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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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Submission of Comments

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- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 4074

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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ISO/TC 157

Secretariat: **DSM**

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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 fourth edition cancels and replaces the third edition (ISO 4074:2015), which has been technically revised. The main changes are as follows:

- a) [Annex P](#) has been made normative. The standard now covers all condom sizes including those with dimensions specified in [Annex P](#).
- b) The electrical test for freedom from holes in [Annex M](#) has been amended to improve the probability of finding small holes in the teat (reservoir tip) and closed end of the condom.
- c) A new [Annex Q](#) is included in the standard which describes procedures for verifying the test methods for freedom from holes described in [Annex M](#) of this standard and ASTM D3492 [2] are meeting performance requirements. The procedures may also be used for personnel training and competency assessment purposes.
- d) Improvements have been made to inflation test procedure specified in [Annex H](#).
- e) The condom handling procedures described in ISO/TR 19969:2018 have been integrated into [Annex H](#), testing for burst properties, and [Annex M](#), testing for freedom from holes.
- f) A statement has been added to [Annex A](#) emphasising that when a minimum sample size is specified by reference to a specific code letter for a test procedure, that minimum sample size applies even if reduced inspection is implemented through the use of the switching rules unless it is agreed between the manufacturer and the purchaser that reduced sampling may be implemented.
- g) The use of technical grade propan-2-ol is permitted for removing lubricant from condoms when determining the lubricant quantity according to [Annex C](#).
- h) In [Annex G](#) it has been made clear that a Stomacher® is a specific type of mixer that may be used along with other types of mixers when preparing samples for microbiological testing of condoms. Some amendments to the test procedures have been made based on current best practices.

- i) An alternative dry vacuum method for testing the integrity of individual condom containers has been included in [Annex N](#). This method provides extra security against leakage, for example when condoms are being shipped by air freight or to high altitude countries.
- j) [Annex K](#) has been updated to provide clearer and more detailed information about conducting real time stability tests.
- k) [Annex L](#) has been updated to include a more rapid accelerated stability test to assess the effect of process and formulation changes on the stability of a product and provide a stress test for condoms that may be stored in high temperature environments.
- l) [Annex O](#) has been made normative and amended to include a new section to verify that technicians can unroll the condoms correctly.

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.

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.

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 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 condom design before the product is placed on the market and to initiate real-time stability studies. Manufacturers are also required to consider the stability of any modified condom design. These requirements are described in [Clause 11](#). The real-time stability test can 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^[5] provides guidance for the application of ISO 4074:2015. It includes additional information on the test methods and requirements specified in this International Standard.

Pictures and diagrams in this standard are to enhance clarity and do not indicate a preference for any specific equipment type or design.

Natural rubber latex male condoms — Requirements and test methods

1 Scope

This international standard specifies requirements and test methods for male latex condoms made from natural rubber latex.

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 skin sensitization*

ISO 10993-23, *Biological evaluation of medical devices — Part 23: Tests for irritation*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — 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*

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

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

modified condom design

established condom design that has been subjected to changes in formulation, manufacturing process, manufacturing site, lubrication, or individual sealed container

3.4

consumer package

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

3.5

expiry date

date after which the condom should not be used

3.6

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.

3.7

individual container

primary package containing a single condom

3.8

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]

3.9

inflation length

length of the condom to be inflated during the burst test

3.10

integral bead

ring formed at the open end of the condom, usually by rolling down a portion of the partially dried and cured latex film, to assist rolling and handling the condom

3.11

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

3.12

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

3.13**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

3.14**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)

3.15**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

3.16**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

3.17**date of manufacture**

date specified by the manufacturer when the product was made subject to the requirements specified in [11.1](#)

3.18**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 regulated medical devices in most countries and should be manufactured and tested using an appropriate quality management system (QMS). A suitable QMS for the manufacture of medical devices is described in ISO 13485^[4].

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, most 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.

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 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 biocompatibility assessments shall be conducted in accordance with ISO 10993-1. When testing is required, in-vitro tests are preferred if possible. In-vivo (animal) testing should be kept to a minimum. For a modified condom design manufacturers shall conduct a risk assessment according to ISO 14971 to determine whether the biocompatibility assessment needs to be repeated.

NOTE 1 Regulatory authorities usually require evaluations to be completed for cytotoxicity according to ISO 10993-5, irritation according to ISO 10993-23, and sensitization according to ISO 10993-10. Some authorities might require additional evaluations.

The condom together with any lubricant, additive, dressing material, or powder applied to it shall be evaluated.

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

NOTE 2 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^[3]. It includes methods for validation testing (ISO 11737-1). 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 are recommended 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 Dimensions

9.1.1 Length

When tested by the method given in [Annex D](#), taking 13 condoms from each lot, no individual measurement shall be below 160 mm except for condoms with dimensions specified in [Annex P](#). For condoms shorter than 160 mm the length shall be within ± 5 mm of the nominal length specified by the manufacturer.

9.1.2 Nominal 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.

9.1.3 Thickness

This standard does not specify limits for condom thickness. If verification is required of the thickness of a condom design, the average thickness of the samples measured in accordance with one of the methods given in [Annex F](#), shall be equal to the claimed nominal thickness, subject to a tolerance of

- $\pm 0,008$ mm for condoms with nominal claimed thickness less than 0,05 mm;
- $\pm 0,01$ mm for condoms with nominal claimed thickness equal to or greater than 0,05 mm.

9.2 Integral bead

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

9.3 Lubrication

This standard does not specify requirements for the quantity and type of lubricant. 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.

Note 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.

10 Bursting volume and pressure

The bursting properties of condoms shall be determined according to the method specified in [Annex H](#). For condoms that are equal to or greater than 160 mm in length, an inflation length of (150 ± 3) mm shall be used. The minimum bursting pressures and volumes are specified in [Table 1](#):

Table 1 — Minimum bursting pressure and volume for condoms ≥ 160 mm long

Width of condom mm	Minimum bursting pressure kPa	Minimum bursting volume dm ³
45,0 to 49,5	1,0	16,0
50,0 to 55,5	1,0	18,0
56,0 to 64,5	1,0	22,0
65,0 to 75,0	0,8	28,0

For the purpose of this test, the mid-body width is the mean width rounded to the nearest 0,5 mm of 13 condoms measured in accordance with [Annex E](#) at a point equal to half the inflation length ± 5 mm from the closed end excluding the teat. For example, condoms longer than 160 mm have an inflation length of 150 mm and a mid-body width measured at 75 ± 5 mm from the closed end, excluding the teat.

For condoms that are shorter than 160 mm in length, the inflation lengths and minimum burst properties are specified in [Annex P](#).

The conformance 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.

11 Stability and shelf life

11.1 General

Manufacturers shall verify that the condoms conform with the requirements of [Clauses 10, 12](#), and [14](#) until the end of the labelled shelf life. Products on the market prior to publication of ISO 4074:2015 (2015-10-15) shall be deemed to conform with the shelf life claims of this International Standard unless the product is a modified design. 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 for each product design. The stored condoms shall be protected from exposure to excessive temperatures, light, ozone, and any other condition that could affect the shelf life of the packaged condoms.

Assessment for minimum stability ([11.2](#)) and shelf life claims ([11.3](#)) and ([11.4](#)) 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 conformance 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 conform 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 provisional shelf-life claims as described in [11.4](#).

NOTE 1 Conformance with the requirements of [11.2](#) does not imply that the shelf life of the product has been determined.

NOTE 2 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 temperature of (30^{+5}_{-2}) °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).

NOTE 3 The choice of (30^{+5}_{-2}) °C as the reference temperature for shelf life estimates is based on studies that have confirmed the mean kinetic temperate of the most extreme temperature zones is approximately 30 °C. [11.12] See Annex L for more details.

11.2 Minimum stability requirements

Test three lots of condoms for conformity with this International Standard, except for [clause 15.2](#) and [15.3](#).

Only lots meeting all 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 conformance 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](#).

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, regulatory authorities, and other interested parties may confirm that condoms meet the minimum stability requirements by testing condom lots for compliance with the requirements of [Clause 10](#) after oven conditioning for (168 ± 2) h (1 week) at (70 ± 2) °C. When such testing is carried out, it might be appropriate to use reduced inspection levels.

The test report shall include the relevant requirements of [Annexes H, K, M](#) and [N](#), and [Clause 16](#).

NOTE Data to verify compliance with [11.2](#) can be extracted from studies for estimates of shelf life (11.4).

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 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 based on 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 conform to the requirements of [clause 16](#) and include the results of testing according to [Annexes H, M](#) and [N](#), and the shelf life together with the methods used to determine the shelf life and supporting data.

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 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 (30^{+5}_{-2}) °C.

The report shall conform to the requirements of [clause 16](#) and include the results of testing according to [Annexes H](#), [M](#), [N](#) and the provisional shelf life together the methods used to determine the provisional shelf life and supporting data.

12 Freedom from holes

When tested by either method described in [Annex M](#), the conformance 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 [\[7\]](#) may also be used.

The methods for testing for freedom from holes include an element of skill and subjectivity depending on how the condoms are rolled or expanded using the contained liquid. Rolling or expanding the condoms has to be done according to the description in the standard under closely defined conditions to ensure the results are reliable. Operator deviations from the correct technique can result in an incorrect finding or damage to the condom. To overcome this problem, method verification and operator training shall be conducted using sets of condoms that have been punctured using a standardised procedure.

Information on test method verification and operator training procedures are given in [Annex Q](#). These procedures should be used for personnel training and evaluation purposes, and equipment validation as frequently as required.

Requirements for the volume of water or electrolyte to be used in the freedom from holes test are given in [Annex M](#) or [Annex P](#) depending on the dimensions of the condoms.

13 Visible defects

For visible defects specified in [3.18](#), 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.

An alternative test method, the dry vacuum test, is included in [Annex N](#). Manufacturers and purchasers may specify this test method when extra assurance against lubricant leakage is required, for example when condoms are being transported by air freight or to high altitude locations.

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 other than those specified in ISO 15223 (all parts) are used on the outside of the consumer packaging or the individual container, their meaning shall be explained in the additional information on the inside of the consumer package or a leaflet contained within the consumer package or in accordance with local regulations.

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 trademark.
- b) The manufacturer's identifying reference for traceability (e.g. the lot number).
- c) The expiry date in one of the following formats:
 - 1) the year expressed as four digits, followed by a dash ('-'), followed by the month expressed as two digits (for example, 2030-06) [preferred]
 - 2) the month, abbreviated to three letters, followed by the year expressed as four digits (for example, Jun2030)
- 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 ISO 20417^[6] for additional requirements for medical devices.

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 including whether it has a teat (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 nominal length of the condom if this is shorter than 160 mm.
- e) 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 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.

- f) The expiry date in one of the following formats:
 1. the year expressed as four digits, followed by a dash ('-'), followed by the month expressed as two digits (for example, 2030-06) [preferred]
 2. the month, abbreviated to three letters, followed by the year expressed as four digits (for example, Jun 2030).
- g) A statement to store the condom in a cool, dry place away from direct sunlight. Accepted symbols may be used as an alternative.
- h) If the individual containers are not opaque to light, a statement that individual containers should not be stored outside the opaque consumer package.
- i) When a medicinal ingredient is added, it shall be identified and its purpose indicated (e.g. spermicidal).
- j) 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.
- k) A statement that the condom is made of natural rubber latex, which might cause allergic reactions including anaphylactic shock if the user is allergic to latex. 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 if the user is allergic to latex.
- l) For condoms intended for distribution within the European Union, the CE Mark.
- m) A statement that the condom is for single use only. An accepted symbol may be used as an alternative.
- n) A statement to read the instructions for use. An accepted symbol may be used as an alternative.

If the condom thickness is stated on the product labelling, the nominal thickness shall be based on measurements made using the test method described in [Annex F](#).

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. This information should be based on globally accepted evidence-based guidance published by the World Health Organisation in Family Planning: A Global Handbook for Providers [\[18\]](#).

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

b) Instructions for use of the condom, including:

- 1) advice that if the individual container is obviously damaged to discard that condom and use a new one from an undamaged package;
- 2) the need to handle the condom carefully, including removal from the package so as to avoid damage to the condom by fingernails, jewellery, etc;
- 3) how and when to put on the condom; mention should be made that the condom should be unrolled onto the erect penis until it reaches the base of the penis before any contact occurs between the penis and the partner's body to assist in the prevention of sexually transmitted infections and pregnancy;
- 4) 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;
- 5) the need to withdraw the penis soon after ejaculation, while holding the condom firmly in place at the base of the penis;
- 6) 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 can damage the condom;
- 7) the need to consult a doctor or pharmacist about the compatibility of topical medicines that might come in contact with the condom;
- 8) advice to seek medical assistance as soon as possible, at least within 72 h should a condom leak or burst during use.

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

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 and a UDI or comparable code if required by National Authorities.

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 requirements of the European Medical Device Regulation [(EU) 2017/745 (MDR)] apply.

NOTE 2 In countries outside of the European Union, 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, 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) the accreditation status of the test laboratory with respect to the tests carried out;
- c) name and address of the client;
- d) identification of the test report;
- e) the identity of the sample (brand or name, sample size, lot number, and lot size);
- f) origin of the sample, date of the sample's arrival at the laboratory;
- g) a reference to this International Standard, i.e. ISO 4074:2024 ¹⁾, and the relevant annexes;
- h) a description of all deviations from this International Standard;
- i) the test results according to relevant annexes, the method used if there are alternatives, the numbers of samples accepted and rejected, the accept/reject requirements and whether the lot was accepted or rejected. Summary results may be substituted by agreement with the client but the full results shall be provided on request to relevant interested parties;
- j) the uncertainty ^[14] in the test result, if available;
- k) date of the test report and the signature and title of the person(s) responsible for the report.

Manufacturers' internal laboratories may omit the information specified in clauses a), b) and c) for internal reports relating to products manufactured on site.

1) Correct date to be inserted at publication.

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 their attention to the manufacturer's quality system. In this connection, it should be noted that ISO 9000^[15] 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 conform to 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 for the requirements specified in [clauses 10](#), [12](#), [13](#) and [14](#).

If reduced sampling is implemented through application of the switching rules, sample sizes for those attributes where a minimum code letter is specified shall not be reduced below the minimum specified for normal inspection for that code letter unless agreed between the manufacturer and the purchaser.

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

Attributes	Inspection level ^a	Acceptance criteria
Length and width	13 condoms	All samples shall meet the criteria specified in this standard
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 conform
Quantity of lubricant	13 condoms	As agreed (see 9.3)
Thickness	13 condoms	As agreed (see 9.1.3)
^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 for the requirements specified in [clauses 10, 12, 13 and 14](#). 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 can 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 specified in this standard
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 conform
Quantity of lubricant	13 condoms	As agreed (see 9.3)
Thickness	13 condoms	As agreed (see 9.1.3)
^a See ISO 2859-1 where relevant.		

These sampling plans should be used for the following:

- type testing as part of a certification procedure;
- in cases where the total number of lots being assessed is insufficient to allow the switching rules to be effective;
- 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 or technical reagent grade.

C.2.2.4 Scissors.

C.2.2.5 Indelible marker pen.

C.2.2.6 Soft absorbent tissue or cloth.

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. If necessary slit the individual container on two sides of the pocket, using scissors if needed, so it can be opened out. 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 Wipe the condom and individual container with soft absorbent tissue or cloth until the lubricant and oily feel are removed as far as possible.

C.2.3.5 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.2.3.7](#) to [C.2.3.9](#).

C.2.3.6 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.2.3.7](#) to [C.2.3.9](#).

C.2.3.7 Remove the condom and individual container from the propan-2-ol and wipe to remove excess propan-2-ol.

C.2.3.8 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.2.3.9 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 conducted by ISO/TC 157 WG12 (N10), 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. an ultrasonic bath may be used for washing subject to a satisfactory validation study being completed. 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 or filtered water**.

C.3.2.5 **Scissors**.

C.3.2.6 **Indelible marker pen**.

C.3.2.7 Soft absorbent tissue or cloth.

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. If necessary slit the individual container on two sides of the pocket, using scissors if needed so it can be opened out. 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 cm³ capacity with 150 cm³ of wash material (a mass fraction of 5 % potassium laurate dissolved in deionised or filtered 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 dm³ of deionised or filtered 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 dm³ of deionised or filtered 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 mass (washed and dried condom and respective individual container) from its original mass (condom in individual container); the difference is measured as the amount of lubricant recovered from a condom.