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Australian Standard 1919-1980

RUBBER CONDOMS



STANDARDS ASSOCIATION OF AUSTRALIA
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THE FOLLOWING SCIENTIFIC, INDUSTRIAL, CONSUMER AND GOVERNMENTAL organizations and departments were officially represented on the committee entrusted with the preparation of this standard:

Australian Department of Health
Australian Federation of Consumer Organizations
Canberra Consumers Inc.
Confederation of Australian Industry
National Biological Standards Laboratory
Royal Australian College of General Practitioners
Royal Australian College of Obstetricians and Gynaecologists
State Departments of Health
The Australian Federation of Family Planning Associations

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AUSTRALIAN STANDARD

RUBBER CONDOMS

AS 1919—1980

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PREFACE

This standard was prepared by the Association's Committee on Contraceptive Devices and first published in 1976, following submissions from Canberra Consumers Inc., the Australian Federation of Family Planning Associations and other organizations. The revision was undertaken at the request of the Australian Department of Health.

In the preparation of the standard the committee considered the work of ISO/TC 157, Devices for Birth Control. It also referred to the British standard for rubber condoms (BS 3704) but the inflation test included in this standard is based on that specified in the Swedish standard.

An important requirement in the standard is that adequate instructions for use and storage be included on or within the pack, and attention is drawn to the committee's recommendations in this regard set out in Appendix E.

The committee also recommends that manufacturers expand the basic instructions given in Clause 11(b) (vi) (a—g). Reference to birth control and prevention of venereal disease would be appropriate. Guidance on spermicidal preparations, to be used in conjunction with condoms, could also be useful.

Based on the present state of the art and as a guide to manufacturers, the committee recommends that Acceptable Quality Levels (AQLs) (see AS 1199, Sampling Procedures and Tables for Inspection by Attributes, and AS 1399, Guide to AS 1199) for the freedom from holes and bursting tests, for quality control purposes, be not more than 0.4 percent and 1.0 percent respectively.

It is strongly recommended that, in view of the nature of this standard, manufacturers and purchasers should make use of the scheme operated by the Standards Association of Australia (see Note to Clause 11) whereby the product may bear the certification mark of the SAA.

This standard may require reference to the following standard:

AS CK15 Code of Recommended Practice for the Storage of Vulcanized Elastomers

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
RUBBER CONDOMS

1 SCOPE. This standard specifies requirements for rubber condoms intended for single use.

NOTE: The efficacy of spermicidal or other dressing materials is not within the scope of this standard.

2 DEFINITIONS. For the purpose of this standard, the following definitions apply:

Condom—a rubber condom for single use, including any dressing or lubricant applied by the manufacturer.

Rim and teat—the sections of the condom indicated in Fig. 1.

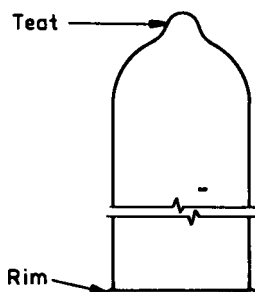


Fig. 1. LOCATION OF RIM AND TEAT

Unit pack—the pack enclosing a single condom.

Primary pack—the complete pack in which a condom or condoms is to be supplied to the consumer, excluding any wrapping, bag, box, carton or similar article in which any complete pack is placed at the time of sale or despatch.

Expiry date—a date which is not more than 5 years after the date of manufacture of the condom, and before which the condom shall be expected to comply with this standard.

Inspection lot—a quantity of some commodity from which a sample is to be drawn and inspected to determine compliance with the acceptability criteria. (It may differ from a quantity of some commodity designated as a batch or lot for other purposes, e.g. for shipment.) Each batch or lot is assumed, as far as practicable, to consist of material or items of single type, grade, class, size, and composition, and to have been manufactured under essentially the same conditions at essentially the same time.

3 MATERIALS. Condoms shall be manufactured from natural or synthetic rubber. The condoms and any dressing material applied to them shall not liberate substances which are toxic or otherwise harmful under normal conditions of use.

Any dressing materials, compound ingredients or pigments used shall not have a deleterious effect on the condom.

4 SAMPLES. Inspection lots shall be submitted packaged for supply or use.

5 DESIGN AND DIMENSIONS.

5.1 Rim. The open end of the condom shall be formed into an integral rim.

5.2 Length. The length of the condom excluding any teat shall be not less than 160 mm.

5.3 Width. The width of a condom, when laid flat and measured at any point within 85 mm of the rim, shall be not more than 56 mm and not less than 47 mm.

5.4 Thickness. When measured in accordance with Appendix A, the double-wall thickness of a condom shall be not more than 0.16 mm at any of the three places measured.

6 FREEDOM FROM HOLES. When tested in accordance with Appendix B, the condom shall present no visual evidence of leakage.

7 BURSTING VOLUME. When tested in accordance with Appendix C, the condom shall not leak or burst at a capacity of less than 15 L.

8 COLOURFASTNESS. When the condom is tested in accordance with Appendix D, there shall be no change in the colour of the buffer solution nor evidence of staining of the absorbent paper by the pigment used to colour the condom. Lubricated condoms shall be tested in the lubricated condition.

9 PACKING. The packing of the condom shall be in accordance with the following requirements:

- (a) Each condom shall be packed in a sealed unit pack in a hygienically satisfactory manner.
- (b) The unit pack shall be packed in a primary pack sufficiently robust to protect the condoms against damage during normal transport and normal storage.
- (c) Either the unit pack or the primary pack shall be opaque.
- (d) Packaging shall be such that, when examined under $10\times$ magnification, there shall be no evidence of mould growth.
- (e) The primary pack shall contain a leaflet carrying the information specified in Clause 10.

10 INFORMATION ON STORAGE AND ON THE USE OF LUBRICANTS. Information on how to store the condoms and on the use of lubricants, based on the notes given in Appendix E, shall be given on a leaflet enclosed in the primary pack.