भारतीय मानक

Indian Standard

IS 15354 (Part 1) : 2023
ISO 11193-1 : 2020

एक बार उपयोग के लिए चिकित्सा परीक्षण दस्ताने

भाग 1 रबर लेटेक्स अथवा रबर घोल से बने दस्ताने — विशिष्टि

(दूसरा पुनरीक्षण)

Single Use Medical Examination Gloves

Part 1 Gloves Made from Rubber Latex or Rubber Solution — Specification

(Second Revision)

ICS 83.140.99; 11.140

भारतीय मानक ब्यूरो
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November 2023 **Price Group 8**

Hospital Equipment and Surgical Disposal Sectional Committee, MHD 12

NATIONAL FOREWORD

This Indian Standard (Part 1) (Second Revision) which is identical with ISO 11193-1 : 2020 ‘Single-use medical examination gloves — Part 1: Specification for gloves made from rubber latex or rubber solution’ issued by the International Organization for Standardization was adopted by Bureau of Indian Standards on the recommendation of the Hospital Equipment and Surgical Disposal Sectional Committee and after approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 2003 which was identical with ISO 11193 : 1994 ‘Single-use rubber examination gloves Specification’. Subsequently on revision of ISO 11193 : 1994 into two parts, IS 15354 : 2003 was also revised in two parts. First revision of this Standard has been undertaken with a view to align its requirements with the corresponding ISO 11193-1 : 2008. Thereafter, the second revision of this standard has been undertaken to align it with the latest version of ISO 11193-1 : 2020.

The text of ISO standard may be approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in the 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, thecurrent practice is to use a point (.) as the decimal marker.

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

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 37 Rubber vulcanized or thermoplastic — Determination of tensile stress-strain properties	IS 3400 (Part 1) : 2021/ISO 37 : 2017 Methods of test for vulcanized rubber: Part 1 Tensile stress-strain properties	Identical
ISO 188 Rubber vulcanized or thermoplastic — Accelerated ageing and heat resistance tests	IS 3400 (Part 4) : 2012/ISO 188 : 2011 Methods of test for vulcanized rubber: Part 4 Accelerated ageing and heat resistance (*third revision*)	Identical
ISO 2859-1 Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) forlot-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	Identical
ISO 10993-2 Biological evaluation of medical devices — Part 2: Animal welfare requirements	IS/ISO 10993-2 : 2006 Biological evaluation of medical devices: Part 2 Animal welfare requirements (*first revision*)	Identical

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 10993-3 Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	IS/ISO 10993-3 : 2014 Biological evaluation of medical devices: Part 3 Tests for genotoxicity, carcinogenicity and reproductive (*first revision*)	Identical
ISO 10993-4 Biological evaluation of medical devices - Part 4 Selection of tests for interactions with blood	IS/ISO 10993-4 : 2017 Biological evaluation of medical devices: Part 14 Selection of tests for interactions with blood	Identical
ISO 10993-5 Biological Evaluation of medical devices — Part 5 Tests for in vitro cytotoxicity	IS/ISO 10993-5 : 2009 Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity	Identical
ISO 10993-6 Biological evaluation of medical devices — Part 6: Tests for local effects after implantation	IS/ISO 10993-6 : 2016 Biological evaluation of medical devices: Part 6 Tests for local effects after implantation	Identical
ISO 10993-7 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	IS/ISO 10993-7 : 2018 Biological evaluation of medical devices: Part 7 Ethylene oxide sterilization residuals	Identical
ISO 10993-9 Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation product	IS/ISO 10993-9 : 2009 Biological evaluation of medical devices: Part 9 Framework for identification and quantification of potential degradation product	Identical
ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	IS/ISO 10993-10 : 2010 Biological evaluation of medical devices: Part 10 Tests for Irritation and skin sensitization	Identical
ISO 10993-11 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	ISO 10993-11 : 2017 Biological evaluation of medical devices: Part 11 Tests for systemic toxicity	Identical
ISO 10993-12 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials	IS/ISO 10993-12 : 2021 Biological evaluation of medical devices: Part 12 Sample preparation and reference materials	Identical
ISO 10993-13 Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymericmedical devices	IS/ISO 10993-13 : 2010 Biological evaluation of medical devices: Part 13 Identification and quantification of degradation products from polymericmedical devices	Identical

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 10993-14 Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics	IS/ISO 10993-14 : 2001 Biological evaluation of medical devices: Part 14 Identification and quantification of degradation products from ceramics	Identical
ISO 10993-15 Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys	ISO 10993-15 : 2000 Biological evaluation of medical devices: Part 15 Identification and quantification of degradation products from metals and alloys	Identical
ISO 10993-16 Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables	IS/ISO 10993-16 : 2017 Biological evaluation of medical devices: Part 16 Toxicokinetic study design for degradationproducts and leachables	Identical
ISO 10993-17 Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances	IS/ISO 10993-17 : 2002 Biological evaluation of medical devices: Part 17 Establishment of allowable limits for leachable substances	Identical
ISO 10993-18 Biological evaluation of medical devices — Part 18: Chemical characterization of materials	IS/ISO 10993-18 : 2020 Biological evaluation of medical devices: Part 18 Chemical characterization of medical device materials within a risk management process	Identical
ISO/TS 10993-19 Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials	IS/ISO/TS 10993-19 : 2006 Part 19 Physico-chemical, morphological and topographical characterization of materials	Identical
ISO/TS 10993-20 Biological evaluation of medical devices — Part 20: Principles and methods for immunotoxicology testing of medical devices	IS/ISO/TS 10993-20 : 2006 Biological evaluation of medical devices: Part 20 Principles and methods for immunotoxicology testing of medical devices	Identical
ISO/TR 10993-22 : 2017 Biological evaluation of medical devices — Part 22: Guidance on nanomaterials	IS/ISO/TR 10993-22 : 2017 Biological evaluation of medical devices: Part 22 Guidance on nanomaterials	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

The technical committee has reviewed the provisions of the following International Standard referred in this draft standard proposed to be adopted and has decided that it is acceptable for usein conjunction with this standard:

International Standard/ Other Publication	*Title*
ISO 10993-1	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO/TR 10993-33	Biological evaluation of medical devices Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3

The standard also makes a reference to the BIS Certification Marking of the product. Details of which are given in National Annex B.

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.

Contents

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Indian Standard

SINGLE USE MEDICAL EXAMINATION GLOVES

PART 1 SPECIFICATION FOR GLOVES MADE FROM RUBBER LATEX OR RUBBER SOLUTION

(Second Revision)

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.

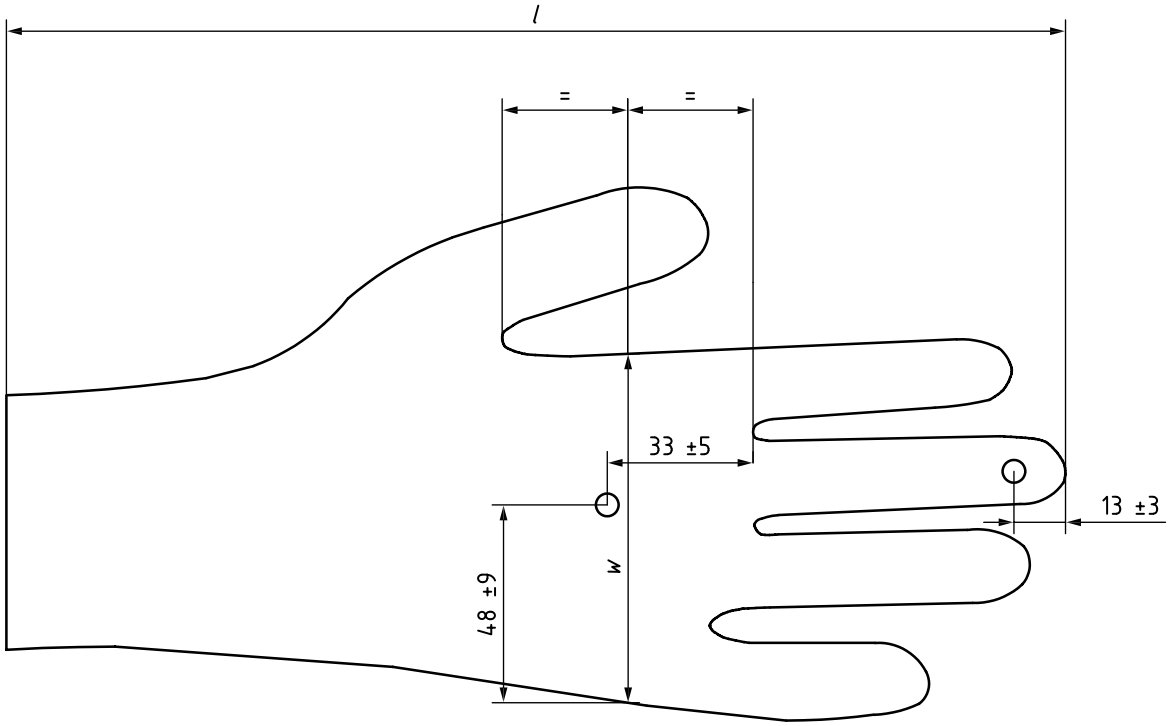
The thickness of the double wall of an intact glove shall be measured in accordance with ISO 23529, with a pressure on the foot of 22 kPa ± 5 kPa, at each of the locations shown in Figure 1: at a point 13 mm ± 3 mm from the extreme tip of the second finger and at the approximate centre of the palm. The 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 aging shall be conducted and the tensile properties need only conform to the "after accelerated aging" 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.

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.

9.2 Unit package

9.2.1 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”, “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.

9.2.2 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”, “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.

9.3 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 9.2.1 or 9.2.2, with the approximate number of gloves and with the addition of instructions for storage.

Annex A
(normative)

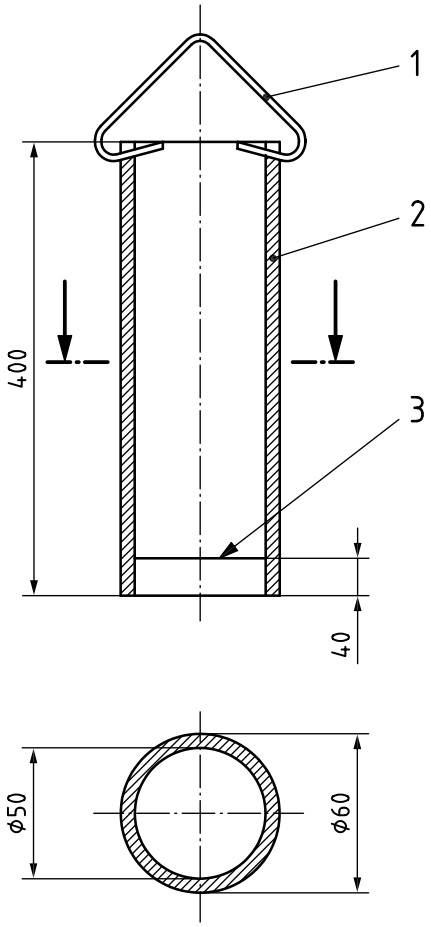
Test method for watertightness

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.

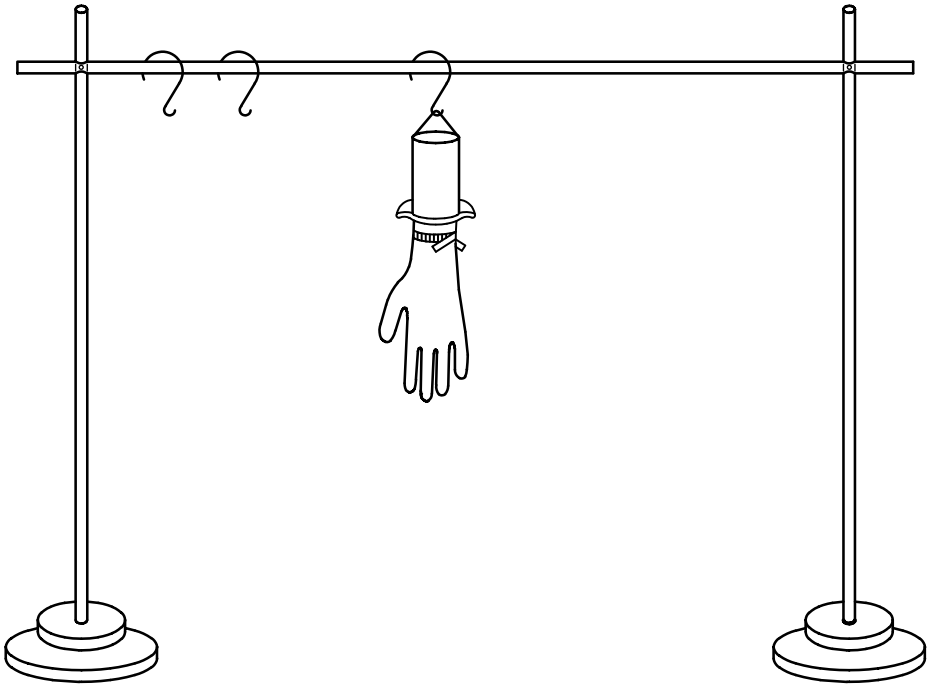


Figure A.2 — Holding device

A.1.3 Graduated cylinder, capacity at least 1 000 cm^3, or other dispensing device 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 ± 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.

Bibliography

[1] ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

[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*

NATIONAL ANNEX B

(*National Foreword*)

B-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 Standards Act,* 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act*, 2016 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

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

This Indian Standard has been developed from Doc No.: MHD 12 (17148).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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Published by BIS, New Delhi