Australian Standard®

Natural latex rubber condoms—Requirements and test methods

This Australian Standard® was prepared by Committee CS-009, Devices for Contraception and Prevention of Sexually Transmitted Infections. It was approved on behalf of the Council of Standards Australia on 18 June 2009.
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The following are represented on Committee CS-009:

- Australian Business
- Australian Federation of Aids Organisations
- Family Planning Association, New Zealand
- Family Planning Australia
- Medical Technology Association of Australia
- Ministry of Health, New Zealand
- Royal Australian and New Zealand College of Obstetricians & Gynaecologists
- Testing Interests, Australia
- The Pharmacy Guild of Australia
- Therapeutic Goods Administration

This Standard was issued in draft form for comment as DR AS 5074.

Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee CS-009, Devices for Contraception and Prevention of Sexually Transmitted Infections. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard.

This Standard is identical with and has been reproduced from ISO 4074:2002, *Natural latex rubber condoms—Requirements and test methods*.

The objective of this Standard is to specify the minimum requirements and the test methods to be used for condoms made from natural rubber latex which are supplied to consumers for contraceptive purposes and to assist in the prevention of sexually transmitted infections.

A regulatory system for medical devices came into effect in Australia on 4 October 2002.

It is proposed that this Standard be considered for inclusion in a Standards Code to support the Medical Device Regulations (Therapeutic Goods (Medical Devices) Regulations 2002).

The Regulations set out Essential Principles and other requirements. The Medical Device Standards and Conformity Assessment Standards included in Standards Orders are the preferred mechanism for demonstrating compliance with the requirements of the Regulations.

Compliance with these standards presumes compliance with the Essential Principles and other requirements in the Regulations. However, Medical Device Standards and Conformity Assessment Standards are not mandatory.

It may be necessary to use a number of appropriate Medical Device Standards to demonstrate compliance because standards may not typically be written to address all of the Essential Principles relevant to a particular medical device.

Under the Regulations, manufacturers are required to document and record the means of compliance used to satisfy the Essential Principles and other requirements, including the use of applicable Medical Device Standards, Conformity Assessment Standards or other standards.

As this Standard is reproduced from an international standard, the following applies:

(a) Its number appears on the cover and title page while the international standard number appears only on the cover.

(b) In the source text 'this International Standard' should read 'this Australian Standard'.

(c) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

Reference to International Standard		*Australian Standard*	
ISO		AS	
188	Rubber, vulcanized or thermoplastic—Accelerated ageing and heat resistance tests	1683	Methods of test for elastomers
		1683.26	Method 26: Rubber, vulcanized or thermoplastic—Accelerated ageing and heat resistance tests
2859	Sampling procedures for inspection by attributes	1199	Sampling procedures for inspection by attributes
2859-1	Part 1: Sampling schemes indexed by acceptable quality level (AQL) for lot-by-lot inspection	1199.1	Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

ISO 15223	Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied	AS —
EN 980	Graphical symbols for use in the labelling of medical devices	—

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the annex to which they apply. A ‘normative’ annex is an integral part of a Standard, whereas an ‘informative’ annex is only for information and guidance.

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AUSTRALIAN STANDARD

Natural latex rubber condoms — Requirements and test methods

1 Scope

This International Standard specifies the minimum requirements and the test methods to be used for condoms made from natural rubber latex which are supplied to consumers for contraceptive purposes and to assist in the prevention of sexually transmitted infections.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 188, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests*

ISO 2859-1:1999, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

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

EN 980, *Graphical symbols for use in the labelling of medical devices*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 2859-1 and the following apply.

3.1
acceptable quality limit
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 mean (according to ISO 2859-1)

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

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

3.3
consumer package
package, intended for distribution to a consumer, containing one or more individual containers