PRODUCT MANUAL FOR SURGICAL RUBBER GLOVES - SPECIFICATION ACCORDING TO IS 4148:1989

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.

1.	**Product**	:	IS 4148:1989
	Title	:	Surgical Rubber Gloves
	No. of Amendments	:	3
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	As per Cl 4.1.1 & 4.1.2 of IS 4148
b)	**Grouping guidelines**	:	Please refer ANNEX –A
c)	**Sample Size**	:	20 pairs of Surgical Rubber Gloves
3.	**List of Test Equipment**	:	Please refer ANNEX –B
4.	**Scheme of Inspection and Testing**	:	Please refer ANNEX –C
5.	**Possible tests in a day :**		i. Dimensions as per Cl. 4.2 , Annex A & Table 1 ii. Thickness as per Cl. 4.3 iii. Tensile Strength and Elongation at Break (Before Ageing) as per Cl. 7.1,7.2,7.3 iv. Autoclave Test as per Cl. 7.5 v. Tension Test as per Cl. 7.6 vi. pH of Aqueous Extract as per Cl. 7.7
6.	**Scope of the Licence :**		
	"Licence is granted to use Standard Mark as per IS 4148:1989 with the following scope:		
	Name of the product	Surgical Rubber Gloves	
	Size	5½, 6, 6½, 7, 7½, 8, 8½, 9, 9½	

ANNEX A

Grouping Guidelines

1. IS 4148 : 1989 covers the following sizes of Surgical Rubber Gloves - 5½, 6, 6½, 7, 7½, 8, 8½, 9, 9½.

2. The Firm shall declare the Sizes of gloves they intend to cover in the Licence.

3. Gloves with the largest and smallest sizes in a group shall be tested for covering all the sizes.

4. The Scope of Licence may be restricted based on the Manufacturing and Testing capabilities of the Manufacturer.

5. During the operation of the Licence, BO shall ensure that all the sizes covered in the Licence are tested in rotation, to the extent possible.

ANNEX – B

List of Test Equipment

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	**Standard Atmospheric Conditions as per Cl. 7.1 of IS 4148:1989.**	a) Humidity Chamber with Temperature Control & Humidity Control. b) Thermometer & Barometer, if required.
23	**Dimensions as per Cl. 4.2, Annex A & Table 1**	a) Thickness gauge b) Steel rule c) Dead Weight Dial Type Gauge
5.	**Thickness as per Cl. 4.3**	
4.	**Tensile Strength and Elongation at Break as per Cl. 7.1,7.2,7.3**	a) Thickness gauge b) Steel rule c) Universal Testing Machine d) Dumb bell Die cutter
5.	**Accelerated Ageing as per Cl. 7.4**	e) Hot Air Oven
6.	**Autoclave Test as per Cl. 7.5**	a) Incubator with Temperature Indicator b) Auto Clave with Temperature Indicator & Pressure Gauge. c) Laminar Air Flow Chamber
7.	**Tension Test as per Cl. 7.6**	a) Any suitable apparatus capable of subjecting test pieces to constant elongation may be used. b) Thermometer. c) Vernier Calliper. d) Stop Watch.
8.	**pH of Aqueous Extract as per Cl. 7.7**	a) Weighing Balance b) Vernier Calliper. c) Chemically Resistant Flask d) Measuring Cylinder d) Water Cooled Reflux Condenser. e) Thermometer & Barometer, if required. f) pH meter calibrated using standard Buffer.

The above list is indicative only and may not be treated as exhaustive.

ANNEX C

Scheme of Inspection and Testing

1. LABORATORY - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

1.1 The manufacturer shall prepare a calibration plan for the test equipments.

2. TEST RECORDS –The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. LABELLING AND MARKING – As per the requirements of IS 4148.

4. CONTROL UNIT – For the purpose of this scheme the entire quantity of gloves of one size manufactured at a time from one compound mix shall be considered as one control unit.

5. LEVELS OF CONTROL - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

5.1 All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

6. REJECTIONS – Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016.

Table 1

(1)				(2)	(3)			
Test Details				**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**Levels of Control**			
Cl.	**Requirement**	**Test Methods**			**No. of Samples**	**Lot Size**	**Frequency**	**Remarks**
		Clause	**Reference**					
4.1.1 & 4.1.4	Manufacture	4.1.1 & 4.1.4	IS 4148	R	Each glove			
4.1.3	Bead of Glove	4.1.3	-do-	R	10	Control unit	Each Control Unit	The Gloves selected for checking dimensions may be used for this purpose.
4.2 & Table 1	Dimensions	4.2 & Table 1	Annex A of IS 4148	R	5 pairs of each size	-do-	-do-	
4.3	Thickness	4.3	IS 4148	R	-do-	-do-	-do-	
4.4.1	Tensile strength and Elongation at break	7.3	IS 4148 & IS 3400 (Pt 1)	R	Three	-do-	-do-	All the three samples should pass.
4.4.2	Accelerated Ageing	7.4	IS 4148 & IS 3400 (Pt 1)	R	-do-	-do-	-do-	-do-
4.4.3	Autoclave Test	7.5	IS 4148	R	One	Control unit	Every Third Control Unit	The sample should Pass
4.4.4	Tension Test	7.6	IS 4148	R	Three	-do-	Each Control Unit	All the three samples should pass.
4.5	pH of Aqueous Extract	7.7	IS 4148	R	One	-do-	-do-	Composite sample to be prepared from 5 to 6 gloves taken for physical testing.

Note-1: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.