
Single-use medical examination gloves —

Part 2:

**Specification for gloves made from
poly(vinyl chloride)**

Gants en caoutchouc pour examen médical, non réutilisables —

Partie 2: Spécifications pour gants fabriqués en chlorure de polyvinyle



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11193-2 was prepared by Technical Committee ISO/TC 45, *Rubber and rubber products*, Subcommittee SC 4, *Products (other than hoses)*.

This part of ISO 11193, together with ISO 11193-2, cancels and replaces ISO 11193:1994, which has been technically revised.

ISO 11193 consists of the following parts, under the general title *Single-use medical examination gloves*:

- *Part 1: Specification for gloves made from rubber latex or rubber solution*
- *Part 2: Specification for gloves made from poly(vinyl chloride)*

Single-use medical examination gloves —

Part 2:

Specification for gloves made from poly(vinyl chloride)

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, poly(vinyl chloride) 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 poly(vinyl chloride) gloves intended for use in handling contaminated medical materials.

This part of ISO 11193 is intended as a reference for the performance and safety of poly(vinyl chloride) examination gloves. The safe and proper usage of examination gloves and sterilization procedures with subsequent handling, packaging and storage procedures are outside the scope of this part of ISO 11193.

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 37:2005, *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*