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British Standard Specification for

# Natural rubber latex condoms

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Préservatifs masculins en caoutchouc naturel — Spécifications

Kondome aus Naturkautschuk

## Foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee and is a revision of BS 3704 : 1979 which is withdrawn.

The first edition of BS 3704 was published in 1964 as a result of a proposal made by the Family Planning Association. In 1972 the second edition was published, in which the stringency of the tests and requirements for the absence of holes was increased and requirements for the tensile properties of the material were introduced. The third edition, published in 1979, took into account the growth in demand for coloured condoms and for condoms having a textured surface by including requirements for colour fastness and for the tensile properties of textured products.

The major difference in this fourth edition is that the maximum wall thickness of the condom has been increased and the maximum mass requirement deleted so as to admit thicker-walled condoms.

Other important differences are as follows.

(a) The removal from the body of the standard of the sampling plans for testing purposes. Previously the standard specified a cumulative sampling plan to determine freedom from holes and specified various fixed sample numbers for the determination of other properties, all intended to be applied to continuous production. Because these sampling requirements were linked to the process of manufacture, being based on batch size and number of production quanta rather than to the assessment of the finished condom, they proved inflexible and sometimes difficult to apply for purposes such as third party certification and market surveillance. Consequently, this edition specifically excludes sampling for third party certification purposes. Reference sampling plans for assessing manufacturers' claims of conformity and guidance on sampling for other purposes are now given in appendices A and B, and the matter is

discussed more fully in the introduction. Also noteworthy is that the reference sampling plans are based on the acceptable quality level (AQL) system used in the draft international standard ISO/DIS 4074-1 and specified in BS 6001 : Part 1.

(b) Provision for different sizes of condoms and the introduction of a classification system based on size and surface type.

(c) The introduction of requirements for the uniformity of wall thickness.

(d) The introduction of requirements for the minimum force at break of the condom.

(e) The provision of more explicit instructions for use.

Wherever possible, cognizance has been taken of, and attempts made to harmonize with, the work of Technical Committee 157, Mechanical contraceptives, of the International Organization for Standardization (ISO), chiefly by the adoption of the relevant technical details of the testing methodology given in Parts 2, 3, 4 and 7 of the incomplete standard ISO 4074.

**Product certification.** Users of this British Standard are advised to consider the desirability of third party certification of product conformity with this British Standard based on testing and continuing surveillance, which may be coupled with assessment of a supplier's quality systems against the appropriate Part of BS 5750. Enquiries as to the availability of third party certification schemes will be forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist, users should consider approaching an appropriate body from the list of Association members.

**Compliance with a British Standard does not of itself confer immunity from legal obligations.**



**Amendment No. 1**  
published and effective from 30 November 1990  
to BS 3704 : 1989

**Specification for natural rubber latex condoms**

## Revised text

**AMD 6644**  
**November 1990**

### Contents

Delete the entry for clause 5, and substitute '5 Wall thickness'.

Delete the entry for appendix E, and substitute 'E Method for determination of wall thickness'.

**AMD 6644**  
**November 1990**

### Clause 0. Introduction

At the end of the clause insert the following new paragraph:

'When performing the tests described in appendices C to J, take care to protect the condom from damage caused by jewellery, finger nails, etc. Remove the condom from the packet by sliding the condom to one side and tearing open the packet without abrading the condom. If the packet has a marked tear line, tear it along that line. Wear rubber gloves when handling the condom before and during each test.'

**AMD 6644**  
**November 1990**

### Clause 5 Wall thickness and uniformity

Delete the existing clause entirely and substitute the following:

#### **5 Wall thickness**

When measured as described in appendix E, none of the values of wall thickness measured at sections a, b or c (see figure 2) shall be lower than 0.04 mm. The percentage nonconforming shall not be greater than 4 %.

**AMD 6644**  
**November 1990**

### Clause A.5 Wall thickness and uniformity

In the clause title delete 'and uniformity.'

**AMD 6644**  
**November 1990**

### Clause B.1 General

In note 1 delete 'NOTE 1' and substitute 'NOTE'.

Delete note 2 entirely.

**AMD 6644**  
**November 1990**

### Clause B.3 Examination of condoms where the batch size is unknown

Delete item (b), and substitute the following:

'(b) if smaller numbers of condoms are involved, regard the batch size as 10 001 to 35 000. The acceptance and rejection numbers for the corresponding sample size given in BS 6001 : Part 1, together with the AQL values given in appendix A should be used to assess if the properties of the condoms comply with this standard or with some other benchmark properties.'



Clause E.2 Apparatus

Delete item (a)(1), and substitute the following:

'(1) has a flat contact of diameter  $5 \pm 0.1$  mm, square to the plunger and parallel to the baseplate, and operates with a pressure of  $20 \pm 1$  kPa; '.

Clause E.3 Preparation of specimen

Delete the existing text, and substitute the following:

'Remove any lubricant or powder by washing in propan-2-ol, then wash in a slurry of talc (fine grade) in propan-2-ol (50 g/L). Dry the specimen and wipe it to remove any excess talc deposits.'

Clause E.4 Procedure

Delete the existing text, and substitute the following:

**E.4.1 Condom with smooth surface**

A condom with a smooth surface is tested as follows. Allow the test specimen and the measuring apparatus (E.2.1) to reach a temperature of  $23 \pm 2$  °C. Using the measuring apparatus, measure the single-wall thickness of the condom at three points, spaced equidistantly around the circumference of the condom, at each of sections a, b and c as designated in figure 2, i.e. total of nine measurements.

**E.4.2 Condom with partly or wholly textured surface**

A condom with a partly or wholly textured surface is tested as follows.

(a) If the position and extent of the textured portion of the surface is such that the surface of the condom is smooth at any or all of sections a, b and c, make measurements as described in E.4.1 at as many of these sections as possible.

(b) If the surface is textured at a section, make measurements as described in E.4.1 on a textured portion and on an adjacent smooth portion between the texturing and the open end of the condom. Calculate the arithmetic mean value of the three readings made on the smooth portion, and subtract this value from the arithmetic mean value of the three readings made on the textured portion, to give the thickness of the texturing ( $t$ ).

Make measurements as described in E.4.1 at those sections a, b or c where the surface is textured. Subtract the value of  $t$  from each measurement.

(c) If the surface has no smooth portion, make measurements as described in E.4.1. Take the true thicknesses as 80 % of the measured values.'



### Clause E.5 Test report

Delete the existing text, and substitute the following:

‘The test report shall include at least the following:

- (a) identity of the condom;
- (b) individual measurements made at sections a, b and c (see E.4.1, E.4.2(a) and E.4.2(c)), corrected for texturing, if appropriate, as described in item (b) of E.4.2, expressed in millimetres;
- (c) date of testing.’

### Clause H.3.7

Delete the text, and substitute the following:

‘H.3.7 If there is no visible leakage through the condom wall after suspension for at least 1 min, take hold of the condom by the closed end and gently stretch the condom to displace water from the area of the rim. Seal the open end of the condom by twisting the condom for not more than 1.5 revolutions, and remove the condom from the mount.

If the condom is lubricated, remove excess lubricant by wiping the condom carefully with a soft cloth, or by rolling it gently on a sheet of absorbent paper.

Transfer the condom onto a sheet of dry absorbent paper. Use one hand to keep the open end of the condom closed so as to prevent water leakage, and use the other hand to roll the condom back and forth once for a distance equal to the circumference of the condom in its water-filled condition.

During rolling, spread the fingers of the hand so as to distribute the force on the condom as equally as possible. Maintain the hand at a distance of 25 mm to 35 mm above the absorbent paper, and move the hand diagonally with respect to the axis of the condom so that all parts of the condom are subjected to hand pressure and come into contact with the absorbent paper.

Inspect the paper for signs of leakage from the condom.’



**Amendment No. 2**  
**published and effective from 15 April 1995**  
**to BS 3704 : 1989**

**Specification for natural rubber latex condoms**

**Revised text**

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Contents (as amended by Amendment No. 1)

Delete the entry for clause 5 and substitute '5 Bursting volume and pressure'.

Delete the entry for appendix E and substitute 'E Method for determination of bursting volume and pressure'.

Delete the entry for appendix F and substitute 'F Method for determination of force and elongation at break of test pieces of condoms'.

After the entry for appendix K insert the following new entries.

L Recommended method for calibrating air inflation equipment for determination of bursting volume and pressure

M Example of method for removing lubricant from condom

After the entry for table 2 insert the following new entry.

3 Tensile properties

Delete the entry for figure 2 and substitute '2 Details of two examples of apparatus for testing bursting volume and pressure'.

After the entry for figure 3 insert the following new entries.

4 System check algorithm

5 Example of apparatus for drying condoms

**AMD 8650/April 1995**

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**Foreword**

Delete paragraph 5 beginning 'Wherever possible...' and substitute the following.

Wherever possible, cognizance has been taken of, and attempts made to harmonize with, the work of Technical Committee 157, Mechanical contraceptives, of the International Organization for Standardization (ISO) and of Technical Committee 205, Non-active medical devices, of the Comité Européen de Normalisation (CEN).

After paragraph 5 insert the following new paragraph.

Amendment No. 2 reflects the latest draft European Standard (prEN 600). The changes include:

- (a) the introduction of requirements and a test method for the volume and pressure of the condom at burst;
- (b) provision for consumer packages to contain more than one type of condom;



- (c) deletion of requirements for wall thickness of the condom;
- (d) revised tensile requirements, including requirements for condoms claimed to be of 'extra strength'.

AMD 8650/April 1995

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## Clause 4 Dimensions

Delete sentence 2 and substitute the following.

The compliance level for each parameter shall be an AQL of 4.

In the note after 'NOTE' insert '1'. After note 1 insert the following new note.

NOTE 2. When performing tests on the contents of consumer packages that contain more than one type of condom, evaluate each type of condom in accordance with the relevant provisions for that type of condom.

AMD 8650/April 1995

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## Clause 5 Wall thickness (as amended by Amendment No. 1)

Delete the clause and substitute the following.

### 5 Bursting volume and pressure

When tested as described in appendix E the bursting volume shall be not less than 18 dm<sup>3</sup> and the bursting pressure shall be not less than 1.0 kPa. The compliance level shall be an AQL of 1.5.

NOTE. A defective condom is a condom that fails the requirement for volume, or the requirement for pressure, or both requirements, i.e. a condom failing both requirements is counted as one defective condom.

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## Clause 6 Tensile properties

Delete the text of clause 6 and substitute the following.

### 6.1 Non-oven-treated condoms

When tested as described in appendix F, taking one ring sample from each of 13 condoms, the median tensile properties shall be not less than the values given in table 3.

NOTE. When performing tests on the contents of consumer packages that contain more than one type of condom, evaluate each type of condom in accordance with the relevant provisions for that type of condom.

| Table 3. Tensile properties                                       |                |                     |
|-------------------------------------------------------------------|----------------|---------------------|
| Strength                                                          | Force at break | Elongation at break |
|                                                                   | N              | %                   |
| Normal                                                            | 39             | 700                 |
| Condoms for which a claim of extra strength is made <sup>1)</sup> | 100            | 700                 |
| <sup>1)</sup> e.g. 'Extra strong', 'extra thick'.                 |                |                     |



## 6.2 Oven-treated condoms

After oven treatment as described in appendix G in individual sealed containers and when tested as described in 6.1, the median tensile properties shall be not less than the values given in table 3.

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## Clause 7 Freedom from holes and visible defects

Delete the text of clause 7 and substitute the following.

When tested for freedom from holes and tears as described in appendix H, the compliance level shall be an AQL of 0.4.

When tested for freedom from visible defects other than holes and tears as described in appendix H, the compliance level shall be an AQL of 0.4.

NOTE. Both tests are carried out on the same sample of condoms. The number of visible defects other than holes and tears and the number of visible holes and tears and pin holes (i.e. the number of the two types of defect) are counted separately. A condom having both types of defect counts towards the totals of both types of defect.

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## Clause 9.2 Packaging

Delete sentences 3 and 4.

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### Clause 9.3.2.1

Delete the text of items (a) and (e) and substitute the following.

(a) the condom type(s), designated in accordance with clause 2, and the brand name;

(e) the expiry date (month and year). The maximum expiry date shall be not more than 5 years from the date of manufacture. If a consumer package includes condoms from different lots, the expiry date shall be within 5 years of the date of manufacture of the oldest lot;

Insert the following new item (h).

(h) an identifying reference for traceability (e.g. an identification number). If different types of condom are packaged together in the same consumer package, the identification number shall allow the unique identification of 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;

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## Clause A.2 Sampling

Delete sentence 1.

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