INTERNATIONAL STANDARD

ISO 11193-1

Third edition
2020-08

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

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

This third edition cancels and replaces the second edition (ISO 11193-1:2008), which has been technically revised. It also partially incorporates the Amendment ISO 11193-1:2008/Amd:2012.

The main changes compared to the previous edition are as follows:

— some general and editorial changes have been made in 4.1, 4.3, and Clause 5;

— the measurement of length has been corrected from the *second finger* to *middle finger* in 7.1, paragraph 2;

— the NOTE has been changed to main text in 7.3.3;

— the value has been corrected in Table 3;

— some general and editorial changes have been made to Annex A;

— the limit of powdered gloves has been included;

— Figures 1 and 2 of the previous edition have been replaced with Figure 1:

— updates have been made to the powdered surface and powder-free surface;

— the statement on aging gloves over six months old has been updated.

A list of all parts in the ISO 11193 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Single-use medical examination gloves —

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

WARNING — Persons using this document should be familiar with normal laboratory practices. This document 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 document 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 document 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 23529, *Rubber — General procedures for preparing and conditioning test pieces for physical test methods*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Classification

4.1 General

Gloves are classified by type and finish, as given in 4.2 and 4.3.

4.2 Type

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.

4.3 Finish

a) Textured surface over part or all of the gloves.

b) Smooth surface.

c) Powdered surface.

NOTE 1 Powdered gloves are gloves to which a powder has been applied on the gloves as a part of the manufacturing process, generally to facilitate donning.

Powdered gloves should have a maximum powder limit of 10 mg per glove.

d) Powder-free surface.

NOTE 2 Powder-free gloves are gloves which have been manufactured without the deliberate application of powdered materials. Powder-free gloves have a maximum of 2,0 mg powder residue limit per glove.

NOTE 3 The cuff termination of the glove can be cut or in the form of a rolled rim.

5 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 if it is in accordance with ISO 10993 (all parts).

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

Gloves as supplied to the user shall meet the requirements of 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 can be included in future parts of ISO 11193.

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

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

6 Sampling and selection of test pieces

6.1 Sampling

For referee 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
Water tightness	G-I	2,5
Force at break and elongation at break (before and after accelerated ageing)	S-2	4,0

6.2 Selection of test pieces

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

7 Requirements

7.1 Dimensions

When measured at the points shown in Figure 1, gloves shall be in accordance 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 middle finger and the cuff termination.

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.

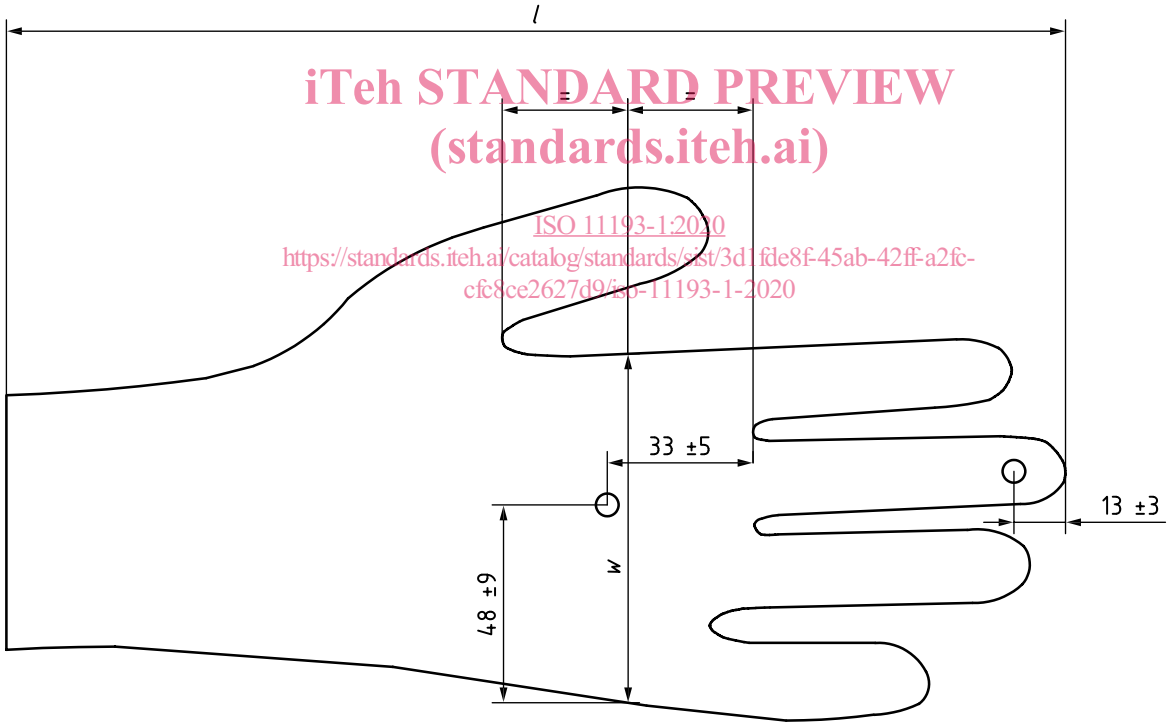
The thickness of the double wall of an intact glove shall be measured in accordance with ISO 23529, with a pressure on the foot of 22 kPa ± 5 kPa, at each of the locations shown in Figure 1: at a point 13 mm ± 3 mm from the extreme tip of the second finger and at the approximate centre of the palm. The single-wall thickness at each point shall be reported as half the measured double-wall thickness and shall be in accordance 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.

Table 2 — Dimensions and tolerances

Size code	Width corresponding to size code (dimension *w*, Figure 1) mm	Descriptive size	Width corresponding to descriptive size (dimension *w*, Figure 1) mm	Minimum length (dimension *l*, Figure 1) mm	Minimum thickness (at locations shown in Figure 1) mm	Maximum thickness (at approximate centre of palm) mm
6 and below	≤82	Extra small (X-S)	≤80	220	Smooth area: 0,08 Textured area: 0,11	Smooth area: 2,00 Textured area: 2,03
6 1/2	83 ± 5	Small (S)	80 ± 10	220		
7	89 ± 5	Medium (M)	95 ± 10	230		
7 1/2	95 ± 5			230		
8	102 ± 6	Large (L)	110 ± 10	230		
8 1/2	109 ± 6			230		
9 and above	≥110	Extra large (X-L)	≥110	230		

Dimensions in millimetres



Key

l length

w width

Figure 1 — Measurement points for the length, width and thickness of the glove

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

7.2 Water tightness

When gloves are tested for water tightness 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.

7.3 Tensile properties

7.3.1 General

Tensile properties shall be measured in accordance with ISO 37, taking three type 2 dumb-bell 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 the gloves.

7.3.2 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 be in accordance with the requirements given in Table 3, using the inspection level and AQL given in Table 1.

7.3.3 Force at break and elongation at break after accelerated ageing

Accelerated ageing shall be conducted in accordance with the method specified in ISO 188. Test pieces can be prepared either by ageing the gloves at 70 °C ± 2 °C for 168 h ± 2 h and cutting the test pieces from the aged gloves, or by cutting the test pieces from unaged gloves and ageing the test pieces at 70 °C ± 2 °C for 168 h ± 2 h. Tensile testing is then conducted as described in 7.3.2. The results shall be in accordance with the requirements given in Table 3, using the inspection level and AQL given in Table 1.

For gloves that are older than 6 months from the date of manufacture or for which the date of manufacture is unknown, no accelerated ageing shall be conducted and the tensile properties need only conform to the "after accelerated ageing" values in Table 3. The 6-month period should begin with the first day of the month immediately after the one in which the gloves were manufactured.

Table 3 — Tensile properties

Property	Requirement	
	Type 1 glove	Type 2 glove
Minimum force at break before accelerated ageing, N	7,0	7,0
Minimum elongation at break before accelerated ageing, %	650	500
Minimum force at break after accelerated ageing, N	6,0	6,0
Minimum elongation at break after accelerated ageing, %	500	400

7.4 Sterility

If gloves are sterilized, the nature of the sterilization process shall be disclosed on request.

8 Packaging

If gloves are sterilized, they shall be packaged individually or in pairs packed in unit packs.