condom type to ensure that any residual inhibitory effects from the condom are inhibited without any direct inhibitory action on bacterial growth due to the additives themselves. Letheen broth may be used as an alternative extraction medium.

G.2.3 In order to remove the bioburden from the condom, mix the contents with a shaker, stomacher or vortex mixer for the time previously determined from validation studies. Care should be taken not to mix too vigorously, as this might kill some microbes.

G.2.4 Using a sterile pipette, transfer 1 cm^3 of the extraction fluid into 20 cm^3 of molten Sabourauds Dextrose Agar (SDA) kept at 40 °C. Mix gently to disperse the sample throughout the media and pour into a sterile Petri dish. Allow to set.

G.2.5 Repeat with another SDA and with 2 × 20 cm^3 of Tryptone Soya Agar (TSA).

G.2.6 Incubate the SDA plates at 20 °C for five days and incubate TSA plates at 30 °C for three days.

G.2.7 Inspect the TSA plates at three days and count colonies. Re-incubate and count at five days.

G.2.8 Count the number of colonies on each TSA plate and find the average of the two counts. Examine the SDA plates and count fungal and yeast colonies. Calculate the average count as above. Make corrections for dilution and recovery factors (previously determined by the validation tests).

The total viable aerobic count is determined by adding together the corrected averages of the fungal and bacterial counts.

G.2.9 Some identification of bacteria is required in order to confirm the absence of the specified organisms. Gram stain and colonial morphology will identify gram positive cocci and gram negative bacilli. A positive coagulase test will indicate probable *Staphylococcus aureus*, while the oxidase test will indicate possible *Pseudomonas* species. Results from these short tests will determine if further identification is required. Biochemical profiling will identify organisms to species level.

G.3 Enumeration of total viable aerobic microbial population and tests for specified microorganisms on foiled condoms

G.3.1 This test is conducted on a pooled sample of 13 condoms. The samples should be taken randomly from a single lot.

G.3.2 Using aseptic technique, remove 13 condoms from packaging with sterile forceps into a large sterile dish, and cut up the condoms using sterile scissors.

G.3.3 Weigh 10 g of material and place it in 100 cm^3 of extraction media in either a 150 cm^3 bottle or a stomacher bag. The extraction media should be capable of neutralizing any residual antimicrobial effect from the condoms. Suggested media is peptone water with the addition of 3 % polysorbate (Tween 80) and 0,3 % lecithin. The lecithin and polysorbate (Tween 80) are added to neutralize any residual inhibitory effect of the condom; the amounts used need to be validated for any specific condom type to ensure that the any residual inhibitory effects from the condom are neutralized without any direct inhibitory effect due to the additives themselves.

G.3.4 Stomach or mix the sample for the time required to remove the bioburden, as previously determined by validation testing.

G.3.5 Using a sterile pipette, transfer 10 cm^3 of the condom extraction fluid into 100 cm^3 of Soya casein digest broth and gently mix.

G.3.6 Proceed using the methods described in USP 31 Microbiological tests <61> and <62> or in the German Pharmacopoeia (DAB) V2.1.8.1 and V.2.1.8.2[10] in order to determine total viable count of bacteria and fungi, and absence of *Escherichia coli, Staphylococcus aureus* and *Pseudomonas aeruginosa*.

G.4 Enumeration of the total viable aerobic bacteria and fungi on Agar plates (direct plating method) according to the methods in the European Pharmacopoeia

G.4.1 Preparation of the sample

Unless otherwise prescribed, use a sample 13 condoms. Select the condoms at random from the bulk material or from the available containers of the preparation under aseptic conditions. If necessary, to obtain the required quantity, mix the contents of a sufficient number of containers to provide each sample. The condoms should be handled using aseptic procedures and conditions.

Cut the condoms using sterile scissors into small pieces. Take a sample of the cut condoms with a total weight of (10 ± 1) g and shake for (5 to 10) min on a mechanical rocker at approximately 1 000 rpm in 100 cm^3 of a suitable medium (e.g. sodium chloride peptone buffer solution [pH 7,0]) with the addition of glass beads. The extraction medium should not have any antimicrobial properties. If necessary, add a suitable surface-active agent such as 1 g/cm^3 of polysorbate 80 to assist the suspension of poorly wettable substances. If the condoms are known to have antimicrobial activity, a neutralizing agent may be added to the diluent. Suitable neutralizing materials are polysorbate and lecithin. The types and amounts of neutralizing additives need to be validated. If necessary adjust the pH to about pH 7 and prepare further serial tenfold dilutions using the same diluent.

G.4.2 Examination of the sample

G.4.2.1 Membrane filtration

Use membrane filters having a nominal pore size not greater than 0,45 µm and whose effectiveness to retain bacteria has been established. The type of filter material is chosen in such a way that the bacteria retaining efficiency is not affected by the components of the sample to be investigated. Cellulose nitrate filters, for example, may be used for aqueous, oily and weakly alcoholic solutions and cellulose acetate filters, for example, for strongly alcoholic solutions. The filtration apparatus is designed to allow the transfer of the filter to the culture medium.

Transfer a suitable amount of the sample prepared as described (preferably representing 1 g of the product, or less if large numbers of colony-forming units are expected) to each of two membrane filters and filter immediately. Wash each filter with three quantities, each of about 100 cm^3 of a suitable liquid such as buffered sodium chloride-peptone solution pH 7,0. To this solution, surface-active agents such as polysorbate 80, or inactivators of antimicrobial agents may be added. If validated, less than three washes may be applied. Transfer one of the membrane filters, intended primarily for the enumeration of bacteria, to the surface of a suitable agar medium, such as medium B and the other, intended primarily for the enumeration of fungi, to the surface of a suitable agar medium, such as medium C. Incubate the plate of agar medium B at 30 °C to 35 °C, and the plate of agar medium C at 20 °C to 25 °C for five days, unless a reliable count is obtained in a shorter time. Select plates with the highest number less than 100 colonies and calculate the number of colony-forming units per gram or millilitre of product. Place one membrane onto agar medium B for total aerobic microbial count, the other membrane onto agar medium C for the count of fungi. The total viable aerobic count is the sum of the bacterial and fungal counts.

G.4.2.2 Plate-count methods

G.4.2.2.1 Pour-plate method

Using Petri dishes 9 cm in diameter, add to each dish 1 cm^3 of the sample prepared as described in G.4.1 and 15 cm^3 to 20 cm^3 of a liquefied agar medium suitable for the cultivation of bacteria (such as medium B), or 15 cm^3 to 20 cm^3 of a liquefied agar medium suitable for the cultivation of fungi (such as medium C) at not more than 45 °C. If larger Petri dishes are used the amount of agar is increased accordingly. Prepare for each medium at least two Petri dishes for each level of dilution. Incubate the plates at 30 °C to 35 °C (20 °C to 25 °C for fungi) for 5 days, unless a reliable count is obtained in a shorter time. Select the plates corresponding to one dilution and showing the highest number of colonies less

than 300 (100 colonies for fungi). Take the arithmetic average of the counts and calculate the number of colony-forming units per gram or millilitre.

G.4.2.2.2 Surface-spread method

Using Petri dishes 9 cm in diameter, add 15 cm^3 to 20 cm^3 of a liquefied agar medium suitable for the cultivation of bacteria (such as medium B) or a liquefied agar medium suitable for the cultivation of fungi (such as medium C) at about 45 °C to each Petri dish and allow to solidify. If larger Petri dishes are used, the volume of the agar is increased accordingly. Dry the plates, for example in a laminar airflow (LAF) bench or in an incubator. Spread a measured volume of not less than 0.1 cm^3 of the sample prepared as described in G.4.1 over the surface of the medium. Use at least two Petri dishes for each medium and each level of dilution. For incubation and calculation of the number of colony-forming units proceed as described for the pour-plate method.

G.4.3 Effectiveness of culture media and validity of the counting method

Grow the bacterial test strains separately in containers containing a suitable liquid medium (such as broth medium A) at 30 °C to 35 °C for 18 h to 24 h. Grow the fungal test strains separately on a suitable agar medium (such as medium C without antibiotics) at 20 °C to 25 °C for 48 h for *Candida albicans* and at 20 °C to 25 °C for 7 days for *Aspergillus niger*.

Suitable test strains for assessing the effectiveness of the culture media and validity of the counting method include:

— *Staphylococcus aureus* such as ATCC 6538 (NCIMB 9518, CIP 4.83);

— *Escherichia coli* such as ATCC 8739 (NCIMB 8545, CIP 53.126);

— *Bacillus subtilis* such as ATCC 6633 (NCIMB 8054, CIP 52.62);

— *Candida albicans* such as ATCC 10231 (NCPF 3179, IP 48.72);

— *Aspergillus niger* such as ATCC 16404 (IMI 149007, IP 1431.83).

Use buffered sodium chloride-peptone solution pH 7,0 to make reference suspensions containing about 100 colony-forming units per millilitre. The actual count should be confirmed using a suitable reference method. Any neutralizing agent or other additives used in the condom assay should be included the microorganism suspensions. Use the suspension of each of the microorganisms separately as a control of the counting methods, in the presence and absence of the product to be examined. When testing the membrane filtration method or the plate-count method, a count of any of the test organisms differing by not more than a factor of five from the calculated value from the inoculum is to be obtained. When testing the most-probable-number method the calculated value from the inoculum is to be within the 95 % confidence limits of the results obtained. To test the sterility of the medium and of the diluent and the aseptic performance of the test, carry out the method using sterile sodium chloride-peptone solution pH 7,0 as the test preparation. There should be no growth of microorganisms.

The solutions and culture mediums recommended are described in the Chapter 2.6.13 of European Pharmacopeia.[9]

G.4.4 Interpretation of the results

The bacterial count will be considered to be equal to the average number of colony-forming units found on agar medium B. The fungal count will be considered to be equal to the average number of colony-forming units on agar medium C. The total viable aerobic count is the sum of the bacterial count and the fungal count as described above. If there is evidence that the same types of microorganisms grow on both media this may be corrected. If the count is carried out by the most-probable-number method the calculated value is the bacterial count. Calculate the total viable aerobic count separately for each of the five samples.

G.4.5 Identification

Some identification of bacteria is required in order to confirm the absence of the specified organisms. Gram stain and colonial morphology will identify gram positive cocci and gram negative bacilli. A positive coagulase test will indicate probable *Staphylococcus aureus*, while the oxidase test will indicate possible *Pseudomonas* species. Results from these short tests will determine if further identification is required. Biochemical profiling will identify organisms to species level.

G.5 Expression of results

The test report should include the information specified in Clause 16 and the results from each test including the total counts, fungal and bacterial counts where these are determined separately, and the identity of any organisms identified by the tests.

Annex H
(normative)

Determination of bursting volume and pressure

H.1 Principle

Inflation of a specified length of the condom with air and recording of the volume and pressure required to burst the condom.

Recommendations on system calibration are given in Annex O.

H.2 Apparatus

H.2.1 Inflation apparatus, suitable for inflating the condom with clean, oil-free and moisture-free air at a specified rate, provided with equipment for measuring volume and pressure and having the following features.

a) A pressure sensor configured such that there is no pressure differential between the interior of the condom and the pressure sensor.

b) An apparatus for measuring and recording the volume of air, configured such that the pressure difference between the condoms and the measuring instrument is taken into account when calculating the volume of air in the condom.

c) Rod or mandrel, of suitable length having a smooth sphere or hemisphere (25 ± 2) mm in diameter at its top for supporting the condom and fixed in a position such that when the condom is clamped the length of the condom excluding the reservoir tip remaining for inflation is (150 ± 3) mm. When testing condoms that are shorter than 160 mm, as described in Annex P, the rod or mandrel should be of such length that the inflation length is as specified in Annex P with a tolerance of ± 3 mm.

d) Pressure and volume measuring equipment with expanded uncertainties (using a 95 % confidence interval) of:

   1) ± 3,0 % for volume at the pass/fail limit;

   2) ± 0,05 kPa for pressure.

H.2.2 Clamping device, to hold the condom to permit it to be inflated without leaking and having no sharp edges or protrusions that could damage the condom.

The clamping shall not stretch the condom axially as it is clamped onto the mount. The mount and clamping device shall permit the condom to be mounted and clamped without creasing in the clamped region.

The upper edge of the external clamping mechanism shall have no sharp edges and a radius of not less than 2 mm wherever it is in contact the inflating condom, and shall not extend more than 3 mm beyond the point where the condom is gripped. It shall be possible to mark the point where the condom is gripped, so that the inflation length can be measured, for example by removing the condom and letting it hang on a suitable mandrel as described in Annex D.

H.2.3 Inflation cabinet, having a facility for viewing the condom during inflation, and being of sufficient size to allow the condom to expand freely without touching any part of the cabinet.

H.3 Procedure

H.3.1 Carry out the test under controlled temperature of (25 ± 5) °C.

H.3.2 Move the condom inside the individual container such that it is away from the area where the container is to be torn. Tear the container and remove the condom.

In no circumstances, use scissors or other sharp instruments to open the package.

H.3.3 It is recommended that suitable gloves or finger cots be worn while handling the condom. In cases of dispute, gloves shall be worn.

H.3.4 Unroll the condom ensuring that it is not excessively stretched in any direction.

NOTE The condom may be unrolled directly onto the rod on the test equipment.

H.3.5 Hang the condom on the rod [H.2.1 c)] and affix to the mount (H.2.2). Take care when placing the clamping ring on its mount to avoid damaging or stretching the condom. Inflate with air at a rate of (0,4 to 0,5) dm^3/s [(24 to 30) dm^3/min]. Check to ensure that the condom expands and that there are no obvious leaks.

If the condom exhibits an obvious leak the test should be discontinued because the condom might never burst. The condom should be replaced and the test continued.

NOTE If a statistical summary of bursting data is reported (such as means and standard deviations) data points that appear to come from unnoticed leaks may be excluded from the analysis (e.g. if a bursting volume exceeds twice the median value it can generally be assumed that the condom has leaked, although this is not necessarily true for all types of condoms).

H.3.6 If the condom does not leak, measure and note the bursting volume, in cubic decimetres rounded to the nearest 0,5 dm^3, and the bursting pressure, in kilopascals rounded to the nearest 0,05 kPa.

H.4 Expression of results

The test report shall include the information specified in Clause 16 and the bursting volume and bursting pressure of each tested condom and the temperature at the time of testing in the test laboratory.

Annex I
(normative)

Oven treatment for condoms

I.1 General

Oven treatment is used to condition condoms for shelf life determination and when assessing compliance with the minimum stability requirements.

I.2 Apparatus

I.2.1 **Oven**, capable of maintaining the temperature conditions specified in Clause 11 and Annexes K and L of this International Standard. Alternatively conditioning rooms or chambers may be used provided the specified temperature conditions can be maintained.

Manufacturers should ensure that precautions are taken to monitor oven temperatures during the conditioning period and have adequate contingency arrangements in place to respond to any loss of temperature control caused by oven breakdown or loss of power.

I.3 Preparation of condoms for test

Before testing, the condoms shall be conditioned in their original individual packages (i.e. remove the individual container from consumer and/or outer packages before conditioning).

I.4 Procedure

I.4.1 Condition the condoms in an oven at the temperature stipulated in the relevant clause or annex of this International Standard.

Condoms shall be mounted in such a manner as to minimize direct contact of the specimens with the heated surfaces especially the base of the oven, and so ensure even heating of the condoms during oven ageing.

I.4.2 Remove the condoms from the oven after the time stipulated in the relevant clause or annex of this International Standard, and keep the packages at (25 ± 5) °C until tested.

I.4.3 Within 96 h but not sooner than 12 h after removal from the oven, determine bursting volume and pressure according to Annex H, freedom from holes according to Annex M and package integrity according to Annex N.

I.5 Expression of results

Details of the storage conditions shall be included in the test reports prepared according to Annexes H, M and N along with the information specified in Clause 16. Any deviations in the storage conditions such as loss of temperature control or power losses shall be noted.

Annex J
(informative)

Determination of force and elongation at break of test pieces of condoms

J.1 General

A test piece is cut from a condom and stretched until it breaks; the force and elongation at break can be measured. There are no requirements for force and elongation at break specified within this International Standard but the test can provide useful information about the latex film and is widely used by manufacturers for process and quality control purposes. For this reason a description of the test method is included in the standard.

J.2 Apparatus

J.2.1 **Cutting die**, consisting of two parallel knives (20 ± 0,1) mm apart set in a press above a suitable board. The length of the cutting edge of each knife should be not less than 70 mm.

J.2.2 **Tensile testing machine**, capable of an essentially constant rate of traverse and complying with the following requirements:

a) capable of equalizing the stress within a specimen either by rotating one roller mechanically at a rotation frequency of approximately 7 min^{-1}, or by lubricating the cylindrical surfaces of the rollers with a material that does not affect the latex film. A suitable lubricant is silicone fluid of viscosity 2×10^{-4} $m^2 \cdot s^{-1}$ (200 cSt);

b) capable of determining the breaking load in the range 0 N to 200 N. The maximum permissible value; accuracy ± 1 %, repeatability 1 %, reversibility 1,5 %, zero ± 0,1 and with a machine resolution of 0,5 %;

c) having a roller separation speed of (500 ± 50) mm/min;

d) having manual or preferably automatic recording of the separation distance of the rollers and of the load during the test.

Further information on test equipment for rubbers and plastics is given in ISO 5893.[1]

J.3 Preparation of test specimen

J.3.1 Move the condom inside the package such that it is away from the area where the package is to be torn. Tear the package and remove the condom.

Under no circumstances, use scissors or other sharp instruments to open the package.

J.3.2 Unroll the condom ensuring that it is not excessively stretched in any direction.

J.3.3 To prevent sticking and allow the cutting of a good test specimen an absorbent powder such as talc may be added to the condom or the lubricant may be removed using a suspension with a mass fraction of 2 % talc in propan-2-ol followed by air drying.

J.3.4 Lay the condom flat with its length at right angles to the cutting edge of the die (J.2.1). Obtain the test piece by cutting the condom with one stroke of the press if possible taking the test piece from a parallel-sided, non-textured region including the portion 80 mm from the open end. If the portion 80 mm from the open end is not parallel-sided or is textured, take the test piece from an adjacent parallel-sided, non-textured region. If no region of the condom is parallel-sided and non-textured, take the test piece from the region 80 mm from the open end.

J.3.5 Lay the test piece flat and put the ruler on top and measure to the nearest 0,5 mm, the distance between the two folded edges.

Each sample should be inspected before testing to make sure that there are no nicks or other edge defects that could give rise to poor results.

J.4 Procedure

J.4.1 Carry out the test under controlled conditions of (25 ± 5) °C. Record the actual temperature of the test to the nearest 0,5 °C.

J.4.2 Place the test piece over the rollers of the tensile testing machine (J.2.2) and stretch it until it breaks.

J.4.3 At break, record the force, to the nearest 0,5 N, and the separation distance between the centres of the rollers to the nearest millimetre.

J.5 Calculation of results

J.5.1 When requested calculate elongation at break (E) as a percentage for each test piece by using the following expression:

$$E = \frac{l_1 + 2d - l_2}{l_2} \times 100$$

where

l_1 is the length of the test piece in millimetres, rounded to the nearest millimetre, in contact with the rollers (equal to 47 mm with rollers of 15 mm diameter);

d is the final distance in millimetres between the centres of the rollers;

l_2 is the original perimeter of the test piece in millimetres (twice the distance obtained in J.3.5).

Round the result to the nearest 10 %.

J.5.2 If it is required to calculate the tensile strength then the following equations may be used:

When the thickness is determined by the mass method the tensile strength, σ, expressed in megapascals (MPa) is given by the formula

$$\sigma = \frac{F_b \rho l}{m}$$

where

F_b is the force at break in Newtons;

ρ is the density of rubber (0,92 g/cm^3);

l is the distance in millimetres between the two folded edges length of the test piece as determined in J.3.5;

m is the mass in milligrams of the test piece.

When the thickness is determined directly by the micrometer method the tensile strength, σ, expressed in megapascals (MPa) is given by the formula

$$\sigma = \frac{F_b}{2wt}$$

where

F_b is the force at break in Newtons;

w is the mean width of the test piece in millimetres (20 mm if the die specified in J.2.1 is used);

t is the thickness in millimetres of the condom.

Round the result to the nearest 0,1 MPa.

J.6 Expression of results

The test report shall include the information specified in Clause 16 and the force at break, elongation at break and, if requested, the tensile strength of each tested condom and the temperature at the time of testing in the test laboratory.

Annex K
(normative)

Determination of shelf life by real-time stability studies

K.1 Principle

Packaged condoms complying with the requirements of Clauses 9, 10, 12, 13 and 14 are conditioned at $\left(30^{+5}_{-2}\right)$ °C for the intended shelf life period and then tested for conformity with the requirements of Clauses 10, 12 and 14. Samples are tested periodically for bursting properties to monitor changes during the ageing period.

For the purposes of this International Standard, conditioning at $\left(30^{+5}_{-2}\right)$ °C has been selected to accommodate storage conditions worldwide.

The procedures described in this annex apply to stability studies on new or modified condoms, or following significant changes to the manufacturing process, formulation or packaging type. Manufacturers conducting ongoing stability studies on products with established shelf lives, for example as part of a quality management programme, may vary the procedures.

K.2 Procedure

NOTE The total number of samples required to complete a real-time stability study to determine shelf life includes:

a) the number of condoms required to confirm conformity with the requirements of Clauses 9, 10, 12, 13 and 14 according to K.2.1;

b) the number of condoms required to confirm compliance with Clauses 10, 12 and 14 at the end of the study, plus any intermediate or repeat testing required, in accordance with K.2.2 and K.2.3;

c) the number of samples required for the monitoring tests during the shelf life period as described in K.2.4.

It is recommended that additional condoms are also included in case it is necessary to repeat any testing.

K.2.1 Test three lots of condoms packed in their respective individual containers for conformity with the requirements of Clauses 9, 10, 12, 13 and 14. It is recommended that the sampling plans in Annex B are used but as a minimum the sampling plans in Annex A shall be used.

K.2.2 Condition sufficient condoms from the same lots tested according to K.2.1 in an oven at $\left(30^{+5}_{-2}\right)$ °C according to Annex I or in a controlled environment at $\left(30^{+5}_{-2}\right)$ °C to allow testing for compliance with Clauses 10, 12 and 14 at the end of the ageing period. It is recommended that the sampling plans in Annex B are used but as a minimum the sampling plans in Annex A shall be used.

Manufacturers should ensure that precautions are taken to monitor temperatures during the conditioning period and have adequate contingency arrangements in place to respond to any loss of temperature control caused by equipment breakdown or loss of power.

It is strongly recommended that additional condoms be conditioned as spares in case there is a need for any re-testing. The number of additional condoms should be sufficient to allow testing for compliance with Clauses 10, 12 and 14 at an intermediate stage during the stability study according to K.2.3.

K.2.3 At the end of the proposed shelf life period or earlier if indicated by the monitoring tests specified in K.2.4, test the condoms for compliance with Clauses 10, 12 and 14 using preferably the sampling plans in Annex B but as a minimum the sampling plans in Annex A.

K.2.4 During the ageing period manufacturers shall monitor the progress of the stability study. This is to provide an early warning should the shelf life prove to be shorter than the provisional shelf life estimated from the accelerated stability studies. Based on practical experience it has been found that determining airburst properties periodically according to Annex H provides the best method of monitoring stability. Manufacturers may opt to use one of the following two methods:

a) Condition sufficient additional samples according to K.2.2 to allow at least 125 condoms to be tested for airburst properties according to Annex H at intervals of one year or less. At each time interval remove at least 125 condoms from the oven or controlled environment and determine bursting volume and pressure according to Annex H. Assess compliance with Clause 10 using the appropriate acceptance number from ISO 2589-1 for the sample size used. Record the number of non-compliers and the mean and standard deviation for the burst properties. Continue the study if not more than one set of samples has failed at any time point. If at any time during the study a second set of samples fails to meet the requirements of Clause 10 then test the predetermined number of samples for compliance with Clauses 10, 12 and 14 according to K.2.3.

   NOTE With a sample size of 125 condoms, the probability of all three lots complying with the AQL of 1,5 specified in Clause 10 is greater than 96 % if the average percentage of nonconforming condoms is less than 1,5 %. If the percentage of nonconforming condoms is greater that 3 % then the probability of all three lots complying with the AQL of 1,5 will be less than 57 %.

b) Condition sufficient additional samples according to K.2.2 to allow at least 32 to be tested for airburst properties according to Annex H at intervals of one year or less. At each time interval remove 32 condoms from the oven or controlled environment and determine bursting volume and pressure according to Annex H. If the mean and standard deviation (or 95 % confidence intervals) of the bursting properties at any time deteriorate to the point where the condoms might be approaching the limit of complying with the air bursting requirements of Clause 10 then test the predetermined number samples for compliance with Clauses 10, 12 and 14 according to K.2.3.

   NOTE The study can be monitored, for example, by plotting the mean and standard deviation (or 95 % confidence intervals) of the bursting pressures and volumes against time for each lot. If the airburst results are normally distributed then the condoms can be considered to be at the limit of compliance with the AQL specified in Clause 10 when the difference between the mean burst pressure or volume and specified minimum burst volume or pressure is 2,17 standard deviations. In practice airburst results are generally skewed to lower values; failure to comply with the AQL specified in Clause 10 can occur when the differences between the mean and the minimum specified values are greater than 2,17 standard deviations. Manufacturers should consider completing testing according to K.2.3 once the differences between the mean and the specified values drop below 3 standard deviations and definitely if the differences drop to 2,17 standard deviations or less.

K.3 Confirmation of shelf life claim

The shelf life shall be up to that period, not to exceed 5 years, during which the condoms comply with the requirements of Clauses 10, 12 and 14 when tested according to K.2.3. Any decision about whether the condoms comply with the requirements of Clauses 10, 12 and 14 shall be made on the basis of test results for the predetermined samples sizes specified in K.2.3 and not on the monitoring tests according to K.2.4.

If the confirmed shelf life is less that the labelled shelf life, adjust the shelf life claim and notify the regulatory authorities and direct purchasers.

K.4 Test report

The test report shall include the requirements of Annex H in the form specified by Clause 16 and:

a) number of nonconforming condoms with respect to Clauses 10, 12 and 14 as determined according to K.2.3;

b) the confirmed shelf life and either of the following;

   1) intermediate results for airburst properties as determined according to K.2.4 a) including the number of nonconforming condoms with respect to Clause 10;

   2) plots of the means and standard deviations or 95 % confidence intervals of the bursting pressure and volume against time as specified in K.2.4 b).

Interim test reports shall be made available to appropriate regulatory bodies on request, to document that the real-time study has begun and that intermediate results are satisfactory.

Annex L
(informative)

Guidance on conducting and analysing accelerated ageing studies

L.1 General

Accelerated ageing studies should be used to support provisional shelf life claims pending completion of real-time studies. This annex describes general procedures that may be used for conducting accelerated ageing studies to estimate a provisional shelf life for market introduction while real-time studies are in progress.

Accelerated studies should be completed on packaged condoms complying with the requirements of Clauses 9, 10, 12, 13 and 14.

If a manufacturer has determined the shelf life of an existing product through real-time stability studies and has established a set of accelerated ageing conditions that can be used to verify the shelf life of this product, then the procedure described in L.3 may be used to establish a provisional shelf life for a new or modified condom. Otherwise an accelerated stability study should be conducted using the conditions specified in L.2.

Manufacturers conducting ongoing stability studies on products with established shelf lives, for example as part of a quality management programme, may vary the procedures.

L.2 Procedure for determining a provisional shelf life in the absence of a control condom with real-time stability data

This method should be used in the absence of real-time stability data for an appropriate control condom.

Condition samples of condoms from three production lots in ovens or a controlled environment at (50 ± 2) °C. It is recommended that sampling is in accordance with Annex B but as a minimum the sampling plans in Annex A shall be used. Manufacturers should ensure that precautions are taken to monitor temperatures during the conditioning period and have adequate contingency arrangements in place to respond to any loss of temperature control caused by equipment breakdown or loss of power.

Remove the condoms from the ovens or controlled environment and assess compliance with the requirements in Clauses 10, 12 and 14. If all lots are in compliance then the appropriate provisional shelf life may be assigned to the product depending on the conditioning period:

— a shelf life of 2 years after a period of 90 days;

— a shelf life of 3 years after a period of 120 days;

— a shelf life of 5 years after a period of 180 days.

L.3 Procedure for determining a set of ageing conditions using a control condom with real-time stability data

L.3.1 This procedure can only be used when a control condom is available for which the shelf life has been determined by a real-time study.

L.3.2 Condition condoms from a minimum of two production lots of control condoms and three production lots of the new or modified condoms in ovens at selected temperatures in accordance with Annex I. It is recommended that a minimum of two temperatures are used.

At appropriate time intervals remove samples of condoms from the ovens or controlled environments and determine the air bursting properties according to Annex H. A minimum of five time points at the selected temperature(s) is recommended. It is recommended that at least 32 condoms be tested at each time/temperature point.

Compare the changes in bursting properties of the control and test condoms at different time points and temperatures. Based on this comparison establish an equivalent set of ageing conditions for the new condom that can be used to assess the provisional shelf life of the product. The temperatures and ageing times should be sufficient to ensure that a significant change in the air bursting properties of the control condoms occurs.

NOTE Once a set of accelerated ageing conditions has been established for a specific control condom, these conditions may be used for subsequent stability studies without repeating this stage of the study.

L.3.3 Having determined a suitable set of ageing conditions take samples of condoms from three production lots and condition the samples according to Annex I using the selected ageing conditions. It is recommended that sampling is in accordance with Annex B but at least Annex A should be used. Manufacturers should ensure that precautions are taken to monitor temperatures during the conditioning period and have adequate contingency arrangements in place to respond to any loss of temperature control caused by equipment breakdown or loss of power.

Remove the condoms from the ovens or controlled environment and assess compliance with the requirements in Clauses 10, 12 and 14. If all lots are in compliance then the appropriate provisional shelf life may be assigned to the product.

For convenience the ageing temperatures may be selected as 70 °C and 50 °C and, providing the ageing periods at these temperatures equal or exceed 7 days at 70 °C and 90 days at 50 °C, then this test can also be used to verify the requirements of 11.2.

L.4 Test report

The test report shall include the requirements of Annex H in the form specified by Clause 16 and:

a) a description of the procedure used (L.2 or L.3);

b) the ageing period used at (50 ± 2) °C (procedure L.2);

c) a summary of all the data used to justify the selected accelerated ageing conditions (procedure L.3);

d) details of the selected accelerated ageing conditions (procedure L.3);

e) the estimated provisional shelf life claim.

Annex M
(normative)

Testing for holes

M.1 General

This annex specifies two of the alternative methods for testing natural rubber latex condoms for holes: the water leak test and the electrical test.

M.2 Water leak test

M.2.1 Principle

Filling of the condom with a specified volume of water and examining for visible water leakage through the wall of the suspended condom. In the absence of any leakage the condom is then rolled on coloured absorbent paper, which is subsequently examined for signs of leakage of water from the condom.

M.2.2 Apparatus

M.2.2.1 Mounting equipment, suitable for mounting the condom at its open end, allowing it to be freely suspended, with a means of filling the condom with water while it is suspended. An example of a suitable mount is shown in Figure M.1. Optionally a rubber ring may be used to retain the condom on the mount.

M.2.2.2 Coloured absorbent paper.

M.2.2.3 Rolling device (optional), incorporating a smooth transparent plate. The device may be placed at a fixed height of (30 ± 5) mm above and parallel to the paper, whose horizontal movement rolls the condom back and forth.

The plate, if used, shall turn the condom through at least one complete revolution, when it is moved through its travel.

M.2.2.4 Clamping device (optional), suitable for holding the twisted open end of a condom and preventing it from leaking, without causing damage to the part to be rolled on absorbent paper. An example is a sprung paper clip.

M.2.3 Procedure

M.2.3.1 Inspect the individual containers and record any that have visibly open seals.

M.2.3.2 Move the condom inside the individual container such that it is away from the area where the container is to be torn. Tear the container and remove the condom.

In no circumstances, use scissors or other sharp instruments to open the package. Wear suitable gloves or finger cots while handling the condom.

M.2.3.3 Unroll the condom ensuring that it is not excessively stretched in any direction. If any hole or tear is noticed, that condom shall be deemed non-compliant and further testing of that condom shall be discontinued.

M.2.3.4 Record condoms with visible defects (see 3.15) other than holes and tears.

M.2.3.5 Fit the open end of the condom onto the mount so that the condom is suspended open end upwards.

M.2.3.6 Add the volume of water specified in Table M.1 within a tolerance of ± 10 cm^3 at a temperature between 10 °C and 40 °C to the condom. Make sure that the humidity in the ambient air does not condense on the outside of the condom. Inspect the condom for visible signs of leakage. Deem any condom exhibiting visible signs of leakage more than 25 mm (determined to an accuracy of ± 1 mm) from the open end a non-complier and discontinue the test. Holes found near the open end shall be marked, and measured after the condom is emptied to determine whether they are more than 25 mm from the open end.

Table M.1 — Fill volumes for conducting the water leakage test

Condom length mm	**Water volume** cm^3			
	Mid-body condom width mm			
	45 to 49,5	**50 to 55,5**	**56 to 65**	**65,5 to 75**
160 to 185	300	300	350	475
186 to 210	300	300	400	525
211 to 240	300	350	450	600

For the purpose of this test, the mid-body width is the mean flat width rounded to the nearest 0,5 mm of 13 condoms measured in accordance with Annex E at a point (75 ± 5) mm from the closed end excluding the reservoir tip. The length of the condom is determined according to Annex D.

If, because of lack of distension of the condom, it is not possible for the specified volume of water to be contained within the condom, permit the remainder of the water to form a pressure head within the filling system.

Then carry out the rolling procedure described in M.2.4.

M.2.4 Rolling procedure

M.2.4.1 If there is no visible leakage through the condom after suspension, take hold of the condom by the closed end, and, if necessary, gently stretch the condom to displace the water from the open end. Seal the condom by twisting it less than 25 mm from the open end, for approximately 1,5 revolutions, and remove it from the mount. Hold the end closed with one hand, or with a suitable clamping device (M.2.2.4). Wipe off any water on the outside on the condom with a soft absorbent cloth or paper.

M.2.4.2 Transfer the condom onto a dry sheet of absorbent paper and lay it down with the axis of the cylinder thus formed parallel to the paper.

a) Manual rolling

Using the free hand, roll the condom on the paper through at least two complete revolutions. During rolling, spread the fingers of the hand so as to distribute the force on the condom as equally as possible. Maintain the hand at a distance of 25 mm to 35 mm above the absorbent paper. Move the hand with respect to the condom so that the condom as a whole is subjected to hand pressure and comes in contact with the absorbent paper.

b) Mechanically assisted rolling

Using the rolling device in M.2.2.3, roll the condom through at least two complete revolutions on the paper.

The condom may be rolled through more than one revolution in order to verify whether or not there is leakage present. It is intended that the number of revolutions be small, and in no case greater than 10 over both pieces of absorbent paper.

Inspect the paper for any sign of leakage of water from the condom. Ignore any marks made by the lubricant. Holes found near the open end shall be marked, and the condoms measured after being emptied to verify that they are more than 25 mm from the open end. Condoms with holes more than 25 mm from the open end shall be counted as non-compliant.

M.2.4.3 Hang the filled condom vertically from one hand and with the other hand squeeze the condom to ensure that most of the water is forced into the lower half. Avoid excessive localized stretching. Firmly press the closed end of the condom onto the absorbent paper and move the hands carefully in a circle twice so that the lower half of the water filled section contacts the absorbent paper while avoiding sliding and abrasion of the condom on the paper. Inspect the paper for any sign of leakage of water from the condom. Ignore any marks made by the lubricant. Condoms with holes more than 25 mm from the open end shall be counted as non-compliant.

NOTE 1 Steps M.2.4.2 and M.2.4.3 may be conducted in any order. For lubricated condoms, the rolling may be done twice on two separate sheets of absorbent paper, to eliminate confusion between marks made by the lubricant and those made by the water.

NOTE 2 Rolling forward by one complete revolution and then back by one complete revolution counts as two complete revolutions.