

Australian/New Zealand Standard™

**Single-use sterile rubber surgical
gloves—Specification
(ISO 10282:2014, MOD)**



AS/NZS 4179:2014

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-013, Surgical Apparel. It was approved on behalf of the Council of Standards Australia on 2 July 2014 and on behalf of the Council of Standards New Zealand on 3 July 2014.

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The following are represented on Committee HE-013:

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Australian College of Operating Room Nurses
Australian Dental Association
Australian Nursing and Midwifery Federation
Department of Health, Vic.
Medical Technology Association of Australia
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This Standard was issued in draft form for comment as DR AS/NZS 4179.

Australian/New Zealand Standard™

Single-use sterile rubber surgical gloves—Specification (ISO 10282:2014, MOD)

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-013, Surgical Apparel, to supersede AS/NZS 4179:1997, *Single-use sterile surgical rubber gloves—Specification*.

This Standard is an adoption with national modifications and has been reproduced from ISO 10282:2014, *Single-use sterile rubber surgical gloves—Specification*.

The variations to ISO 10282, which are necessary for Australian/New Zealand conditions, are listed in Appendices ZZ and ZA, following the source text.

The objective of this revision is to adopt the ISO Standard with Australian/New Zealand technical variations to the following Clauses of ISO 10282:

- (a) Clause 2, Normative references.
- (b) Clause 3.2, Type.
- (c) Clause 4, Materials.
- (d) Clause 5.1, Sampling.
- (e) Clause 5.2, Selection of test pieces.
- (f) Clause 6.3, Tensile properties.
- (g) Clause 6.4, Sterility.
- (h) Clause 8.3, Unit package.
- (i) Annex A, Clause A.2, Procedure.

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

- (i) In the source text ‘this International Standard’ should read ‘this Australian/New Zealand Standard’.
- (ii) 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:

<i>Reference to International Standard</i>		<i>Australian/New Zealand Standard</i>	
ISO		AS	
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 acceptable quality limit (AQL) for lot-by-lot inspection
		AS/NZS ISO	
11137	Sterilization of health care products—(all parts) Radiation	11137	Sterilization of health care products—(all parts) Radiation

Only international references that have been adopted as Australian or Australian/New Zealand Standard have been listed.

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

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NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

**Single-use sterile rubber surgical gloves—Specification
(ISO 10282:2014, MOD)****1 Scope**

This International Standard specifies requirements for packaged sterile rubber gloves intended for use in surgical procedures to protect the patient and the user from cross-contamination. It is applicable to single-use gloves that are worn once and then discarded. It does not apply to examination or procedure gloves. It covers gloves with smooth surfaces and gloves with textured surfaces over part or the whole glove.

This International Standard is intended as a reference for the performance and safety of rubber surgical gloves. The safe and proper usage of surgical gloves and sterilization procedures with subsequent handling, packaging, and storage procedures are outside the scope of this International Standard.

2 Normative references

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

ISO 37, *Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*

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

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

ISO 10993 (all parts), *Biological evaluation of medical devices*

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

ISO 23529, *Rubber — General procedures for preparing and conditioning test pieces for physical test methods*

3 Classification**3.1 General**

Gloves are classified by type, design, and finish, as given in [3.2](#) to [3.4](#).

3.2 Type

Two types are classified:

- a) Type 1: gloves made primarily from natural rubber latex.
- b) Type 2: gloves made primarily from nitrile rubber latex, isoprene rubber latex, polychloroprene rubber latex, styrene-butadiene rubber solution, styrene-butadiene rubber emulsion or thermoplastic elastomer solution.