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REAFFIRMED

Indian Standard (Reaffirmed 2017)

2006

SURGICAL RUBBER GLOVES — SPECIFICATION (*First Revision*)

भारतीय मानक

बीरा-फाड़ी के लिए रबड़ के बस्ताने — विशिष्ट

(पहला पुनरीक्षण)

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BHADUR SHAH ZAFAR MARG
NEW DELHI 110002

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Price Group 3

Rubber Products Sectional Committee, PCDC 13

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards on 15 April 1989, after the draft finalized by the Rubber Products Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

This standard was first published in 1967 and only sizes 6, 6½, 7, 7½ and 8 were covered, as the data for other sizes was not available. Through this revision, sizes 5½, 8½, 9 and 9½ have also been included and only critical dimensions have been given. Care has also been taken to introduce a performance test along with critical dimensional and physical tests, which are expected to ensure reasonable performance for their use after repeated sterilization.

In the preparation of this standard, considerable assistance has been derived from BS 4005 : 1984 'Single use, sterilized surgical rubber gloves', issued by the British Standards Institution, UK.

This standard contains clauses 4.1.1 and 5.1 which call for agreement between the purchaser and the supplier.

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 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

AMENDMENT NO. 2 OCTOBER 1997
TO
IS 4148 : 1989 SURGICAL RUBBER
GLOVES — SPECIFICATION
(*First Revision*)

[*Page 2, Table 1, Sl No. (iii), last column 'Distance*(mm)'*] — Substitute
'260' for '270'.

(PCD 13)

Reprography Unit, BIS, New Delhi, India

**AMENDMENT NO. 3 DECEMBER 2009
TO
IS 4148 : 1989 SURGICAL RUBBER GLOVES —
SPECIFICATION**

(First Revision)

(Page 2, clause 5.2) — Insert the following new clause at the end:

‘5.2.1 BIS Certification Marking

The product may also be marked with the Standard Mark.

5.2.1.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.’

(PCD 13)

Reprography Unit, BIS, New Delhi, India

Indian Standard

SURGICAL RUBBER GLOVES—SPECIFICATION

(First Revision)

1 SCOPE

1.1 This standard prescribes the requirements and methods of sampling and test for surgical rubber gloves of sizes 5½, 6, 6½, 7, 7½, 8, 8½, 9 and 9½.

2 REFERENCES

2.1 The following Indian Standards are necessary adjuncts to this standard:

IS No.	Title
IS 196 : 1966	Atmospheric conditions for testing (<i>first revision</i>)
IS 3400	Methods of test for vulcanized rubbers
Part 1 : 1987	Tensile stress-strain properties (<i>second revision</i>)
Part 4 : 1987	Accelerated ageing (<i>second revision</i>)
IS 7503	Glossary of terms used in rubber industry
Part 1 : 1988	Basic terms (<i>first revision</i>)
Part 2 : 1988	Definitions of additives (<i>first revision</i>)
Part 3 : 1988	Definitions relating to properties and testing (<i>first revision</i>)
Part 4 : 1988	Definitions relating to processing (<i>first revision</i>)

3 TERMINOLOGY

3.1 For the purpose of this standard, the definitions given in IS 7503 (Parts 1 to 4) : 1988 shall apply.

4 REQUIREMENTS

4.1 Manufacture

4.1.1 The gloves shall be made by the dipping process using latex. The finish of the outer surface shall be rough or smooth as agreed to between the purchaser and the supplier. The gloves shall be transparent or translucent. No colouring ingredients shall be used.

4.1.2 The gloves shall not contain any ingredient known to be harmful either to the wearer or to persons they may come in contact with.

4.1.3 The gloves shall be provided with a bead of not more than 3.00 mm and shall have a rolled wrist.

4.1.4 The gloves shall be free from visible imperfections.

4.2 Dimensions

When measured as described in Annex A, the dimensions of the glove shown in Fig. 1A and 1B shall be as specified in Table 1.

4.3 Thickness

The thickness of rubber shall be 0.24 ± 0.06 mm when measured with a dead weight dial type gauge, graduated to read directly to 0.02 mm, the foot of which exerts a pressure of 20 kPa on the rubber.

4.4 Physical Properties

4.4.1 Tensile Strength and Elongation at Break

The tensile strength and elongation at break for the rubber of the glove when tested as prescribed under 7.3 shall be as follows:

- a) Tensile strength, MPa*, *Min* : 18
- b) Elongation at break, percent, *Min* : 700

4.4.2 Accelerated Ageing

The glove or suitable portion of glove, when subjected to accelerated ageing at a temperature of $70 \pm 1^\circ\text{C}$ for 240 h (*see* 7.4) shall have tensile strength and elongation at break as follows:

- a) Tensile strength after ageing, MPa, *Min* : 15.5
- b) Elongation at break after ageing, percent, *Min* : 630

4.4.3 Heat Ageing in Autoclave (Autoclave Test)

Tensile strength and elongation at break of the sample subjected to autoclave test as prescribed in 7.5 shall be as follows:

- a) Tensile strength after autoclaving, MPa, *Min* : 13.5
- b) Elongation at break after autoclaving, percent, *Min* : 560

4.4.4 Tension Set

The tension set shall not exceed 10 percent when tested according to the method prescribed in 7.6.

4.5 pH of Aqueous Extract

The aqueous extract from rubber (*see* 7.7) shall have pH between 6 to 8.

*1 MPa = 10.2 kgf/cm².

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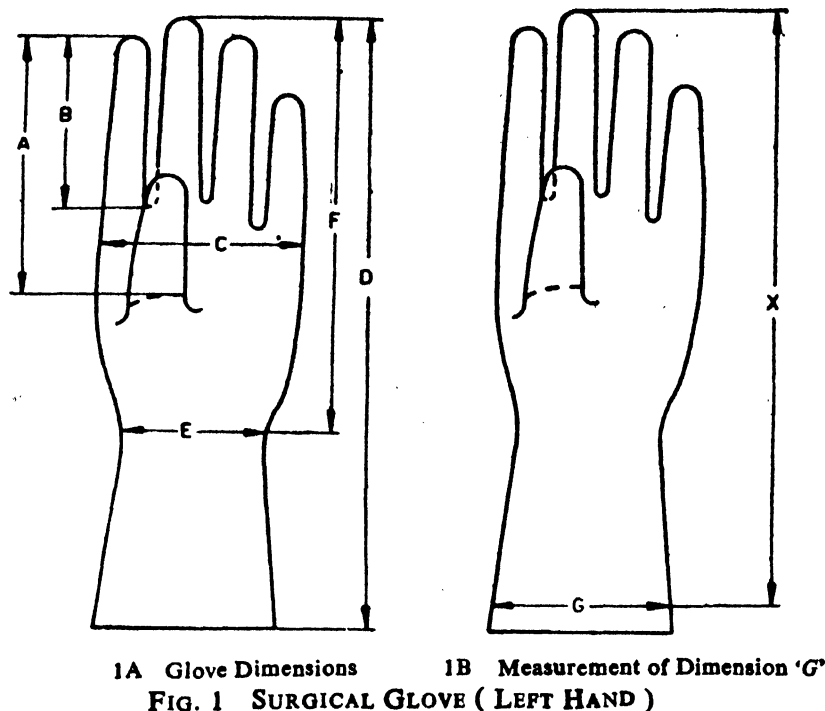


Table 1 Dimensions
(Clauses 4.2 and A-2.6)

Sl No.	Size No.	Dimensions (mm)						Distance* (mm)	
		A	B	C	D, Min	E	F, Min		
i)	5½	98±6	58±4.5	75±3	250	60±3	170	80±5	250
ii)	6	105±6	60±4.5	80±4	260	65±3	175	85±5	260
iii)	6½	110±6	62±4.5	85±4	260	70±3	180	90±5	270
iv)	7	115±6	65±4.5	93±4	270	75±3	185	95±5	270
v)	7½	120±6	69±4.5	98±5	270	80±3	190	100±5	270
vi)	8	120±6	74±4.5	103±5	270	85±3	195	105±5	270
vii)	8½	125±6	78±4.5	108±5	280	90±3	200	110±5	280
viii)	9	129±6	82±4.5	115±6	280	95±3	200	115±5	280
ix)	9½	133±6	85±4.5	120±6	280	100±3	200	120±5	280

*This distance defines the position at which dimension G is measured.

5 PACKING AND MARKING

5.1 Packing

The gloves shall be packed as agreed to between the purchaser and the supplier.

NOTE — The gloves shall be stored in a cool and dark place since they tend to deteriorate under warm conditions.

5.2 Marking

Each glove shall be legibly marked with the following particulars:

- a) Manufacturer's name or trade-mark, if any;
- b) Size of the glove; and
- c) Month and year of manufacture.

6 SAMPLING AND CRITERIA FOR CONFORMITY

6.1 For the purpose of ascertaining the conformity of the gloves in a consignment to this specification, the scale of sampling and criteria for conformity shall be as prescribed in Annex B.

7 TEST METHODS

7.1 Standard Atmospheric Conditions for Physical Tests

The test specimens shall be conditioned to a moisture equilibrium in an atmosphere of 65 ± 5 percent relative humidity and 27 ± 2°C temperature (see IS 196 : 1966) and if possible, tested in that atmosphere or soon after removal from the atmosphere.

7.2 Preparation of Sample

For tensile strength and elongation at break, carry out all the tests on the material obtained from a smooth portion of a glove. Use four dumb-bell test pieces for each test. Cut the dumb-bell in such a way so that the test length is parallel to the length of the glove. For accelerated ageing and autoclave test, take representative sample of glove as such or a suitable test piece cut from the glove.

7.3 Tensile Strength and Elongation at Break

Test the material in accordance with the method prescribed in IS 3400 (Part 1): 1987 using universal testing machine.

7.4 Accelerated Ageing

Age the material in an air-oven at a temperature of $70 \pm 1^\circ\text{C}$ for 240 h in accordance with the method prescribed in IS 3400 (Part 4): 1987. Calculate the depreciation in the values of the tensile strength and elongation at break as percentage of the original values.

7.5 Autoclave Test

Sterilize the material in steam under a pressure of 1.00 kgf/cm^2 for 20 minutes (115 to 120°C). Repeat the sterilization five times with 20-minute interval between the successive treatments. At the end of six successive treatments, cool the sample, condition in standard atmosphere (see 7.1) and subject it to tensile strength and elongation at break as prescribed in IS 3400 (Part 4): 1987. Calculate the depreciation in the values of tensile strength and elongation at break as percentage of the original values.

NOTE — Cut specimens of the glove shall be wrapped in cotton cloth in order to avoid it coming in contact with metallic parts.

7.6 Tension Test

7.6.1 Apparatus

Any suitable apparatus capable of subjecting test pieces to constant elongation may be used. Care should be taken to ensure that the test piece does not slowly creep out of the grips.

7.6.2 Test Temperature

The test shall be carried out at $27 \pm 2^\circ\text{C}$.

7.6.3 Procedure

Stamp reference marks 50 mm apart on a parallel sided test piece 6 mm wide, cut longitudinally. Fix it in the apparatus and stretch it so that the distance between the reference lines is increased to 250 mm. Hold the test piece in this position for 10 minutes and then release, allow to lie on a smooth flat surface for 10 minutes and then measure the distance between the reference lines. Note the increase in this distance and calculate as percentage of the original length.

7.7 pH of Aqueous Extract

7.7.1 Preparation of Aqueous Extract

Weigh 10 g of the sample, cut into small pieces 3 mm square into a chemically resistant glass flask and add 300 ml of water. Fit the flask with a water-cooled reflux condenser with a ground glass connection and heat the water to boiling point. Continue boiling for half an hour. Detach the flask from the condenser and cover immediately to prevent any possible contamination and cool the contents to room temperature.

7.7.2 Measure the pH of the aqueous extract.

ANNEX A (Clause 4.2)

METHOD FOR MEASUREMENT OF GLOVE DIMENSIONS

A-1 APPARATUS

A-1.1 Rule, graduated in mm.

A-1.2 Measuring Device (see Fig. 2)

It shall consist of a rule graduated in mm and mounted vertically. For measurements on straight fingered gloves, the rule shall be straight for curved finger gloves, the upper part of the rule shall be formed to the approximate curve of the index and middle fingers of the glove to be measured. For ease of reading, the scale shall be marked in black and the rule shall be opaque, white or clear, depending on whether front or rear illumination is preferred.

A-2 PROCEDURE

A-2.1 Dimensions A and B

Place the index finger of the glove over the measuring device (see A-1.2) with the glove freely suspended in a relaxed position and free from folds or creases.

A-2.1.1 Taking care not to stretch the glove, gently bend the thumb forward to form a right angle with the index finger and the plane of the face of the rule, measure the distance from the tip of the index finger to the thumb/index finger crotch (dimension A). For greater ease of measurement, the rule may be angled backwards slightly so that the front of the glove is in contact with the rule.

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A-2.1.2 Measure the distance from the tip of the index finger to the index/middle finger crotch (dimension *B*) by gently bending the middle finger away from the index finger to form a right angle. For greater ease of measurement, the rule may be angled backwards slightly so that the front of the index finger is in contact with the rule.

NOTE — It is estimated that this procedure gives an accuracy of measurement of ± 1 mm.

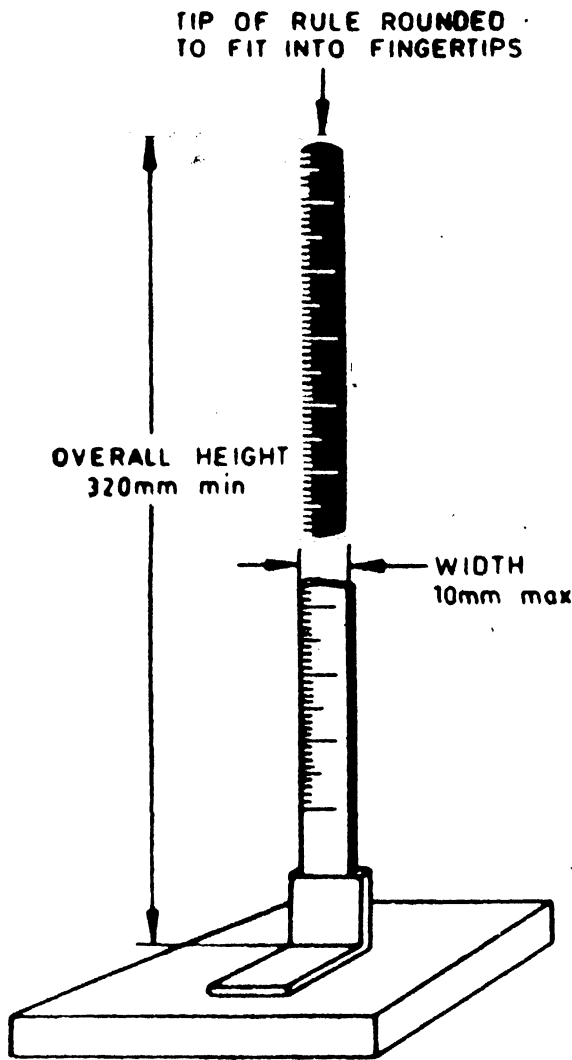


FIG. 2 DEVICE FOR MEASUREMENT OF GLOVE DIMENSIONS

A-2.2 Dimension C

Lay the glove on a flat surface, thumb uppermost and measure in width across the palm (dimension *C*) at a position midway between the thumb/index finger crotch and the index/middle finger crotch, with the glove pressed flat using the rule.

A-2.3 Dimension D

Place the middle finger of the glove over the measuring device (see A-1.2) with the glove freely suspended in a relaxed position and free from folds or creases.

A-2.3.1 Measure the total length of the glove (dimension *D*) by gently holding the cuff of the glove in contact with, and centrally disposed to, the rule, taking care not to stretch the glove.

A-2.4 Dimension E

Lay the glove on a flat surface, thumb uppermost, and measure the width at a position where the glove is having minimum width, that is from where the wrist starts, with the glove pressed flat using the rule.

A-2.5 Dimension F

Place the middle finger of the glove over the measuring device (see A-1.2) with the glove freely suspended in a relaxed position free from folds and creases.

A-2.5.1 Measure the distance from the tip of the middle finger to the point where dimension *E* is measured, that is, from where the wrist starts. For greater ease of measurement, the rule may be angled backwards slightly so that the front of the glove is in contact with the rule.

A-2.6 Dimension G

With the glove suspended and the cuff held as described in A-2.2, mark the distance *X* from the tip of the middle finger towards the cuff, as shown in Fig. 1B and specified in Table 1. Remove the glove from the measuring device (see A-1.2) and measure the width of the cuff at this marked position (dimension *G*) using the rule (see A-1.1) with the glove on a flat surface and pressed flat.

ANNEX B
(Clause 6.1)

SAMPLING PLAN FOR SURGICAL RUBBER GLOVES

B-1 SCALE OF SAMPLING

B-1.1 Lot

All the surgical gloves of the same type and size produced from a single mix or raw materials and processed exactly under identical conditions shall be grouped to constitute a lot.

B-1.2 Each lot shall be examined separately for judging its conformity to the requirements of this specification. For this purpose, a number of gloves shall be selected at random from the lot. The number of gloves to be selected shall depend on the size of the lot and shall be in accordance with col 1 and 2 of Table 2.

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B-1.3 The gloves shall be selected from the lot at random. In order to ensure randomness of selection, random number tables shall be used. In case random number tables are not available, the following procedure may be adopted:

Starting from any item in the lot, count them in one order as 1, 2, 3, . . . , up to r and so on, where r is the integral part of N/n , N being the number of items in the lot and n the number of items to be selected. Every r th item thus counted shall be withdrawn to constitute the sample.

B-2 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

B-2.1 All the gloves selected in B-1.2 shall be examined for all the requirements of this specification except those specified for physical properties of rubber in 4.4. Any glove failing in one or more of these requirements shall be considered as defective. The lot shall be regarded as satisfactory in respect of these requirements, if the number of defectives does not exceed the corresponding number given in col 3 of Table 2. Only the satisfactory lot shall be passed on for further testing according to 4.4.

Table 2 Scale of Sampling
(Clauses B-1.2, B-2.1 and B-2.2)

No. of Gloves in the Lot	No. of Gloves to be Selected	Permissible No. of Defectives in Respect of Requirements Other Than 4.4	No. of Gloves for Physical Properties of Rubber
(1)	(2)	(3)	(4)
2 to 5	All	0	1
6 to 15	5	0	1
16 to 25	8	0	1
26 to 50	13	0	2
51 to 100	20	0	2
101 to 300	32	1	2
301 to 1 000	50	2	3
1 001 and above	80	3	5

B-2.2 If the lot has been found satisfactory in B-2.1, it will be subjected to tests for requirements given in 4.4. The number to be tested for this purpose shall be in accordance with col 4 of Table 2 and shall be taken at random from those already selected from the lot. If none of these gloves fail in any of the requirements of 4.4 the lot shall be declared to have met the requirements of this specification.

Standard Mark

The use of the Standard Mark is governed by the provisions of the *Bureau of the Indian Standards, Act, 1986* and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

Bureau of Indian Standards

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BUREAU OF INDIAN STANDARDS

Headquarters :

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones : 331 01 31, 331 13 75

Telegrams : Manaksanstha
(Common to all Offices)

Regional Offices :

Telephone

Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg
NEW DELHI 110002

{ 331 01 31
{ 331 13 75

Eastern : 1/14 C.I.T. Scheme VII M, V.I.P. Road, Maniktola
CALCUTTA 700054

37 86 62

Northern : SCO 445-446, Sector 35-C, CHANDIGARH 160036

53 38 43

Southern : C.I.T. Campus, 4 Cross Road, MADRAS 600113

235 02 16

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