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Male condoms — Requirements and test methods for condoms made from synthetic materials

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee CH/157, Mechanical contraceptives.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Male condoms — Requirements and test methods for condoms made from synthetic materials

Préservatifs masculins — Exigences et méthodes d'essai pour les préservatifs fabriqués en matières synthétiques

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Contents

Page

Foreword iv
Introduction v
1 Scope 1
2 Normative references 1
3 Terms and definitions 1
4 Quality verification 3
5 Lot size 4
6 Biocompatibility 4
7 Product claims 4
8 Design 4
9 Preclinical evaluation 5
10 Clinical (human use) investigations 6
11 Bursting volume and pressure 6
12 Freedom from holes 7
13 Stability and shelf-life 7
14 Visible defects 8
15 Package integrity for individual container 8
16 Packaging and labelling 8
17 Data sheet and test report 11
Annex A (normative) **Sampling plans intended for assessing compliance of a continuing series of lots with sufficient number to allow the switching rules to be applied** 12
Annex B (informative) **Sampling plans that are intended for assessing the compliance of isolated lots** 13
Annex C (normative) **Determination of total lubricant for condoms in individual containers** 14
Annex D (normative) **Determination of length** 16
Annex E (normative) **Determination of width** 18
Annex F (normative) **Determination of thickness** 19
Annex G (informative) **Determination of barrier properties using the bacteriophage method** 20
Annex H (normative) **Determination of the bursting volume and pressure** 24
Annex I (informative) **Calibration of air inflation equipment for determination of burst volume and pressure** 27
Annex J (normative) **Testing for holes** 31
Annex K (normative) **Determination of shelf-life by real-time stability tests** 36
Annex L (informative) **Guidance on conducting and analysing ageing studies** 38
Annex M (normative) **Tests for individual container integrity** 40
Annex N (informative) **Oven treatment for condoms made from synthetic materials** 42
Bibliography 43

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 23409 was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

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Introduction

Synthetic condoms can be made from 100 % synthetic materials or a blend of synthetic materials and natural rubber latex. The material(s) used in synthetic condoms should be validated as constituting a barrier to human immunodeficiency virus (HIV), to other infectious agents responsible for the transmission of sexually transmitted infections (STIs), and to spermatozoa. It is essential that the condoms fit the penis properly, remain on the penis during use, are free from holes and have adequate physical strength so as not to break or tear during use so that the condoms can be deemed to be effective for contraceptive purposes and in order to help prevent the transmission of STIs. It is also important that they be correctly packaged so that they are protected during storage and suitably labelled. All of these issues are addressed in this International Standard.

To be safe, it is essential that the condom and any lubricant, additive, marking materials, dressing, individual packaging material or powder applied to it neither contain nor liberate substances in amounts that are toxic, likely to produce allergies (sensitization), locally irritating or otherwise harmful under normal conditions of storage and use.

Condoms are medical devices. To ensure high quality product, it is essential that condoms be produced under a quality management system using design controls. Reference can be made, for example, to ISO 9001[4], to ISO 14971, and to ISO 13485[8]. Additional guidance can be found in ISO 16038[9].

Condoms are non-sterile medical devices; however, a clean environment is essential to minimize microbiological contamination of the product during manufacturing and packaging.

Condoms can be of the designs given in the following terms, which are not intended to be exhaustive: smooth, textured, parallel-sided, non-parallel-sided, plain-ended, reservoir-ended, dry, lubricated, transparent, translucent, opaque, coloured, preshaped, welded or non-welded.

This International Standard specifies preclinical, clinical, and lot-by-lot physical requirement testing for condoms made from synthetic materials, including condoms made from a blend of synthetic materials and natural rubber latex. Application of lot-by-lot testing requirements becomes relevant only after the preclinical and clinical requirements of this International Standard have been met.

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INTERNATIONAL STANDARD ISO 23409:2011(E)

Male condoms — Requirements and test methods for condoms made from synthetic materials

1 Scope

This International Standard specifies the minimum requirements and the test methods applicable to male condoms produced from synthetic materials or blends of synthetic materials and natural rubber latex which are used for contraceptive purposes and to aid in the prevention of sexually transmitted infections.

2 Normative references

The following referenced documents are indispensable for the application of this document. 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 4074, *Natural latex rubber condoms — Requirements and test methods*

ISO/TR 8550 (all parts), *Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots*

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 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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

ISO 15223 (all parts), *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied*

ISO 16037, *Rubber condoms for clinical trials — Measurement of physical properties*

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

[ISO 2859-1:1999, 3.1.26]

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

NOTE If a consumer can responsibly consider a device to be a male condom (due to its shape, packaging, etc.) it is considered to be a male condom for the purposes of this International Standard.

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 a condom is not suitable for use

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 When the consumer package contains only one type of condom, then the identification number can be the same as the lot number. However, if the consumer package contains several different types of condoms, e.g. condoms of different shapes or colours, then the identification number is different from the lot numbers.

3.6
individual container
primary package containing a single condom

3.7
inspection level
relationship between lot size and sample size

NOTE For a description, see ISO 2859-1:1999, 10.1.

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 and 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 the stages of manufacture up to packaging

3.10
lot test
test to assess the conformity of a lot

NOTE A lot test may be limited to include only those parameters that can change from lot to lot.

3.11
non-visible hole
hole in a condom that is not visible under normal or corrected vision, but is detected by a suitable water leak test or electrical test

NOTE Suitable tests are specified in this International Standard.

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3.12
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)

3.13
shelf-life
period from date of manufacture, during which condoms are required to conform to specified requirements for burst pressure, burst volume, freedom from holes, and pack integrity

NOTE Suitable requirements are specified in this International Standard.

3.14
synthetic material
any base material other than 100 % natural rubber latex that is used to make condoms

NOTE This term applies to both condoms made from all synthetic materials and to condoms made from synthetic and latex blends.

3.15
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

3.16
date of manufacture
date of sheath formation or the date the condoms are packed in their individual containers provided that, in the latter case, a maximum period of bulk storage is specified and shelf-life studies have been conducted on condoms that have been subjected to the maximum bulk storage period

3.17
visible defect (other than hole or tear)
broken, missing or severely distorted rim, and permanent creases with adhesion of the film

4 Quality verification

Condoms are mass produced articles manufactured in very large quantities. Inevitably, there is some variation between individual condoms, and a small portion of condoms in each production run that might not meet the requirements of 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. Refer to ISO/TR 8550 for guidance on the selection of an acceptance sampling system, scheme or plan for the inspection of discrete items in a lot. For testing purposes, sampling shall be conducted by lot number, not by identification number.

When ongoing verification is required of the quality of condoms, it is recommended 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 the ISO 9000[3] family and in particular ISO 13485[8] cover the provision of an integrated quality system.

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 cannot offer their full protection for the first two lots tested, but become progressively more

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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 switching rules. It is recommended that these sampling plans be used for the assessment of fewer than five lots, e.g. in cases of dispute, for referee purposes, for type testing, for qualification purposes or for short runs of continuous lots.

c) Handling and storage conditions shall be documented before drawing the samples.

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 varies between manufacturers and is regarded as part of the process and quality controls used by the manufacturer.

5 Lot size

The maximum individual lot size for production is 500 000.

Otherwise, 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 product which is new or which has undergone a significant change to the formulation or manufacturing process, biocompatibility assessments shall be conducted in accordance with ISO 10993-1. Testing 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. Many synthetic 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. The condom together with the any lubricant, additive, dressing material, or powder applied to it shall be tested. Regulatory bodies might also specify specific local requirements. Accredited laboratories shall be used for the testing. Regulatory bodies might require the results to be interpreted by a qualified toxicologist or other suitably qualified expert. The biological assessment report shall justify that the product is safe under normal conditions of use.

7 Product claims

Condoms meeting the requirements of this International Standard can be used for contraceptive purposes and 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 clinical investigation. Manufacturers shall make information justifying such claims available to regulatory bodies, notified bodies, and consumer protection authorities.

8 Design

8.1 Retention mechanism

If a mechanism to retain the condom on the penis or an integral bead is required by the condom design, then it shall comply with Clause 14.

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8.2 Lubrication

If verification is required of the quantity of lubricant in a package, the method given in Annex C shall be used. The criteria of compliance shall be as agreed between the parties concerned.

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

8.3 Dimensions

8.3.1 Length

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

8.3.2 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.

Where the design of the condom is such that this measurement cannot be made reliably or the narrowest point within the first 50 mm from the open end of the condom is at the bead, the method of measurement shall be provided by the manufacturer.

8.3.3 Thickness

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

a) ±0,008 mm for condoms with thickness less than 0,05 mm;

b) ±0,01 mm for condoms with thickness between 0,05 mm and 0,08 mm;

c) ±0,015 mm for condoms with thickness greater than 0,08 mm.

9 Preclinical evaluation

A risk analysis of the product shall be conducted in accordance with ISO 14971. The analysis shall identify safety and efficacy concerns, and shall address at least the areas where the risks are in excess of those encountered with natural rubber latex condoms conforming to ISO 4074.

The barrier properties of the condom shall be established by viral penetration studies using simulated use conditions and a suitable surrogate virus, e.g. bacteriophage phiX 174. Viral penetration properties shall be compared with those of a latex condom that meets the requirements of ISO 4074. A suitable procedure for conducting these studies is given in Annex G. The number of test condoms exhibiting leakage of virus suspension fluid above the detection limit of 2×10^{-6} ml should not be significantly worse than for the control latex condom. Appropriate statistical procedures may be used to analyse the results using a 95 % confidence interval.

Biocompatibility for the finished product and its components shall be established in accordance with the relevant clauses of ISO 10993-1, ISO 10993-5, and ISO 10993-10. Condoms are a surface device with repeated contact with mucosa and possibly compromised tissue surfaces. The tests shall indicate whether the device produces cytotoxicity, sensitization, or mucosal irritation. It is possible for additional testing, e.g. for systemic toxicity in accordance with ISO 10993-11[6], to be required, depending upon the nature of the materials used or to meet local regulatory requirements. If there is a likelihood of systemic absorption of any

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components or residuals, mutagenicity testing shall be performed. Regulatory bodies can require the results to be interpreted by a qualified toxicologist or suitably qualified scientist. The biological assessment report shall justify that the product is safe under normal conditions of use.

All data generated in these investigations shall be available to regulatory authorities on request.

The manufacturer shall obtain, and make available on request from regulatory authorities, toxicity data on all the additives and residual monomers, residual solvents and known impurities resulting from the manufacture of the condom. Suitable material safety data sheets are to be supplied as requested for materials used in the manufacture of products in compliance with this International Standard.

10 Clinical (human use) investigations

The manufacturer shall conduct a randomized controlled clinical investigation comparing the synthetic condom to a control condom made from natural rubber latex.

a) Clinical investigations in humans shall be conducted in accordance with local regulatory requirements, as well as ISO 14155.

b) The clinical failure rate (combined slippage and breakage rates) of the synthetic condom shall be non-inferior to the clinical failure rate of the control condom made from natural rubber latex.

c) In order to demonstrate non-inferiority the upper limit of the one-sided 95 % confidence interval for the test condom clinical failure rate minus the control condom clinical failure rate shall be less than or equal to 2,5 %.

   The limit shall be calculated using a method that accounts for the unique characteristics of data such as:

   1) each study participant may contribute data from more than one condom use;

   2) very low event rates.

d) For the control condom, the clinical failure rate shall be less than 4,0 %.

e) The control condom shall be made from natural rubber latex and shall conform to ISO 4074.

f) The physical properties of the natural rubber control condom shall be determined in accordance with ISO 16037.

NOTE See ISO 29943-1[10].

For products in the market prior to the publication of this International Standard, manufacturers may use data from existing clinical investigations. Information on the studies shall be made available to regulatory and governmental authorities upon request.

11 Bursting volume and pressure

Manufacturers shall establish appropriate minimum pressure and volume limits for the specific condom based on the airburst properties of the lot or lots used for the clinical trial. Determine the airburst properties of the lot or lots used in the clinical study using a sample size of at least 2 000 condoms. If more than one lot was used in the clinical study then the sample shall be drawn across all the lots, each individual lot being sampled proportionally to its size. Set the minimum airburst limits at 80 % of the 1,5 percentile values of the airburst volumes and pressures determined above.

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For the purposes of this International Standard, the relevant percentile, x, shall be determined by ranking the N data values and taking the value of the nth rank, where

$$n = \frac{Nx}{100} + \frac{1}{2}$$

rounded to the nearest integer (e.g. for $N = 2\ 000$, the lower 1,5 percentile is the 31st lowest value).

NOTE 1 Based on data supplied by manufacturers for both synthetic and natural rubber latex condoms, taking 80 % of the 1,5 percentile values provides an adequate tolerance for the long-term lot-to-lot variability seen in normal manufacture.

For products in the market prior to the publication of this International Standard, manufacturers may use existing specifications as established by their regulatory bodies for bursting properties, subject to those specifications being consistent with the above requirements based on a representative sample of the product tested at the time of the clinical trial. Information regarding the establishment of these values shall be made available to regulatory and governmental authorities upon request.

NOTE 2 To ensure that the limits are appropriate, testing can be done by a laboratory accredited to ISO/IEC 17025[32], by an accreditation body, or organization that is a member of the International Laboratory Accreditation Cooperation.

When tested using the methods given in Annex H, the bursting volumes and bursting pressures shall not be less than the minimum values specified above. The compliance level shall be an acceptance quality limit (AQL) of 1,5 for non-conforming condoms. A non-conforming condom is defined as a condom that fails the requirements for volume, pressure or both, or any condom that exhibits obvious leakage.

12 Freedom from holes

When tested by the methods described in Annex J, 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.

13 Stability and shelf-life

13.1 General

Manufacturers shall verify that the condoms comply with the requirements of Clauses 11, 12, and 15 until the end of the shelf-life on the label. Shelf-life claims shall not exceed 5 years.

Data supporting shelf-life claims shall be made available to the appropriate regulatory authorities and direct purchasers upon request.

Before compliance with this International Standard may be claimed, the manufacturer shall provide evidence that:

a) a real-time study as described in 13.2 to determine shelf-life has commenced;

b) pending completion of the real-time study, shelf-life claims as described in 13.3 can be substantiated.

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

After testing according to Annex K, the condom shall meet the requirements of Clauses 11, 12 and 15.

If the real-time data indicate a shorter shelf-life than that claimed on the basis of accelerated ageing (13.3), the manufacturer shall notify the relevant regulatory authorities and direct purchasers. The manufacturer shall change the shelf-life claims for the product to the one based on the real-time study. In no case shall the shelf-life exceed 5 years.

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For condoms placed on the market based on accelerated stability studies, real-time stability studies shall be completed for the full period of the shelf-life claim.

13.3 Estimating shelf-life based upon accelerated stability studies

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

Further information on stability studies is provided in Annex L. Data generated from such studies should support the claim that the condoms fulfil the requirements in Clauses 11, 12, and 15 for the duration of the shelf-life on the label at 30^{+5}_{-2} °C.

14 Visible defects

For visible defects as described in Annex J (J.2.3.3), the compliance level for each lot shall be an AQL of 0,4.

15 Package integrity for individual container

When an individual container comprising one or more flexible laminated films sealed together is tested in accordance with Annex M, it shall pass the test. The compliance level for each test shall be an AQL of 2,5. An AQL of 0,4 shall be applied to individual containers that have visibly open seals.

For other designs of individual containers, 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 M may be used with suitable adjustment to the level of vacuum applied. Details of the test method shall be provided on request.

16 Packaging and labelling

16.1 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 protect the condom from environmental damage as is appropriate for the product. If condoms are supplied directly to consumers in individual containers then the individual container shall be regarded as a consumer package and shall meet all the labelling requirements.

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

Individual containers and any other packaging shall protect the condom from damage during transport or 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.

Manufacturers shall ensure that each lot complies with the established specification for packaging.

16.2 Labelling

NOTE National or other regulations relating to labelling, e.g. for latex allergy, which could be more stringent, can apply.

16.2.1 Symbols

Any symbols used on packaging, information, and marketing materials shall meet the requirements of ISO 15223.

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16.2.2 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 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 the individual container is distributed outside a consumer pack within Europe then the CE Mark and address of the manufacturer or European Authorized Representative shall be printed on the individual pack and the requirements of 16.2.4 shall be met.

16.2.3 Consumer package

16.2.3.1 General. Where products are supplied for distribution in consumer packages, the packages shall conform to the requirements of 16.2.3.2 and 16.2.3.3.

16.2.3.2 Consumer package exterior. The outside of the consumer package shall bear at least the following information in at least one of the official languages of the country of destination or as stipulated differently by that country or the purchaser and the seller:

a) a description of the condom, whether it is contoured or has a reservoir, and if it is coloured or textured;

b) the number of condoms contained in the consumer package;

c) the nominal width of the condom;

d) the name or trade name and address of the manufacturer and/or distributor, depending on national and regional requirements;

e) the expiry date (year-month or month-year). If a consumer package contains condoms from different lots, the earliest expiry date shall apply to all condoms;

f) a statement of storage instructions appropriate for the material used;

g) conditions that are impervious to light or other environmental conditions deleterious to the packaging of the condom;

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), and if the condom or lubricant is fragranced or flavoured, this shall also be stated;

i) the manufacturer's identifying reference for traceability (e.g. the identification number/lot number) — if different types of condoms, e.g. of 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 indicating the type of synthetic material used, and whether the material contains natural rubber;

k) a statement indicating that the condom is for single use;

l) the number of this International Standard (ISO 23409:2010);

m) any other applicable warning as required;

n) if necessary, a statement alerting consumers to any potential allergic reactions as a result of product use.

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