INTERNATIONAL STANDARD

ISO 11193

First edition
1994-12-01

Single-use rubber examination gloves — Specification

Gants en caoutchouc pour examen non réutilisables — Spécifications

Reference number
ISO 11193:1994(E)

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.

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.

International Standard ISO 11193 was prepared by Technical Committee ISO/TC 45, *Rubber and rubber products*, Subcommittee SC 4, *Miscellaneous products*.

Annex A forms an integral part of this International Standard.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

Single-use rubber examination gloves — Specification

1 Scope

This International Standard 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.

This standard applies to single-use gloves that fit either hand, paired gloves and gloves by size. It covers gloves with smooth surfaces or with textured surfaces over part or all of the glove.

This standard does not apply to gloves made from plastic film either of a dipped or welded construction or as a substitute for gloves for use in surgical procedures.

This standard 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 and storage procedures are outside the scope of this International Standard.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

ISO 188:1982, *Rubber, vulcanized — Accelerated ageing or heat-resistance tests.*

ISO 2859-1:1989, *Sampling procedures for inspection by attributes — Part 1: Sampling plans indexed by acceptable quality level (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 7000:1989, *Graphical symbols for use on equipment — Index and synopsis.*

3 Materials

Gloves shall be manufactured from compounded natural or synthetic latex or compounded rubber solution. To facilitate donning the gloves, any surface treatment, lubricant or powder may be used. Any pigment used shall be safe. It is essential that substances used for surface treatment which are capable of being transferred are bio-absorbable.

NOTE 1 It is recognized that some individuals may, over a period of time, become sensitized to a particular rubber compound (allergenic reaction) and require gloves of an alternative formulation.

4 Design

The cuff shall fit closely without being constrictive. It shall not roll back or ruck whilst in use.

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 acceptable quality levels (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	S-4	2,5
Tensile strength 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 cuff of unused gloves, avoiding textured areas if possible.

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 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 1: a point approximately 15 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 measurements shall be made in that area using a single-wall thickness. The thickness of a single wall when measured as described in this subclause, using a test piece cut from the glove, shall be not less than 0,08 mm.

The nominal thickness values are not specified, but absolute values shall not fall below the minima.

6.2 Watertightness

When tested for watertightness as described in annex A, there shall be no leakage, using the inspection level and AQL given in table 1.

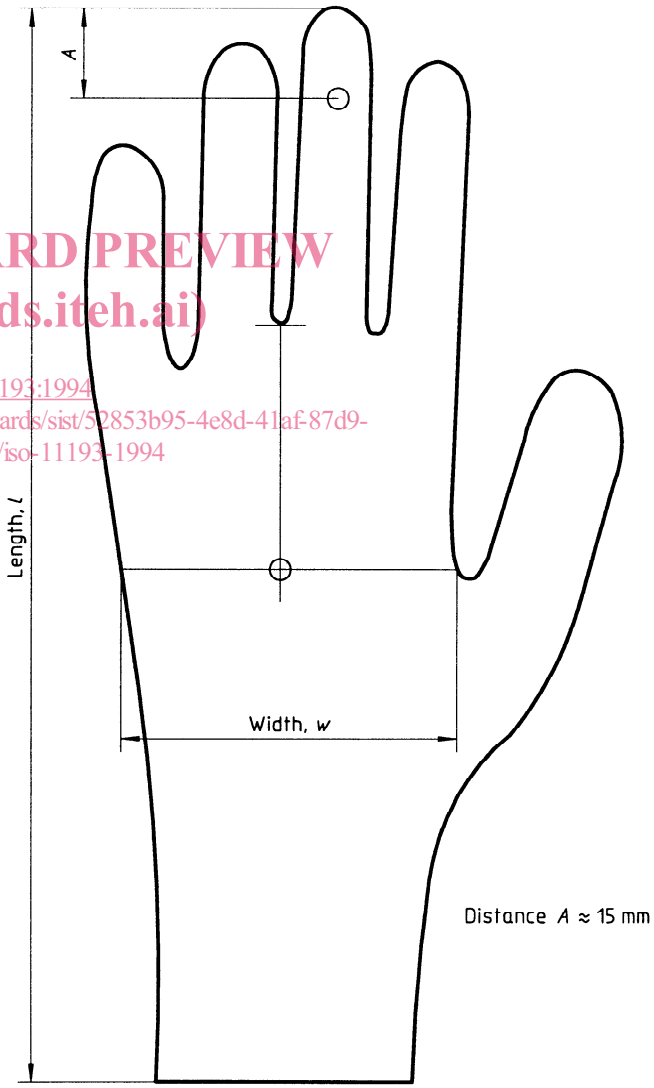

Figure 1 — Location of measurement points

Table 2 — Dimensions and tolerances

Dimension	Size, mm					Tolerance, mm
	Extra-small	Small	Medium	Large	Extra-large	
Palm width	70	80	95	110	120	± 10
Length	230 all sizes					min.
Thickness at palm and finger:	For all sizes:					
smooth area	0,08					min.
textured area	0,11					min.

6.3 Tensile properties

Requirements on tensile properties for quality control purposes apply to new gloves only. Tensile properties shall be measured in accordance with ISO 37, taking a minimum of three test pieces from each glove and using the median value as the test result.

6.3.1 Tensile strength and elongation at break before accelerated ageing

When determined in accordance with the method specified in ISO 37, using a type 1 or type 2 dumb-bell test piece, the tensile strength and elongation at break shall comply with the requirements given in table 3, using the inspection level and AQL given in table 1.

6.3.2 Tensile strength and elongation at break after accelerated ageing

After gloves packed in unit packages or gloves taken from bulk packages packed in paper wallets have been aged for 7 days at 70 °C ± 2 °C in air, in a normal oven, as described in ISO 188, test pieces cut from the gloves and tested as described in 6.3.1 shall comply with the requirements given in table 3, using the inspection level and AQL given in table 1.

Table 3 — Tensile properties

Property	Unit	Requirement[1)]
Minimum tensile strength before accelerated ageing	MPa	21
Minimum elongation at break before accelerated ageing	%	700
Minimum tensile strength after accelerated ageing	MPa	16
Minimum elongation at break after accelerated ageing	%	500

1) If it is necessary for the test piece to be taken from a textured portion, then the requirements shall be 10 % lower than those given in this table.

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 individually packed in unit packs or pairs as unit packs.

8 Marking

8.1 Unit package

8.1.1 Sterile package

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

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

b) the type of glove, material used and size;

c) 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;

d) the manufacturer's identifying lot number;

e) the month and year of manufacture;

f) the words "STERILE UNLESS THIS PACKAGE IS OPENED OR DAMAGED";

g) the words "FOR SINGLE USE".

8.1.2 Non-sterile package

The wrapping shall be clearly marked with the following:

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

b) the type of glove, material used and size;

c) the manufacturer's identifying lot number;

d) the words "FOR SINGLE USE";

e) the words "NON-STERILE".

NOTE 2 Symbol 1051 of ISO 7000:1989 may be used.

8.2 Multi-unit package

Multi-unit packages shall be marked in accordance with 8.1.1 or 8.1.2, with the addition of instructions for storage.

Annex A
(normative)

Test for watertightness

A.1 Apparatus

A.1.1 Circular hollow mandrel, of nominal external diameter 60 mm and adequate length (about 400 mm) to hold the glove and to accommodate with the attached glove 1 000 cm^3 of water. An example is given in figure A.1.

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.

A.1.3 Graduated cylinder, capacity 1 000 cm^3.

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 device. Note any leaks immediately evident. If the glove does not leak immediately, make a second observation for leaks 2 to 3 minutes after the addition of water to the glove. To assist observation, the water may be coloured with a water-soluble dye.

Dimensions in millimetres

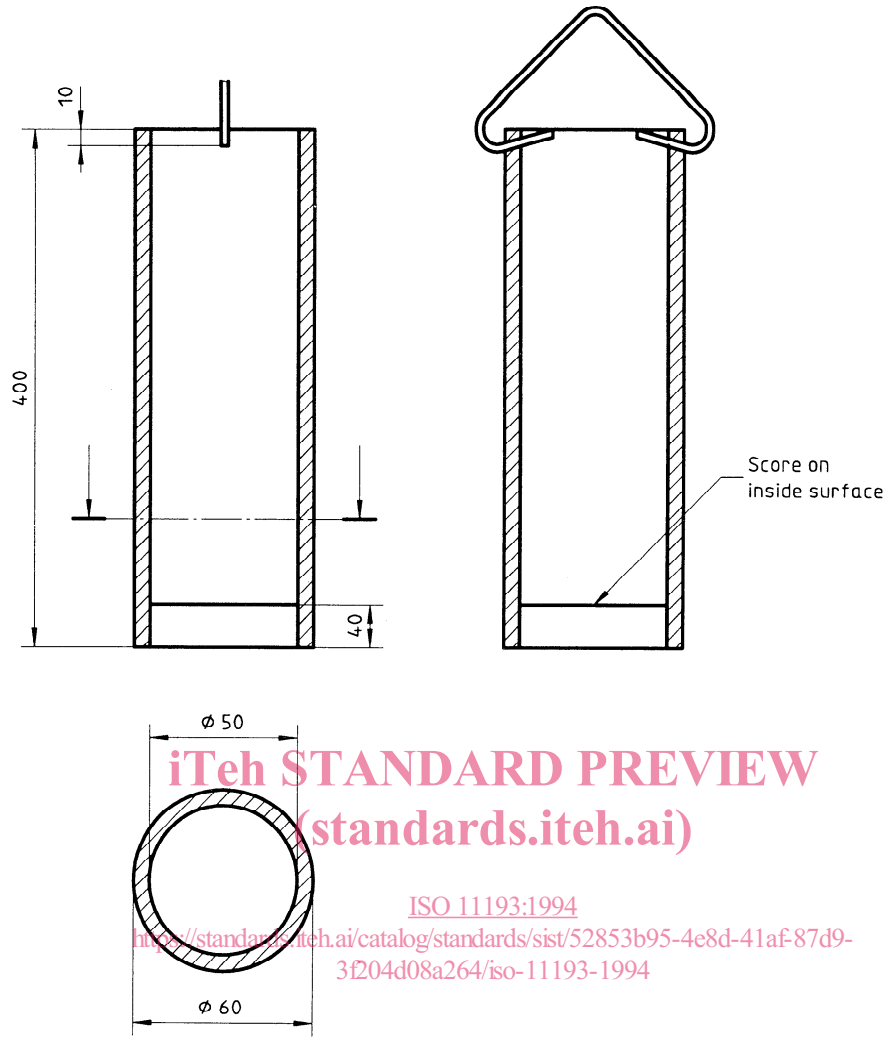

Figure A.1 — Mandrel

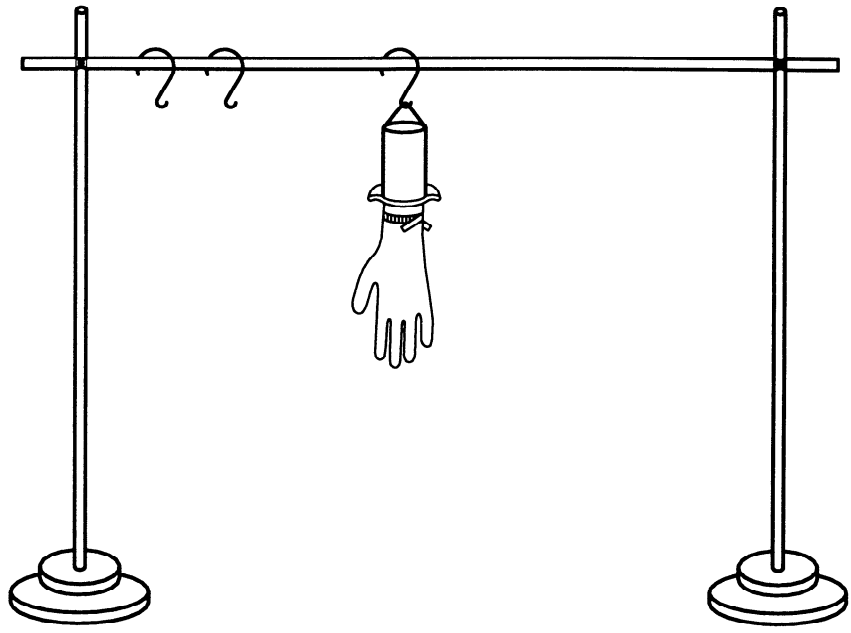

Figure A.2 — Holding device