PRODUCT MANUAL FOR DISPOSABLE SURGICAL RUBBER GLOVES ACCORDING TO IS 13422:1992

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 13422:1992
	Title	:	DISPOSABLE SURGICAL RUBBER GLOVES
	No. of Amendments	:	NIL
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	-
b)	**Grouping guidelines**	:	Please refer ANNEX – A
c)	**Sample Size**	:	20 pairs for all tests
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) General Characteristics and Dimensions of the Cuff as per Cl. 5.2.1 (ii) Dimensions as per Cl. 5.2.2 (iii) Thickness as per Cl. 5.2.3 (iv) Tensile Strength and Elongation at Break (Before Ageing) as per Cl. 5.3.1 (v) Airtight Test as per Cl. 5.5		
6.	**Scope of the Licence :**		
	"Licence is granted to use Standard Mark as per IS 13422:1992 with the following scope:		
	Name of the product	DISPOSABLE SURGICAL RUBBER GLOVES	
	Type	Type 1/ Type 2	
	Class	Not Applicable.	
	Grade	Not Applicable.	
	Size	5½, 6, 6½, 7, 7½, 8, 8½, 9	
	Any other aspect required as per the Standard	NIL	

ANNEX A

Grouping Guidelines

1. The parameters as given below shall be considered for grouping of Disposable Surgical Rubber Gloves as per IS 13422 : 1992 for GOL/Inclusion:

   i. Type of gloves- Type 1 / Type 2

   ii. Glove size- 5½, 6, 6½, 7, 7½, 8, 8½, 9

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

3. Gloves with different sizes shall be considered as one group, provided the type remains the same. Gloves with the largest and smallest sizes in a group shall be tested for covering all the sizes of gloves in that group.

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 types and sizes covered in the Licence are tested in rotation, to the extent possible.

ANNEX B

List Of Test Equipment

Major test equipment essentially required to test as per the Indian Standard

S. No.	Tests used in with Clause Reference	Test Equipment
1.	General Characteristics and Dimensions of the Cuff as per Cl. 5.2.1	a) Thickness gauge
2.	Dimensions as per Cl. 5.2.2	a) Thickness gauge b) Steel rule
3.	Thickness as per Cl. 5.2.3	
4.	Tensile Strength and Elongation at Break as per Cl. 5.3.1	a) Thickness gauge b) Steel rule c) Universal Testing Machine d) Dumb bell Die cutter
5.	Accelerated Ageing as per Cl. 5.3.2	a) Thickness gauge b) Steel rule c) Universal Testing Machine d) Dumb bell Die cutter e) Hot Air Oven
6.	Sterility Test as per Cl. 5.4	a) Incubator with Temperature Indicator b) Auto Clave with Temperature Indicator & Pressure Gauge c) Laminar Air Flow Chamber
7.	Airtight Test as per Cl. 5.5	a) Circular Mandrel b) Inflation Apparatus with Pressure gauge c) Stop Watch
8.	Standard Atmospheric Conditions as per Cl. 7	a) Humidity Chamber with Temperature Control and Humidity Control.

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 equipment.

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 13422:1992.

4. CONTROL UNIT – Entire quantity of Disposable Surgical Rubber Gloves of same type manufactured from one mix in one day shall be considered as a 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 Standard 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 Sample	Frequency	Remarks
		Clause	Reference				
5.1	Materials	5.1	IS 13422:1992	-		Each consignment	#
5.2.1	The Cuff	5.2.1	IS 13422:1992	R	10 pairs	Each Control Unit	
5.2.2 & Table 1	Dimensions	5.2.2 & Table 1	IS 13422:1992	R	5 pairs of each size	Each Control Unit	
5.2.3 & Table 1	Thickness	5.2.3 & Table 1	IS 13422:1992	R	5 pairs of each size	Each Control Unit	
5.3.1 & Table 2	Tensile Strength and Elongation at Break	5.3.1 & Table 2	IS 13422:1992	R	3 pairs	Each Control Unit	
		IS 3400 (Part 1) : 2012					
5.3.2 & Table 2	Accelerated Ageing	5.3.2 & Table 2	IS 13422:1992	R	3 pairs	Once in a week	
		IS 3400 (Part 4) : 2012					
5.4	Sterility Test	5.4	IS 13422:1992	S	4 pairs ##	Each bulk package sent for irradiation	
		Latest Edition of Indian Pharmacopeia.					
5.5	Airtight Test	5.5	IS 13422:1992	R	3 pairs of each size	Each Control Unit	

No further testing is required if accompanied with the Test Certificate or ISI marked.

One pair from top, one pair from bottom and two pairs from sides to be taken from bulk packaging

Note-1: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-2: 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.