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JIS T 9111-1 : 2000

**Rubber condoms—
Part 1 : Requirements**

ICS 11.200

Descriptors : contraceptive sheaths, latices, quality assurance systems

Reference number : JIS T 9111-1 : 2000 (E)

Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of International Trade and Industry and Minister of Health and Welfare through deliberations at the Japanese Industrial Standards Committee in accordance with the Industrial Standardization Law:

JIS T 9111 *Rubber condoms* consists of the following parts.

- JIS T 9111-1 *Rubber condoms—Part 1 : Requirements*
- JIS T 9111-2 *Rubber condoms—Part 2 : Determination of length*
- JIS T 9111-3 *Rubber condoms—Part 3 : Determination of width*
- JIS T 9111-5 *Rubber condoms—Part 5 : Testing for holes—Water leak test*
- JIS T 9111-6 *Rubber condoms—Part 6 : Determination of bursting volume and pressure*
- JIS T 9111-7 *Rubber condoms—Part 7 : Oven conditioning*
- JIS T 9111-9 *Rubber condoms—Part 9 : Determination of tensile properties*
- JIS T 9111-10 *Rubber condoms—Part 10 : Packaging and labelling*

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Rubber condoms—Part 1 : Requirements

Introduction This part of **JIS T 9111** was made on the basis of **ISO 4074-1 Rubber condoms—Part 1 : Requirements** published in 1996 as the second edition, by modifying part of its contents.

The portions underlined with dots and sidelined in this Standard are matters not included in the corresponding International Standard.

The intact latex film has been shown to be a barrier to human immunodeficiency virus (HIV), other infectious agents responsible for the transmission of sexually transmitted diseases (STDs) and spermatozoa. In order to help ensure that condoms are effective for contraceptive purposes and in assisting in the prevention of transmission of STDs, it is essential that condoms fit 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 Standard.

The sampling plans and acceptable quality levels (AQLs) given in the body of this part of **JIS T 9111** are intended for referee testing. 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 **JIS Z 9900** series and associated guides is recommended to meet this requirement.

The condom and any lubricant, dressing material or powder applied to it should neither contain nor liberate substances in amounts that are toxic, sensitizing, locally irritating or otherwise harmful under normal conditions of use. (Reference should be made to **ISO 10993-10**.)

1 Scope This part of **JIS T 9111** specifies requirements for male condoms made from compounded natural rubber latex, supplied to consumers and designed for contraceptive purposes and to assist in the prevention of sexually transmitted diseases (hereafter referred to as “condom”).

This part of **JIS T 9111** does not contain requirements for width, oven conditioning and tensile properties of condoms. If determination of width, oven conditioning and tensile properties is desired, the test method given in **JIS T 9111-3**, **JIS T 9111-7** and **JIS T 9111-9** can be used.

Remarks : The following standard is the corresponding International Standard to this Standard:

ISO 4074-1 : 1996 *Rubber condoms—Part 1 : Requirements* (MOD)

The symbols for indicating the degree of correspondence are IDT (identical), MOD (modified) and NEQ (not equivalent) as specified in **ISO/IEC Guide 21**.

NOTE 1 Condoms are mass-produced articles. Inevitably there will be some variation between individual condoms, and a small proportion of condoms in each production run may contain defects. Information regarding the

verification of quality of condoms and sampling plans to assess compliance of a batch of condoms with this part of **JIS T 9111** are given in Annex A.

NOTE 2 Guidance on the determination of properties of condoms that have been stored after purchase is given in Annex B.

NOTE 3 Recommendations on the storage of packaged condoms are given in Annex C.

2 Normative references The following standards contain provisions which, through reference in this text, constitute provisions of this part of **JIS T 9111**. If the indication of the year of publication is given to these referred standards, only the edition of indicated year constitutes the provision of this Standard but the revision and amendment made thereafter are not applied. The normative references without the indication of the year of publication apply limiting only to the most recent edition (including the amendment).

JIS T 9111-2 *Rubber condoms—Part 2 : Determination of length*

Remarks : **ISO 4074-2** : 1994 *Rubber condoms—Part 2 : Determination of length*: which is identical with the above standard.

JIS T 9111-3 *Rubber condoms—Part 3 : Determination of width*

Remarks : **ISO 4074-3** : 1994 *Rubber condoms—Part 3 : Determination of width*: which is identical with the above standard.

JIS T 9111-5 *Rubber condoms—Part 5 : Testing for holes—Water leak test*

Remarks : **ISO 4074-5** : 1996 *Rubber condoms—Part 5 : Testing for holes—Water leak test*: whose corresponding part is equivalent to that of the above standard.

JIS T 9111-6 *Rubber condoms—Part 6 : Determination of bursting volume and pressure*

Remarks : **ISO 4074-6** : 1996 *Rubber condoms—Part 6 : Determination of bursting volume and pressure*: whose corresponding part is equivalent to that of the above standard.

JIS T 9111-7 *Rubber condoms—Part 7 : Oven conditioning*

Remarks : **ISO 4074-7** : 1996 *Rubber condoms—Part 7 : Oven conditioning*: which is identical with the above standard.

JIS T 9111-9 *Rubber condoms—Part 9 : Determination of tensile properties*

Remarks : **ISO 4074-9** : 1996 *Rubber condoms—Part 9 : Determination of tensile properties*: which is identical with the above standard.

JIS T 9111-10 *Rubber condoms—Part 10 : Packaging and labelling*

Remarks : **ISO 4074-10** : 1990 *Rubber condoms—Part 10 : Packaging and labelling—Condoms in consumer packages*: whose corresponding part is equivalent to that of the above standard.

ISO 2859-1 : 1989 *Sampling procedures for inspection by attributes—Part 1 : Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection*

3 Definitions For the purposes of this part of JIS T 9111, the following definitions apply.

3.1 batch Number of condoms manufactured or considered to be manufactured under the same conditions.

NOTE — This Standard does not specify the size of a batch, 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 control of very large batches.

Batches normally range in size from 50 000 to 500 000 condoms, the most usual size in current and past practice being approximately 150 000.

3.2 acceptable quality level (AQL) When a continuous series of batches are considered, the quality level which, for the purposes of sampling inspection, is the limit of a satisfactory process average.

3.3 individual package The package in which an individual condom is sealed separately. It is also called internal package.

3.4 consumer package The package in which one or more individual packages are contained for consumers. It is also called external package.

4 Sampling Sampling and establishment of the sampling plan shall be carried out in accordance with ISO 2859-1.

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

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

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

6 Dimensions When tested by the method given in JIS T 9111-2, the length of the condom shall be not less than 160 mm.

Each batch shall be sampled in accordance with ISO 2859-1, special inspection level S-2, the compliance level shall be an AQL of 4.0.

7 Bursting volume and pressure When tested in accordance with JIS T 9111-6, the bursting pressure shall be not less than 1.0 kPa and the bursting volume shall be not less than $0.004\,92 \times w^2 \text{ dm}^3$ (rounded off to the nearest 0.5 dm³), where w is the average width (rounded off to the nearest 0.5 mm) of 13 condoms, expressed in millimetres of the shank portion of the condom, measured $70 \text{ mm} \pm 5 \text{ mm}$ from the open end, determined in accordance with JIS T 9111-3. If w is impossible to be measured due to the shape of condom, the value of w is assumed to be 52 mm.

Each batch shall be sampled in accordance with **ISO 2859-1**, general inspection level 1 and the compliance level shall be an AQL of 1.0 for each individual property.

8 Freedom from holes When tested in accordance with **JIS T 9111-5** or Annex 1, there shall be no holes, tears or leakage on the condom.

Each batch shall be sampled in accordance with **ISO 2859-1**, general inspection level 1, but at least code letter M and the compliance level shall be an AQL of 0.25.

9 Packaging and labelling Condoms in consumer packages shall be packaged and labelled as specified in **JIS T 9111-10**.

Each batch shall be sampled in accordance with **ISO 2859-1**, special inspection level S-2, and the compliance level shall be an AQL of 4.0.