INTERNATIONAL STANDARD

ISO 10282

Second edition
2002-09-15

Single-use sterile rubber surgical gloves — Specification

Gants en caoutchouc à usage chirurgical, stériles, non réutilisables — Spécifications

Reference number
ISO 10282:2002(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 3.

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

ISO 10282 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 10282:1994), which has been technically revised.

Annex A forms a normative part of this International Standard.

Single-use sterile rubber surgical gloves — Specification

1 Scope

This International Standard specifies requirements for packaged sterile rubber gloves intended for use in surgical procedures to protect the patient and the user from cross-contamination. It is applicable to single-use gloves that are worn once and then discarded. It does not apply to examination or procedure gloves. It covers gloves with smooth surfaces and gloves with textured surfaces over part or all of the glove.

This standard is intended as a reference for the performance and safety of rubber surgical gloves. The safe and proper usage of surgical gloves and sterilization procedures with subsequent handling, packaging and storage procedures are outside the scope of this International Standard.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard 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, design and finish, as given in 3.2 to 3.4.

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 Design

Two designs are classified:

a) gloves with straight fingers;

b) gloves with fingers curved in the palmar direction.

The glove shall be anatomically correct, with the thumb positioned towards the palmar surface of the index finger rather than lying flat. The fingers and thumb may be straight or curved in the palmar direction.

3.4 Finish

Four finishes are classified:

a) textured surface over part or all of the glove;

b) smooth surface;

c) powdered surface;

d) powder-free surface.

NOTE 1 Powdered gloves are gloves where a powder has been added as a part of the manufacturing process, generally to facilitate donning. Powder-free gloves are gloves which have been manufactured without the deliberate addition of powdered materials to facilitate donning.

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 editions of this International Standard.

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 International Standard, 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 acceptable 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	I	1,5
Force at break and elongation at break (before and after accelerated ageing) and force at 300 % elongation (before 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 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 $\pm$ 5 kPa, at each of the locations shown in Figure 2: a point 13 mm $\pm$ 3 mm from the extreme tip of the second finger, the approximate centre of the palm and a point 25 mm $\pm$ 5 mm from the cuff termination. 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 0,10 mm and 0,13 mm respectively.

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

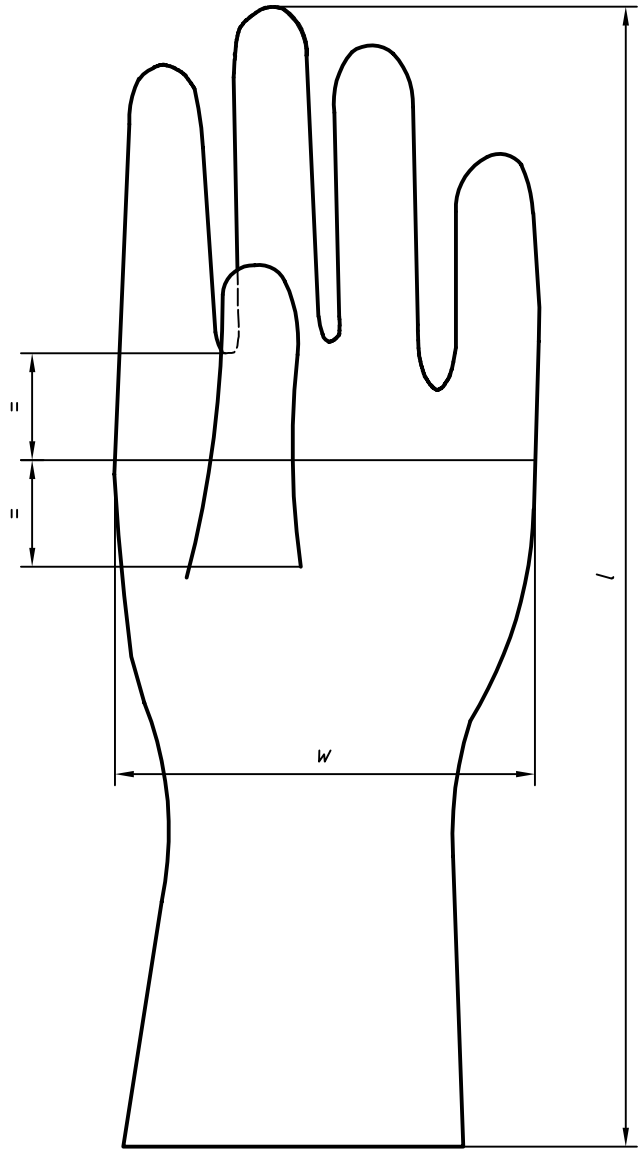
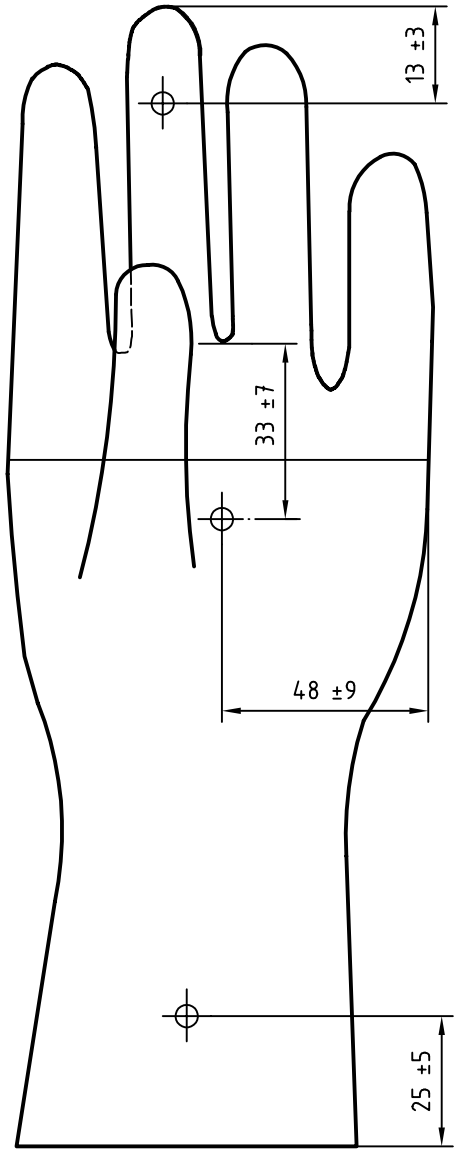


Figure 1 — Measurement points for width and length

Table 2 — Dimensions and tolerances

Size code	Width (dimension w, Figure 1) mm	Minimum length (dimension l, Figure 1) mm	Minimum thickness (at the locations shown in Figure 2) mm
5	67 ± 4	250	For all sizes: Smooth area: 0,10 Textured area: 0,13
5,5	72 ± 4	250	
6	77 ± 5	260	
6,5	83 ± 5	260	
7	89 ± 5	270	
7,5	95 ± 5	270	
8	102 ± 6	270	
8,5	108 ± 6	280	
9	114 ± 6	280	
9,5	121 ± 6	280	

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

6.2 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.

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, force at 300 % elongation and elongation at break 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	12,5	9,0
Minimum elongation at break before accelerated ageing, %	700	600
Maximum force required to produce 300 % elongation before accelerated ageing, N	2,0	3,0
Minimum force at break after accelerated ageing, N	9,5	9,0
Minimum elongation at break after accelerated ageing, %	550	500

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 the force at break and the elongation at break shall comply with the requirements given in Table 3, using the inspection level and AQL given in Table 1.

6.3.4 Force required to produce 300 % elongation

When determined in accordance with the method specified in ISO 37, using type 2 dumb-bell test pieces, the force required to produce an elongation of 300 % shall comply with the requirements given in Table 3, using the inspection level and AQL given in Table 1.

6.4 Sterility

Gloves shall be sterilized. The nature of the sterilization process shall be disclosed on request.

7 Packaging

Gloves shall be packaged in sequential two-layered packaging.

8 Marking

8.1 General

The marking shall include a reference to this International Standard. Appropriate international symbols taken from ISO 15223 may be used for labelling.

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

8.2 Inner package

Inner packages shall be clearly marked with the following:

a) the size;

b) the designation “left” or “L” or “right” or “R” on the package;

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 undertaking operative procedures.

8.3 Unit package

The outer wrapping for each unit 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 “STRAIGHT FINGERS” or “CURVED FINGERS” or words to that effect for the appropriate glove design;

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

e) the size;

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”;

j) the words “SURGICAL 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.

8.4 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 8.3 a), 8.3 b), 8.3 c), 8.3 d), 8.3 e), 8.3 f), 8.3 g), 8.3 i) and 8.3 j), with the words “xx pairs of surgical 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 It is useful if the mandrel is transparent.

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.

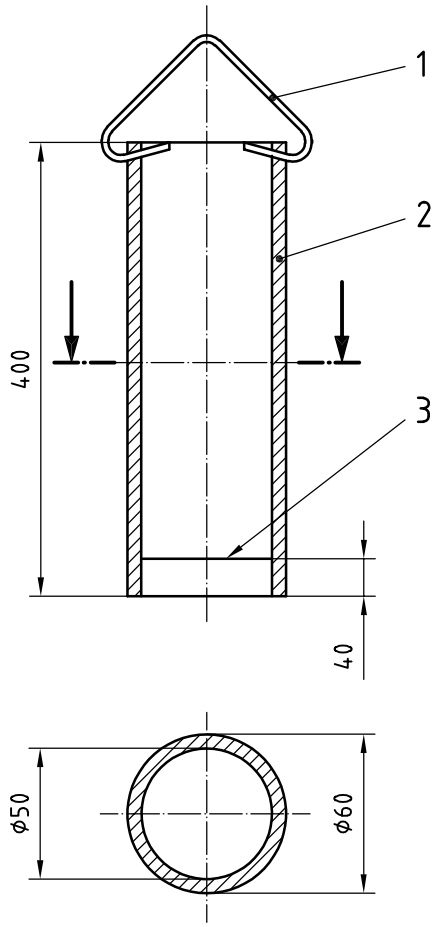
A.1.3 Graduated cylinder, capacity at least 1 000 cm^3 or other dispensing apparatus capable of delivering 1 000 cm^3 at a time.

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 device. Remove any water that has inadvertently splashed on to 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 to 4 minutes 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.

Dimensions in millimetres



Key

1 Hook
2 Cylinder
3 Score line on inside surface of wall

Figure A.1 — Mandrel

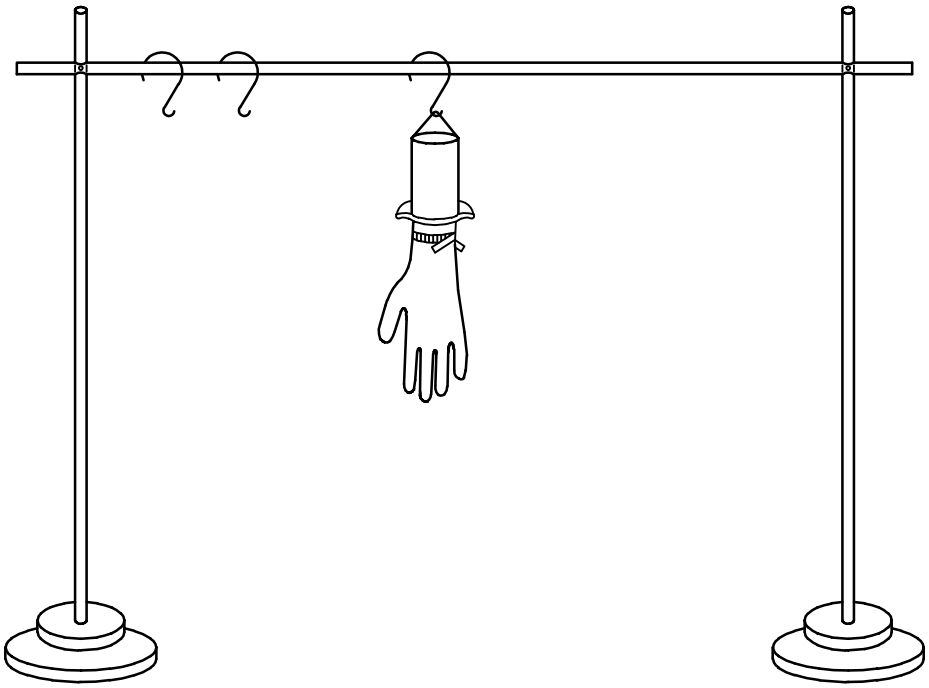


Figure A.2 — Holding device

ICS 11.140; 83.140.99

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