AS/NZS 4011.1:2014

Australian/New Zealand Standard™

Single-use medical examination gloves

Part 1: Specification for gloves made from rubber latex or rubber solution (ISO 11193-1:2008, MOD)

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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.
This Standard was published on 21 July 2014.

The following are represented on Committee HE-013:

Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
Australian Dental Association
Australian Nursing and Midwifery Federation
Department of Health, Vic.
Medical Technology Association of Australia
New Zealand Nurses Organisation
NSW Ministry of Health
Product Evaluation Health, New Zealand
Queensland Health
Royal College of Pathologists of Australasia
Testing Interests (Australia)
Therapeutic Goods Administration

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We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia or Standards New Zealand at the address shown on the back cover.

This Standard was issued in draft form for comment as DR AS/NZS 4011.1.

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Originated in Australia as part of AS 4011—1992.
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-013, Surgical Apparel, to supersede, in part, AS/NZS 4011:1997, *Single-use examination gloves—Specification*.

AS/NZS 4011:1997 was a modified adoption of ISO 11193:1994. The ISO Standard covered rubber gloves only. The variations in AS/NZS 4011:1997 included the extension of the materials clause to cover poly(vinyl chloride) gloves. As ISO revised ISO 11193 as Parts 1 and 2 to cover rubber and poly(vinyl chloride) gloves respectively, this Part 1 of AS/NZS 4011 specifies rubber gloves only, and Part 2 specifies poly(vinyl chloride) gloves.

This Standard is an adoption with national modification and has been reproduced from ISO 11193-1:2008, *Single-use medical examination gloves*—Part 1: *Specification for gloves made from rubber latex or rubber solution*, and its Amendment 1, ISO 11193-1:2008/Amd.1:2012. The amendments are to Clause 6.3.3 and Table 3 of the ISO source text which have been deleted and replaced in variations Appendix ZZ.

The variations to ISO 11193-1:2008, which are necessary for Australian/New Zealand conditions, are listed in Appendices ZZ and ZA, following the source text.

Australian/New Zealand technical variations in Appendix ZZ have been made to the following Clauses of ISO 11193-1:

(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 6.1, Dimensions.

(g) Clause 6.3, Tensile properties.

(h) Clause 6.4, Sterility.

(i) Clause 8.2.1, Sterile package.

(j) Clause 8.2.2, Non-sterile package.

(k) Annex A, Clause A.2, Procedure.

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

(i) In the source text, 'this part of ISO 11193' and '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:

Reference to International Standard		*Australian/New Zealand Standard*	
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 acceptance quality limit (AQL) for lot-by-lot inspection

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Only international references that have been adopted as Australian or Australian/New Zealand Standards 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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AUSTRALIAN/NEW ZEALAND STANDARD

Single-use medical examination gloves

Part 1:
Specification for gloves made from rubber latex or rubber solution
(ISO 11193-1:2008, MOD)

WARNING — Persons using this International Standard should be familiar with normal laboratory practices. This standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user to establish appropriate safety and health practices and to ensure compliance with any regulatory conditions.

1 Scope

This part of ISO 11193 specifies requirements for packaged sterile, or bulked non-sterile, rubber gloves intended for use in medical examinations and diagnostic or therapeutic procedures to protect the patient and the user from cross-contamination. It also covers rubber gloves intended for use in handling contaminated medical materials and gloves with smooth surfaces or with textured surfaces over all or part of the glove.

This part of ISO 11193 is intended as a reference for the performance and safety of rubber examination gloves. It does not cover the safe and proper usage of examination gloves and sterilization procedures with subsequent handling, packaging and storage procedures.

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 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*

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3 Classification

3.1 General

Gloves are classified by type and finish, as given in 3.2 and 3.3.

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, polychloroprene rubber latex, styrene-butadiene rubber solution, styrene-butadiene rubber emulsion or thermoplastic-elastomer solution.

3.3 Finish

Four finishes are classified:

a) textured surface over part or all of the gloves;

b) smooth surface;

c) powdered surface;

d) powder-free surface.

NOTE 1 Powdered gloves are gloves where a powder has been applied on the gloves as a part of the manufacturing process, generally to facilitate donning. Powder-free gloves are gloves which have been manufactured without the deliberate application of powdered materials. Powder-free is also referred to as “powderless”, “no powder” or “non-powdered”, or other words to that effect.

NOTE 2 The cuff termination of the glove may be cut or in the form of a rolled rim.

4 Materials

Gloves shall be manufactured from compounded natural rubber or nitrile rubber or polychloroprene rubber latex, or compounded styrene-butadiene rubber or thermoplastic-elastomer solution, or compounded styrene-butadiene rubber emulsion. To facilitate donning the gloves, any surface treatment, lubricant, powder or polymer coating may be used subject to compliance with ISO 10993.

Any pigment used shall be non-toxic. It is essential that substances used for surface treatment which are capable of being transferred are bio-absorbable.

Gloves as supplied to the user shall comply with the relevant part(s) of ISO 10993. The manufacturer shall make available to the purchaser, on request, data to support compliance with these requirements.

NOTE 1 Other suitable polymeric materials may be included in future parts of ISO 11193.

NOTE 2 It is recognized that some individuals may, over a period of time, become sensitized to a particular rubber compound (allergic reaction) and require gloves of an alternative formulation.

NOTE 3 Limits of extractable proteins, allergenic proteins, residual chemicals, endotoxins and residual powder in gloves may be specified in future editions of this part of ISO 11193, subject to the availability of relevant ISO standard test methods.

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