AS ISO 8009—2009
ISO 8009:2004



Australian Standard®

# Mechanical contraceptives—Reusable natural and silicone rubber contraceptive diaphragms—Requirements and tests



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.
This Standard was published on 30 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 and Gynaecologists
- Testing Interests, Australia
- The Pharmacy Guild of Australia
- Therapeutic Goods Administration

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This Standard was issued in draft form for comment as DR AS ISO 8009.

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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Australian Standard®

# Mechanical contraceptives—Reusable natural and silicone rubber contraceptive diaphragms—Requirements and tests

Originated as AS 1808—1975.
Previous edition AS 1808—1984.
Revised and redesignated as AS ISO 8009—2009.

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Published by Standards Australia GPO Box 476, Sydney, NSW 2001, Australia

ISBN 0 7337 9180 8

# PREFACE

This Standard was prepared by the Standards Australia Committee CS-009, Devices for Contraception and Prevention of Sexually Transmitted Infections, to supersede AS 1808—1984, *Contraceptive devices—Diaphragms*.

The objective of this Standard is to provide the minimum requirements and test methods to be used for reusable diaphragms intended for contraceptive use.

This Standard is identical with, and has been reproduced from, ISO 8009:2004, *Mechanical contraceptives—Reusable natural and silicone rubber contraceptive diaphragms—Requirements and tests*.

The principal changes in this edition include new tests for tensile properties of the dome and the twisting of the spring. This edition also includes recommendations on biological safety and mechanical testing according to ISO 10993. Requirements are given for compliance on batch release testing.

The adoption of the ISO Standard has resulted in minor modifications to other 1984 edition requirements.

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<br>1683.26 | Methods of test for elastomers<br>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 acceptance quality limit (AQL) for lot-by-lot inspection | 1199.1 | Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection |
| | | AS ISO | |
| 10993 | Biological evaluation of medical devices | 10993 | Biological evaluation of medical devices |
| 10993-5 | Part 5: Tests for in vitro cytotoxicity | 10993.5 | Part 5: Tests for in vitro cytotoxicity |
| 10993-10 | Part 10: Tests for irritation and delayed-type hypersensitivity | 10993.10 | Part 10: Tests for irritation and delayed-type hypersensitivity |

Only international references that have been adopted as Australian Standards have been listed.

The term ‘normative’ has been used in this Standard to define the application of the annex to which it applies. A ‘normative’ annex is an integral part of a Standard.

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# INTRODUCTION

Diaphragms are medical devices. Therefore, they should be produced under a good quality management system. Reference should be made, for example to the ISO 9000 series, in conjunction with ISO 13485 or ISO 13488 as appropriate.

The sampling plans and acceptance quality limits (AQLs) given in this International Standard are for referee testing. The AQLs represent the maximum tolerable level of defects in the products. As diaphragms are intended for re-use, manufacturers should strive for entirely defect-free product.

Manufacturers may devise and apply additional and alternative quality control measures for their use and after production. These methods may differ among manufacturers.

AUSTRALIAN STANDARD

# Mechanical contraceptives — Reusable natural and silicone rubber contraceptive diaphragms — Requirements and tests

## 1 Scope

This International Standard specifies the minimum requirements and test methods to be used for reusable diaphragms made from natural rubber and silicone rubber. These diaphragms are intended for contraceptive use.

This International Standard is not applicable to other vaginal contraceptive barriers, such as those known as cervical caps, vaginal sponges and vaginal sheaths.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 463, *Geometrical Product Specifications (GPS) — Dimensional measuring equipment — Design and metrological characteristics of mechanical dial gauges*

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 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-10*, Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity*

## 3 Terms and definitions

For the purpose of this document, the terms and definition given in ISO 2859-1 and the following apply.

**3.1**
**lot**
**batch**
collection of diaphragms of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, common lots of raw materials, common equipment and personnel

NOTE The size of a lot is not specified in this International Standard, but it may be possible for a purchaser to do so as part of a purchasing contract. Depending on the method of manufacture, multiple sizes can be produced in a defined lot/batch. In such cases, traceability can be maintained by using both the lot number and the size.


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