AS/NZS 4592:2005

Australian/New Zealand Standard™

Latex barrier membranes (dams) for prophylactic use in sexual activity

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This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee CS-009, Devices for Contraception and Prevention of Sexually Transmitted Infections. It was approved on behalf of the Council of Standards Australia on 21 October 2005 and on behalf of the Council of Standards New Zealand on 11 November 2005.
This Standard was published on 20 December 2005.

The following are represented on Committee CS-009:

Australian Business
Australian Chamber of Commerce and Industry
Australian Federation of AIDS Organisations
Commonwealth Department of Health and Ageing
Family Planning Association, New Zealand
Family Planning Australia
Medical Industry Association of Australia
Ministry of Health, New Zealand
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PREFACE

This Standard was prepared by Joint Standards Australia/Standards New Zealand Committee CS-009, Devices for Contraception and Prevention of Sexually Transmitted Infections.

The objective of this Standard is to ensure that prophylactic dams provide adequate protection against the spread of sexually transmitted diseases. It therefore contains minimum dimensions and requirements for the strength and integrity of the latex film. The minimum size is stipulated so that adequate coverage can be achieved without excessive stretching of the membrane.

Supply of therapeutic goods and medical devices is regulated in Australia by the Therapeutic Goods Administration. Enquiries about the supply of latex barrier membranes (dams) for prophylactic use should be directed to the TGA. Their contact details are www.tga.gov.au; PO Box 100 Woden ACT 2606 Australia; phone 1800 020 653.

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

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STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard
Latex barrier membranes (dams) for prophylactic use in sexual activity

1 SCOPE

This Standard gives requirements for latex barrier membranes (dams) for prophylactic use. These include allowable materials, dimensions, surface finish, taste and smell, thermal stability, packaging and labeling as well as the physical properties such as elongation and tear and rupture resistance.

This specification applies to natural rubber latex barrier membranes (dams) suitable for use in sexual activity to prevent the spread of sexually transmitted infections. It therefore differentiates prophylactic dams from other barrier products, such as dental dams, which are not intended for, and may not be suitable for use in, sexual situations.

NOTE: Appendix A gives indicative sampling plans and AQLs for demonstrating compliance with this Standard.

2 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS

1199	Sampling procedures for inspection by attributes	
1199.0	Part 0:	Introduction to the ISO 2859 attribute sampling system
1199.1	Part 1:	Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
2193	Calibration and classification of force-measuring systems	

AS/NZS ISO

9001	Quality management systems—Requirements
9004	Quality management systems—Guidelines for performance improvements

AS/SANZ

HB 18.28	Guidelines for third-party certification and accreditation—Guide 28: General rules for a model third-party certification system for products

ISO

34	Rubber, vulcanized or thermoplastic—Determination of tear strength	
34-1	Part 1:	Trouser, angle and crescent test pieces
37	Rubber, vulcanized or thermoplastic—Determination of tensile stress-strain properties	
188	Rubber, vulcanized or thermoplastic—Accelerated ageing and heat resistance tests	
2859	Sampling procedures for inspection by attributes (series)	
10993	Biological evaluation of medical devices	
10993-1	Part 1:	Evaluation and testing
10993-5	Part 5:	Tests for in vitro cytotoxicity
10993-10	Part 10:	Tests for irritation and delayed-type hyper sensitivity

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