INTERNATIONAL STANDARD

ISO 11193-1

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Single-use medical examination gloves —

Part 1: Specification for gloves made from rubber latex or rubber solution

Gants en caoutchouc pour examen, non réutilisables —

Partie 1: Spécifications pour gants fabriqués à partir de latex de caoutchouc ou d'une solution de caoutchouc

Reference number
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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 3.

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 part of ISO 11193 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11193-1 was prepared by Technical Committee ISO/TC 45, *Rubber and rubber products*, Subcommittee SC 4, *Products (other than hoses)*.

This part of ISO 11193 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)*

Annex A forms a normative part of this part of ISO 11193.

Single-use medical examination gloves —

Part 1:
Specification for gloves made from rubber latex or rubber solution

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 part or all of the glove.

This part of ISO 11193 is intended as a reference for the performance and safety of rubber 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 normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11193. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11193 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 37:1994, *Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*

ISO 188:1998, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests*

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 4648:1991, *Rubber, vulcanized or thermoplastic — Determination of dimensions of test pieces and products for test purposes*

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

ISO 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

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.

5 Sampling and selection of test pieces

5.1 Sampling

For reference purposes, gloves shall be sampled and inspected in accordance with ISO 2859-1. The inspection levels and acceptance quality limits (AQLs) shall conform to those specified in Table 1 for the characteristics listed.

When a lot size cannot be determined, a lot of 35 001 to 150 000 shall be assumed.

Table 1 — Inspection levels and AQLs

Characteristic	Inspection level	AQL
Physical dimensions (width, length, thickness)	S-2	4,0
Watertightness	G-I	2,5
Force at break and elongation at break (before and after accelerated ageing)	S-2	4,0

5.2 Selection of test pieces

Where test pieces are required, they shall be taken from the palm or back of gloves.

6 Requirements

6.1 Dimensions

When measured at the points shown in Figure 1, gloves shall comply with the dimensions for palm width and length given in Table 2, using the inspection level and AQL given in Table 1.

The measurement of length shall be the shortest distance between the tip of the second finger and the cuff termination.

NOTE 1 The length measurement may be taken by hanging the glove on a suitable mandrel with a tip radius of 5 mm.

The measurement of width shall be at the midpoint between the base of the index finger and the base of the thumb. The width measurement shall be made with the glove placed on a flat surface.

The thickness of the double wall of an intact glove shall be measured in accordance with ISO 4648, with a pressure on the foot of 22 kPa ± 5 kPa, at each of the locations shown in Figure 2: a point 13 mm ± 3 mm from the extreme tip of the second finger and the approximate centre of the palm. The single-wall thickness at each point shall be reported as half the measured double-wall thickness and shall comply with the dimensions given in Table 2, using the inspection level and AQL given in Table 1.

If visual inspection indicates the presence of thin spots, then single-wall thickness measurements shall be made in such areas. The thickness at the smooth area and textured area of a single wall when measured as described in this subclause shall not be less than 0,08 mm and 0,11 mm respectively.

NOTE 2 The thickness of the cuff termination measured in accordance with ISO 4648 should preferably not exceed 2,50 mm.

6.2 Watertightness

When gloves are tested for watertightness as described in annex A, the sample size and allowable number of non-conforming (leaking) gloves in the sample shall be determined in accordance with the inspection level and AQL given in Table 1.

6.3 Tensile properties

6.3.1 General

Tensile properties shall be measured in accordance with ISO 37, taking three test pieces from each glove and using the median value as the test result. Test pieces shall be taken from the palm or back of gloves.

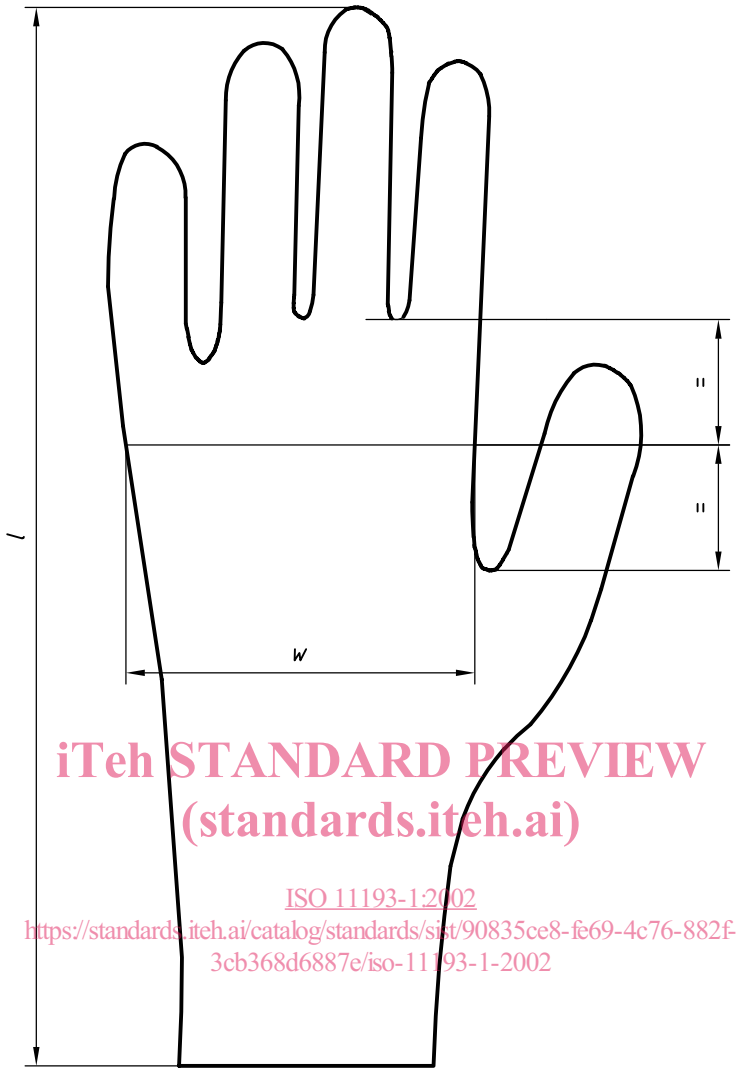
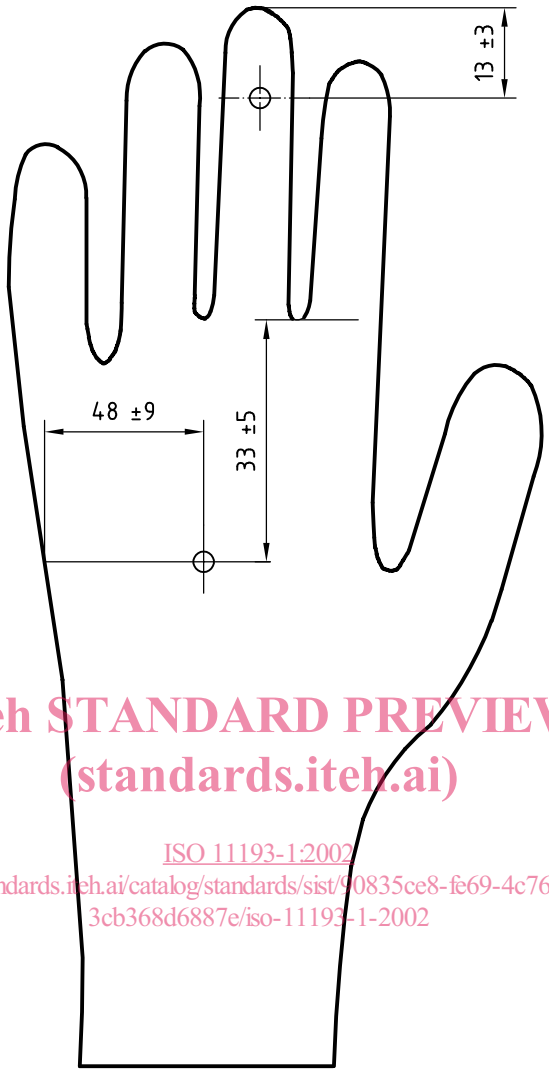


Figure 1 — Measurement points for width and length

Table 2 — Dimensions and tolerances

Size code	Nominal size	Width (dimension w, Figure 1) mm	Minimum length (dimension l, Figure 1) mm	Minimum thickness (at the locations shown in Figure 2) mm	Maximum thickness (at the approximate centre of the palm) mm
6 and below	Extra small (X-S)	$\leqslant 80$	220	For all sizes: Smooth area: 0,08 Textured area: 0,11	For all sizes: Smooth area: 2,00 Textured area: 2,03
6 1/2	Small (S)	80 ± 5	220		
7	Medium (M)	85 ± 5	230		
7 1/2	Medium (M)	95 ± 5	230		
8	Large (L)	100 ± 5	230		
8 1/2	Large (L)	110 ± 5	230		
9 and above	Extra large (X-L)	$\geqslant 110$	230		

Dimensions in millimetres



NOTE The distance 48 mm ± 9 mm locates the approximate centre of the palm for different glove sizes.

Figure 2 — Measurement points for thickness

6.3.2 Force at break and elongation at break before accelerated ageing

When determined in accordance with the method specified in ISO 37, using type 2 dumb-bell test pieces, the force at break and elongation at break shall comply with the requirements given in Table 3, using the inspection level and AQL given in Table 1.

6.3.3 Force at break and elongation at break after accelerated ageing

Accelerated ageing tests shall be conducted in accordance with the method specified in ISO 188. After the test pieces cut from the gloves have been subjected to a temperature of 70 °C ± 2 °C for 168 h ± 2 h, the value of force at break and elongation at break shall comply with the requirements given in Table 3, using the inspection level and AQL given in Table 1.