SLOVENSKI STANDARD
SIST EN 600:2000

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Moġki kondomi iz naravnega kavļuka

Natural rubber latex male condoms

Kondome aus Naturkautschuklatex für Männer

Préservatifs masculins en latex de caoutchouc naturel

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11.200	Naļrtovanje druġine. Mehanski kontracepcijski pripomoļki	Birth control. Mechanical contraceptives

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English version

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

This European Standard was prepared by the Technical Committee CEN/TC 205 "Non-active medical devices" of which the Secretariat is held by the BSI.

This European Standard is based on ISO 4074, prepared by IS0/TC 157.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 1996, and conflicting national standards shall be withdrawn at the latest by August 1996.

This European Standard has been prepared under a Mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directives, see informative annex ZA, which is an integral part of this standard.

Annexes C, D, E, F, G, H, J and K are normative and form part of this European Standard. Annexes A, B, L, M, N and ZA are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

0 Introduction

This European standard covers the minimum properties which address the essential requirements detailed in the Medical Device Directive (EEC/93/42) and was mandated by the Commission of the European Communities and EFTA.

The intact latex film has been shown to be a barrier to Human Immunodeficiency Virus (HIV)[1)], other organisms responsible for the transmission of sexually transmitted diseases (STD)[2)] and spermatazoa[3)]. In order that condoms can be effective in assisting in the prevention of transmission of STDs and for contraceptive purposes, 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 European standard.

Condoms are mass produced articles. Manufacturers strive to achieve the lowest defect rate possible. Inevitably there will be some variation between individual condoms, and a small proportion of condoms in each production run may contain defects.

The sampling plans and Acceptable Quality Levels (AQL) given in this European standard are intended for referee testing, e.g. by a Notified Body. Manufacturers may devise and apply other quality control measures during production. These measures will be specific to production methods and plants, and may differ between manufacturers.

Condoms are not sterile medical devices but manufacturers should take appropriate precautions to minimize microbiological contamination of the product during manufacture and packaging. Reference to the EN ISO 9000 series and associated guides is recommended to meet this recommendation.

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1) Cornelis AM Rietmeijer et al. Condoms as physical and chemical barriers against HIV. JAMA, 1988 Vol. 259 No. 2.

2) Judson FN In vitro evaluations of condoms with and without Nonoxynol 9 as physical and chemical barriers against Chlamydia trachomatis, Herpes Simplex virus Type 2 and HIV. Sexually Transmitted Diseases April-June 1989 p. 51-56.

3) Population Information Program
Update on Condoms - Products, protection, promotion, population reports, Series H, No. 6, Sept-Oct 1982.

The condom and any lubricant, dressing material or powder applied to it should not liberate substances in amounts that are toxic, sensitizing, locally irritating or otherwise harmful under normal conditions of use. Reference should be made to EN 30993-1 for test methods to evaluate the safety of condoms particularly in respect of the risk of local irritation and sensitization. Manufacturers may be required to provide data at the request of a Notified Body to demonstrate the acceptability of their products.

1 Scope

This European standard specifies requirements for male condoms made from compounded natural rubber latex (referred to in this European Standard as condoms) supplied to consumers and designed to assist in the prevention of sexually transmitted diseases and for contraceptive purposes.

NOTE 1: Guidance on the determination of properties of condoms that have been stored after purchase is given in annex A, which does not form a normative part of this European standard.

NOTE 2: Recommendations on the storage of packaged condoms are given in annex B, which does not form a normative part of this European standard.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

ISO 188 Rubber, vulcanized - accelerated ageing or heat-resistance tests

ISO 2859-1 Sampling procedures and tables for inspection by attributes - Part 1: Sampling plans indexed by accepable quality level (AQL) for lot-by-lot inspection

EN 10 002-2 Tensile testing of metallic materials - Part 2 : Verification of the force measuring system of the tensile testing machine.

3 Definitions

For the purposes of this European standard, the following definitions apply.

3.1 lot: A number of condoms of the same design, colour, shape, size and latex formulation, manufactured continuously at essentially the same time, using the same process, common lots of raw materials, common equipment and packed with the same lubricant and any other additive or dressing in the same type of individual sealed container.

NOTE: This European standard does not specify the size of a lot, but it may be possible for a purchaser to do so as part of the purchasing contract. Attention is drawn to the difficulties that can be associated with the distribution and control of very large lots. The recommended lot size for production is 150 000 and should not exceed 500 000.

3.2 lot number: Number, or combination of numerals, symbols or letters given by a manufacturer to each lot of individually packaged condoms, to identify uniquely that lot, and from which it is possible to trace that lot through all stages of manufacture up to packaging.

3.3 identification number: Number, or combination of numerals, symbols or letters given by a manufacturer to each lot of goods packed in 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 packaging and distribution.

NOTE: The identification number may be the same as the lot number of the individual packaged condoms if the consumer package contains only one type of condom.

3.4 acceptable quality level; AQL: When a continuous series of lots is considered, the quality level which for the purposes of sampling inspection is the limit of a satisfactory process average.

3.5 visible hole: A hole in the condom that is visible under normal or corrected vision.

3.6 non-visible hole: A hole in the condom that is not visible under normal or corrected vision and is defined as a defect through which a quantity of water can be forced by rolling a condom containing 300 ml of water (or electrolyte) on coloured absorbent paper such that all parts of the surface of the condom are brought into contact with the absorbent paper, the quantity of water being such that it can be detected visually as a wet mark on the paper.

3.7 inspection level: The inspection level defines a relationship between lot size and sample size.

3.8 sampling plan: A 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).

4 Design

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

NOTE: Condoms may be of the designs given in the following list, which is not intended to be exhaustive: smooth, textured, parallel-sided, non-parallel-sided, plain-ended, reservoir-ended, dry, lubricated, transparent, translucent, opaque or coloured, form-fitting.

5 Dimensions

When tested by the methods given in annexes C and D respectively, taking 10 samples from each lot, the minimum average length of the condom shall be not less than 170 mm, and the average width shall equal the nominal width stated by the manufacturer with a limit deviation of ± 2 mm. The nominal width shall be in the range of 44 mm to 56 mm.

NOTE: Condoms marketed in Europe usually have a nominal width of 52 mm.

6 Bursting volume and pressure

When tested as described in annex E the bursting volume shall not be less than 18 dm^3 and the bursting pressure shall not be less than 1,0 kPa.

Each lot shall be sampled in accordance with ISO 2859-1 general inspection level I. When tested as described in annex E, the compliance level shall be an AQL of 1,5.

NOTE 1: This inspection level meets the requirements of annex IV point 6.3 of the Medical Device Directive, and does not entail excessive sample sizes which would impact on manufacturing and testing costs.

NOTE 2: A defective condom is defined as a condom which fails the requirement for volume or the requirement for pressure or both requirements, i.e. a condom failing both requirements is counted as 1 defective condom.

7 Tensile properties

7.1 Non-oven-treated condoms

When tested as described in annex F, taking one ring sample from each of 13 condoms, the median tensile properties shall be not less than the values given in table 1.

Table 1: Tensile properties

	Force at break (N)	Elongation at break (%)
Normal strength condoms	39	700
Condoms for which a claim of extra strength is made[1)]	100	700
[1)] e.g. "extra strong", "extra thick".		

7.2 Oven-treated condoms

After oven treatment as described in annex G in individual sealed containers and when tested as described in 7.1, the median tensile properties shall conform to those given in table 1.

8 Freedom from holes

Each lot shall be sampled in accordance with ISO 2859-1 general inspection level I, but utilising a minimum sample size and corresponding acceptance/rejection numbers equivalent to sample size code letter M. When tested by either method described in annex H, the compliance level for the sum of condoms with visible and non-visible holes shall be an AQL of 0,25.

NOTE 1: This inspection level meets the requirements of annex IV point 6.3 of the Medical Device Directive, and does not entail excessive samples sizes which would impact on manufacturing and testing costs. A minimum sample size equivalent to sample code letter M is necessary to ensure that an adequate assessment of the quality of the lot is obtained.

NOTE 2: When using single normal sampling plans a sample size of 315 is utilized for all lot sizes upto 500 000. Code N i.e. 500 samples, is used for lot sizes in excess of 500 000.

9 Colour fastness

Condoms which appear to contain a pigment or dye shall not stain the absorbent paper when tested as described in annex J. From each lot 10 condoms shall be tested.

10 Packaging and labelling

The condom shall be packaged and labelled as specified in annex K. From each lot 10 consumer packages and 10 individual sealed containers shall be inspected for compliance.

NOTE 1: Under certain conditions it may be permissible for the manufacturer/distributor 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 sealed containers into new compliant consumer packages before placing on the market.

NOTE 2: If condoms from the same lot are packed into different consumer packages, then at least one consumer package of each variant should be inspected. The number of packages inspected should not exceed 10.

Annex A (informative)

Sampling plans and testing for determination of properties of condoms that have been stored after purchase

A.1 General

It is sometimes necessary or desirable to determine the properties of condoms that have been stored after purchase. The most usual instances are:

a) the wish of a purchaser to ensure that condoms which have been in store since purchase are suitable for release and use; or

b) to establish the properties of condoms purchased in small numbers, usually 'over-the-counter', in order to compare their properties with those given in this standard.

NOTE: The sampling can only apply to condoms from one and the same lot.

A.2 Selection of sample size

If the lot size is known, the sampling plans given in this European standard should be used, and the relevant acceptance and rejection numbers given in ISO 2859-1 should be used to assess the properties of the condoms. If the lot size is less than 10 001, 10 001 should be assumed to be the lot size.

If the size of the lot from which the condoms in question were derived is unknown, it should be assumed that the lot size is between 10 001 and 35 000.

A summary of the tests and requirements is given in table A1 and examples of sample sizes are given in table A2.

Table A1: Summary of Tests and Requirements

Test	Clause	Sample requirement	Accept criteria
Dimensions	5	10	Length: average of 10 condoms ≥ 170 mm Width: average of 10 condoms in range ± 2 mm of manufacturer's specified width
Bursting volume and pressure	6	ISO 2859-1 General inspection Level I	AQL 1,5 Bursting volume ≥ 18 dm^3 Bursting pressure ≥ 1,0kPa
Tensile properties before and after ageing	7		
Force at break		13	Normal condoms Median ≥ 39 N Extra strength Median ≥ 100 N
Elongation at break	13		Median ≥ 700 %
Freedom from holes	8	ISO 2859-1 General inspection Level I Minimum sample size M	AQL 0,25
Colourfastness	9	10	No defects in sample
Packaging and labelling	10	10	No defects in sample

Table A2: Examples of sample size based on IS0 2859-1 single normal sampling plans[1)]

Test	Batch size 10,001 to 35,000	Batch size 35,001 to 150,000	Batch size 150,001 to 500,000
Bursting volume and pressure	125 Ac 5/Re 6	200 Ac 7/Re 8	315 Ac 10/Re 11
Freedom from holes	315 Ac 2/Re 3	315 Ac 2/Re 3	315 Ac 2/Re 3

[1)] Double or multiple sampling plans may be used: Switching rules may be applied if appropriate.

A.3 Oven treatment of condoms tested after time of supply

The test and requirements given in this European standard for force and elongation at break (see clause 7) are intended to be applied to condoms at the time of supply. Therefore they include an oven treatment procedure intended to simulate the effect of normal storage, which together with requirements for non-oven-treated and oven-treated condoms, should ensure that the mechanical properties of the condom will remain satisfactory upon normal storage.

When testing the tensile properties of condoms that have been held in store for more than 1 year after the date of manufacture, the application of the oven treatment procedure is considered to be inappropriate, since the effect of the simulated ageing will already have been brought about naturally. For this reason tests on condoms after storage for more than 1 year should not include the oven treatment procedure.