भारतीय मानक
Indian Standard

IS 13422 : 2024
ISO 10282 : 2023

एकल-उपयोग रोगाणुमुक्त रबड़ सर्जिकल दस्ताने — विशिष्टि

(पहला पुनरीक्षण)

Single-Use Sterile Rubber Surgical Gloves — Specification

(First Revision)

ICS 11.140; 83.140.99

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Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12

NATIONAL FOREWORD

This Indian Standard (First Revision) which is identical to ISO 10282 : 2023 'Single-use sterile rubber surgical gloves — Specification' issued by the International Organization for Standardization was adopted by Bureau of Indian Standards on the recommendation of the Hospital Equipment and Surgical Disposable Products Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1992 as IS 13422 'Disposable surgical rubber gloves — Specification'. This revision of this standard has been brought out to align it with the latest version of ISO 10282 : 2023.

The text of ISO standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 37 Rubber, vulcanized or thermoplastic — Determination of tensile stress-stain properties	IS 3400 (Part 1) : 2021/ISO 37 : 2017 Methods of test for vulcanized rubber: Part 1 Tensile stress-strain properties (*fourth revision*)	Identical
ISO 2859-1 Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	IS 2500 (Part 1) : 2000/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 (*third revision*)	Identical
ISO 23529 Rubber — General procedures for preparing and conditioning test pieces for physical test methods	IS 13867 : 2021/ISO 23529 : 2016 Rubber — General procedures for preparing and conditioning test pieces for physical test methods (*first revision*)	Identical

(*Continued on third cover*)

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Indian Standard

SINGLE-USE STERILE RUBBER SURGICAL GLOVES — SPECIFICATION

(First Revision)

1 Scope

This document specifies requirements for packaged sterile rubber gloves intended for use in surgical procedures to protect the patient and the user from cross-contamination.

This document is applicable to single-use gloves that are worn once and then discarded. It does not apply to examination or procedure gloves.

This document covers gloves with smooth surfaces and gloves with textured surfaces over part or the whole glove.

This document is intended to be 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 document.

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

For the purposes of this document, the following terms and definitions apply.

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

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

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

3.1
powdered glove
glove where a powder has been added as a part of the manufacturing process, generally to facilitate donning

3.2
powder-free glove
glove which has been manufactured without the deliberate addition of powdered materials to facilitate donning

Note 1 to entry: Powder-free is also referred to as “powderless”, “no powder” or “non-powdered” or other words to that effect.

3.3
lot
definite amount of some product, material or service, collected together

Note 1 to entry: An inspection lot may consist of several batches or parts of batches.

[SOURCE: ISO 2859-1:1999, 3.1.13]

3.4
lot size
number of items in a lot

[SOURCE: ISO 2859-1:1999, 3.1.14]

3.5
inspection level
index of the relative amount of inspection of an acceptance sampling scheme, chosen in advance, and relating the sample size to the lot size

[SOURCE: ISO 3534-2:2006, 4.3.5, modified — Notes 1 and 2 to entry have been deleted.]

3.6
acceptance quality limit
AQL
quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling

[SOURCE: ISO 2859-1:1999, 3.1.26, modified — Notes 1 and 2 to entry have been deleted.]

3.7
force at break
tensile stress recorded at the moment of rupture

[SOURCE: ISO 37:2017, 3.4, modified — the term has been modified from "tensile strength at break".]

3.8
elongation at break
tensile strain in the test length at breaking point

[SOURCE: ISO 37:2017, 3.5, modified — the symbol "E_b" and Note 1 to entry have been deleted.]

3.9
force at a given elongation
tensile stress in the test length required to produce a given elongation

[SOURCE: ISO 37:2017, 3.7, modified — "stress" has been changed to "force" in the term, and "S_e" and Note 1 to entry have been deleted.]

4 Classification

4.1 General

Gloves are classified by material, design and finish, as given in 4.2 to 4.4.

4.2 Material

Two materials are classified:

a) type 1: gloves made primarily from natural rubber latex;

b) type 2: gloves made primarily from nitrile rubber latex, isoprene latex, polychloroprene rubber latex, solution styrene-butadiene rubber (S-SBR) latex, emulsion styrene-butadiene rubber (E-SBR) latex or thermoplastic elastomer solution.

4.3 Design

4.3.1 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 can be straight or curved in the palmar direction.

4.3.2 Cuff termination of the glove can be:

a) cut;

b) rolled rim.

4.4 Finish

Four finishes are classified:

a) textured surface over part or the entire glove;

b) smooth surface;

c) powdered surface;

NOTE 1 Powdered gloves have a maximum powder limit of 15 mg/dm^2.

NOTE 2 The test method to measure the powder on the surface of the glove is given in ISO 21171:2006.

d) powder-free surface.

NOTE 1 Powder-free gloves have a maximum of 2,0 mg powder residue per glove.

NOTE 2 The test method to measure the powder on the surface of the glove is given in ISO 21171:2006.

5 Materials

5.1 Gloves shall be manufactured from compounded natural rubber or nitrile rubber or isoprene rubber or polychloroprene rubber latex, or compounded styrene-butadiene rubber or thermoplastic elastomer solution, or compounded styrene-butadiene rubber emulsion.

5.2 To facilitate donning the gloves, any surface treatment, lubricant, powder or polymer coating may be used subject to compliance with the ISO 10993 series.

5.3 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.

5.4 Gloves shall comply with the relevant part(s) of the ISO 10993 series. The manufacturer shall make available to the purchaser, on request, data to support compliance with these requirements.

NOTE 1 Other suitable polymeric material can be included in future editions of this document.

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.

6 Sampling and selection of test pieces

6.1 Sampling

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	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

6.2 Selection of test pieces

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

7 Requirements

7.1 Dimensions

The dimensions of gloves shall be measured in accordance with Annex A. 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.

Table 2 — Dimensions and tolerances

Dimensions in millimetres

Size code	Width (dimension *W*, Figure A.1)	Minimum length (dimension *L*, Figure A.1)	Minimum thickness (at the locations shown in Figure A.1) and
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	

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

7.2 Watertightness

When gloves are tested for watertightness in accordance with Annex B, 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 the 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, 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

7.3.3 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.

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.

7.3.4 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.

7.4 Sterility

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

8 Packaging

The packaging system should provide physical protection and integrity.

9 Marking

9.1 General

The marking shall include a reference to this document. Appropriate international symbols taken from ISO 15223-1 and ISO 15223-2 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.

In the case of gloves that have been treated with any surface-dusting material, a warning note shall be clearly marked on the inner package and/or unit package; to the effect that surface powder should be aseptically removed prior to undertaking operative procedures.

9.2 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.

9.3 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", "POWDERED" or "POWDER-FREE" or words to that effect for the appropriate glove finish;

e) the size;

f) 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 expiration date;

l) the words “Product is made from natural rubber latex which can cause allergic reactions” or words to that effect for type 1 gloves.

9.4 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 9.3 a), 9.3 b), 9.3 c), 9.3 d), 9.3 e), 9.3 f), 9.3 g), 9.3 i), 9.3 j) and 9.3 k), with the words “xx pairs of surgical gloves” and with the addition of instructions for storage.

Annex A
(normative)

Measurement of dimensions (width, length and thickness)

When measured at the points shown in Figure A.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 can be taken by hanging the glove on a suitable mandrel with a tip radius of 5 mm.

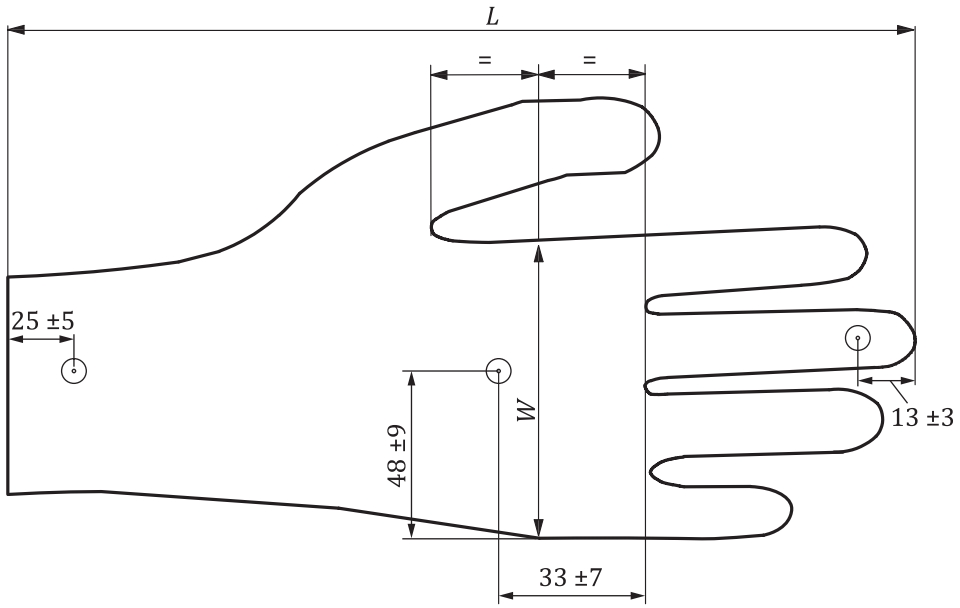
The measurement of width shall be at the midpoint between the base of the index finger and the base of the thumb. The width measurement shall be made with the glove placed on a flat surface.

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 A.1: a point 13 mm ± 3 mm from the extreme tip of the second finger, the approximate centre of the palm, and a point 25 mm ± 5 mm from the cuff termination.

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 7.1 shall not be less than 0,10 mm and 0,13 mm respectively.

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

Dimensions in millimetres



Key

L length

W width

Figure A.1 — Measurement points for width and length

Annex B
(normative)

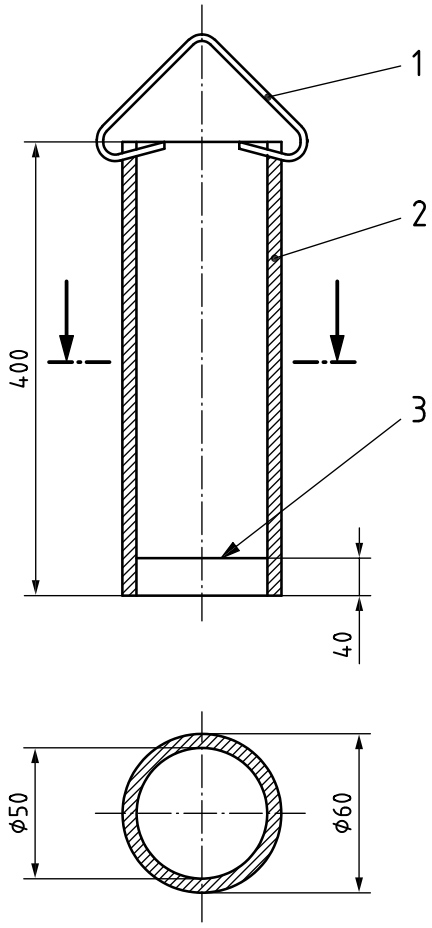
Test method for watertightness

B.1 Apparatus

B.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 B.1.

NOTE It is useful if the mandrel is transparent.

Dimensions in millimetres



Key

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

Figure B.1 — Mandrel

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

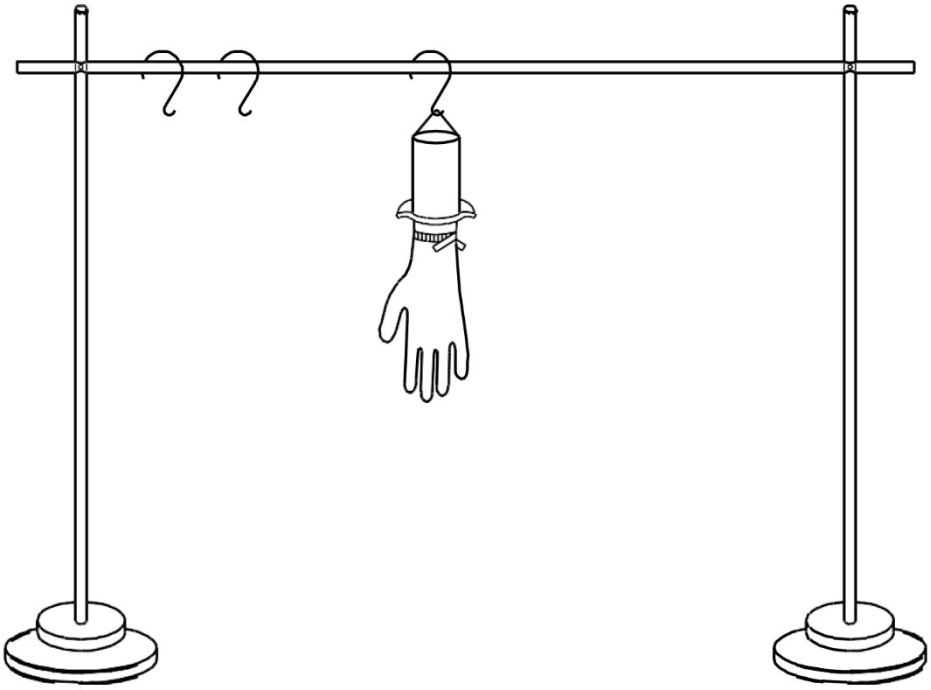


Figure B.2 — Holding device

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

B.2 Procedure

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

Introduce 1 000 cm^3 ± 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 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 can be coloured with a water-soluble dye.

Bibliography

[1] ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

[2] ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

[3] ISO 21171:2006, *Medical gloves — Determination of removable surface powder*

NATIONAL ANNEX C

(National Foreword)

C-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standard Act*, 2016 and the Rules and Regulations framed there under, and the product(s) may be marked with the Standard Mark.

(*Continued from second cover*)

The Committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decided that they are acceptable for use in conjunction with this standard.

International Standard	*Title*
ISO 188	Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests
ISO 10993 (all parts)	Biological evaluation of medical devices

This standard also makes a reference to the BIS certification marking of the product, details of which is given in National Annex C.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

Bureau of Indian Standards

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the website-www.bis.gov.in or www.standardsbis.in.

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