KENYA STANDARD

KS ISO 11193-1:2008

ICS 11.140; 83.140.99

Second Edition

APPROVED
2020-04-08

Single-use medical examination gloves

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

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In order to keep abreast of progress in industry, Kenya Standards shall be regularly reviewed. Suggestions for improvements to published standards, addressed to the Managing Director, Kenya Bureau of Standards, are welcome.

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NATIONAL FOREWORD

This Kenya Standard was prepared by the Medical Devices, Instruments and Hospital Equipment Technical Committee under the guidance of the Standards Projects Committee, and it is in accordance with the procedures of the Kenya Bureau of Standards

This standard is identical with and has been reproduced from ISO 11193-1, Single-use medical examination gloves — Part 1: Specification for gloves made from rubber latex or rubber solution, published by the International Organization for Standardization (ISO). The National Standards Council has endorsed the adoption of the 2008 edition of this standard as a Kenya Standard.

For the purposes of this standard, the ISO text should be modified as follows:

a) Terminology

The words ‘this Kenya Standard’ should replace the words ‘this ISO Standard’ whenever they appear.

b) References

The references to ISO should be replaced by references to the appropriate Kenya Standards, where they have been declared.

INTERNATIONAL STANDARD

ISO 11193-1

Second edition
2008-09-01

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
ISO 11193-1:2008(E)

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

This second edition cancels and replaces the first edition (ISO 11193-1:2002), of which it constitutes a minor revision intended to incorporate the Technical Corrigendum ISO 11193-1:2002/Cor.1:2005 and the Amendment ISO 11193-1:2002/Amd.1:2007. In addition, the normative references have been updated.

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

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*

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 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
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.

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 $\pm$ 5 kPa, at each of the locations shown in Figure 2: at a point 13 mm $\pm$ 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 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.

The thickness of the cuff termination, measured in accordance with ISO 23529, should preferably not exceed 2,50 mm.

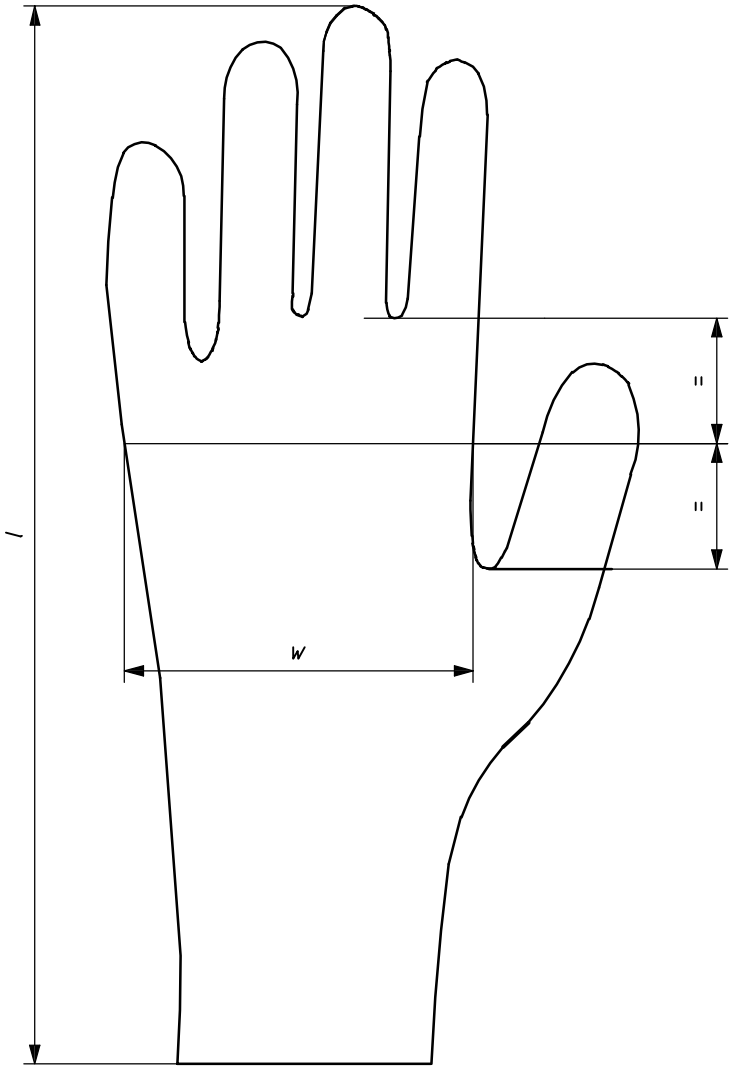
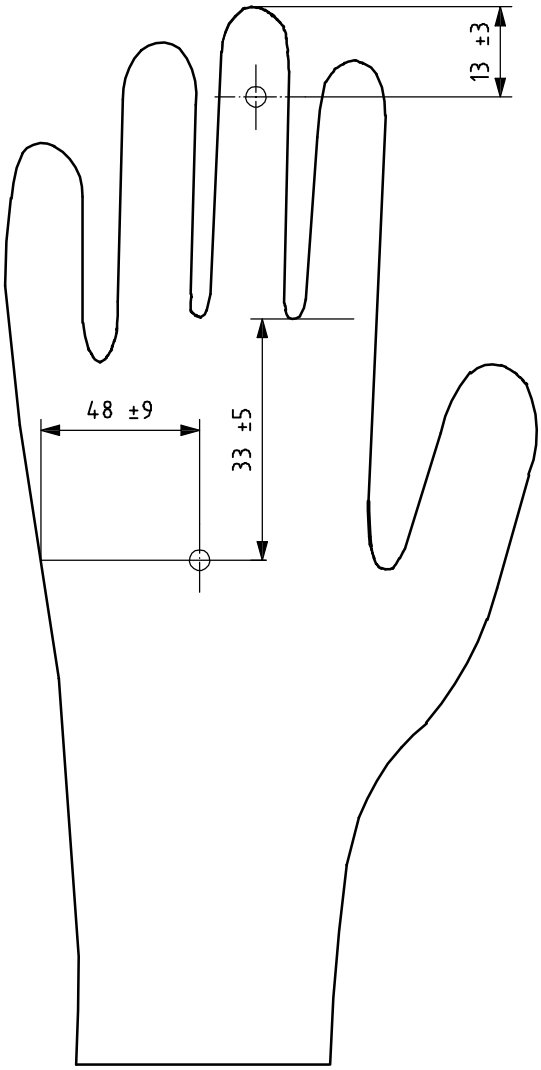


Figure 1 — Measurement points for the width and length of the glove

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 2) mm	Maximum thickness (at approximate centre of palm) mm
6 and below	$\leqslant$ 82	Extra small (X-S)	$\leqslant$ 80	220	Smooth area: 0,08 Textured area: 0,11	Smooth area: 2,00 Textured area: 2,03
6 1/2	83 $\pm$ 5	Small (S)	80 $\pm$ 10	220		
7	89 $\pm$ 5	Medium (M)	95 $\pm$ 10	230		
7 1/2	95 $\pm$ 5			230		
8	102 $\pm$ 6	Large (L)	110 $\pm$ 10	230		
8 1/2	109 $\pm$ 6			230		
9 and above	$\geqslant$ 110	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 the thickness of the glove

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 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.

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 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 6.3.2. The results shall comply with the requirements given in Table 3, using the inspection level and AQL given in Table 1.

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	7,0
Minimum elongation at break after accelerated ageing, %	500	400

6.4 Sterility

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

7 Packaging

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

8 Marking

8.1 General

The marking shall include a reference to this part of ISO 11193. Appropriate international symbols taken from ISO 15223 may be used for labelling in addition to the wording given below.

The language used for marking shall be as agreed upon between the interested parties.

8.2 Unit package

8.2.1 Sterile package

The wrapping for each unit package of an individual glove or pair of gloves shall be clearly marked with the following:

a) the name or trademark of the manufacturer or supplier;

b) the material used;

c) the words “TEXTURED” or “SMOOTH”, “PRE-POWDERED” or “POWDER-FREE” or words to that effect for the appropriate glove finish;

d) the size;

e) in the case of gloves that have been treated with any surface-dusting material, a warning note to the effect that surface powder should be aseptically removed prior to use;

f) the manufacturer's identifying lot number;

g) the words “DATE OF MANUFACTURE” or words to that effect, and the year in four digits and month of manufacture;

h) the words “STERILE UNLESS THIS PACKAGE IS OPENED OR DAMAGED”;

i) the words “FOR SINGLE USE” or words to that effect;

j) the words “EXAMINATION GLOVE” (or “EXAMINATION GLOVES”) or “EXAM GLOVE” (or “EXAM GLOVES”);

k) the words “PRODUCT IS MADE FROM NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTIONS” or words to that effect for type 1 gloves.

8.2.2 Non-sterile package

The package shall be clearly marked with the following:

a) the name or trademark of the manufacturer or supplier;

b) the material used;

c) the words “TEXTURED” or “SMOOTH”, “PRE-POWDERED” or “POWDER FREE” or words to that effect for the appropriate glove finish;

d) the size;

e) the manufacturer's identifying lot number;

f) the words “FOR SINGLE USE” or words to that effect;

g) the words “NON-STERILE”;

h) the words “EXAMINATION GLOVE” (or “EXAMINATION GLOVES”) or “EXAM GLOVE” (or “EXAM GLOVES”);

i) the words “DATE OF MANUFACTURE” or words to that effect, and the year in four digits and month of manufacture;

j) the words “PRODUCT IS MADE FROM NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTIONS” or words to that effect for type 1 gloves.

8.3 Multi-unit package

A multi-unit package is one containing a predetermined number of unit packs of the same glove size, intended to facilitate safe transport and storage. Multi-unit packages shall be marked in accordance with 8.2.1 or 8.2.2, with the approximate number of gloves and with the addition of instructions for storage.

Annex A
(normative)

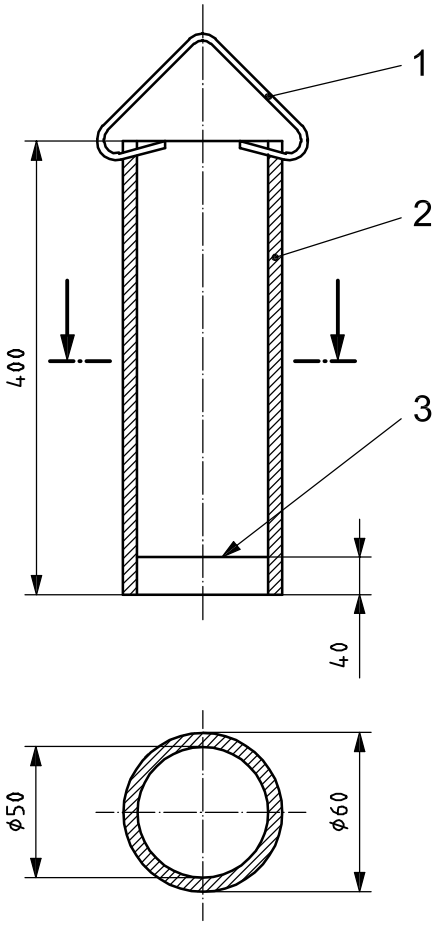
Test for watertightness

A.1 Apparatus

A.1.1 Circular hollow mandrel, of minimum external diameter 60 mm and adequate length to hold the glove and, with the glove attached, to accommodate 1 000 cm^3 of water. An example is given in Figure A.1.

NOTE A transparent circular hollow mandrel would be suitable.

Dimensions in millimetres



Key

1 hook
2 cylinder
3 score line on inside surface of wall

Figure A.1 — Mandrel

A.1.2 Holding device, designed to hold the glove in the vertical position when filled with water. An example is given in Figure A.2.

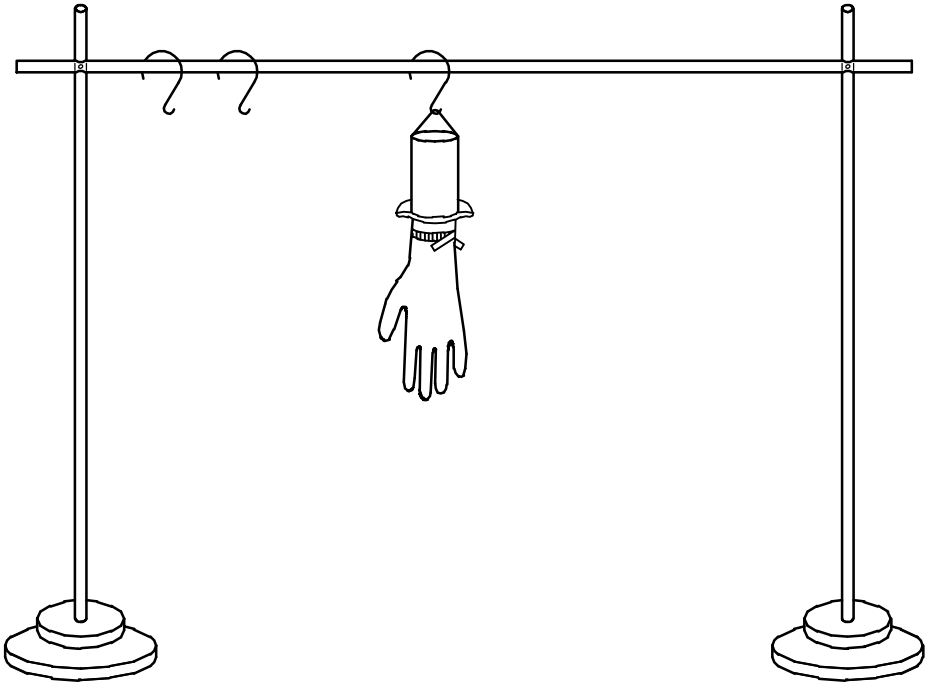


Figure A.2 — Holding device

A.1.3 Graduated cylinder, capacity at least 1 000 cm^3, or other dispensing apparatus capable of delivering 1 000 cm^3 at a time.

A.2 Procedure

Attach the glove to the circular hollow mandrel by a suitable device, e.g. an O-ring, so that the glove does not extend more than 40 mm over the mandrel.

Introduce 1 000 $cm^3 \pm 50$ cm^3 of water at a maximum temperature of 36 °C into the hollow mandrel. Remove water that has inadvertently splashed onto the outside of the glove. If the water does not rise to within 40 mm of the cuff end, raise the glove to ensure that the whole of the glove, excluding the part 40 mm from the cuff end, is tested. Note any leaks immediately evident. If the glove does not leak immediately, make a second observation for leaks 2 min to 4 min after pouring the water into the glove. Disregard leakage within 40 mm of the cuff end. To assist observation, the water may be coloured with a water-soluble dye.

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