

**PRODUCT MANUAL FOR  
SINGLE-USE MEDICAL EXAMINATION GLOVES- GLOVES  
MADE FROM RUBBER LATEX OR RUBBER SOLUTION  
ACCORDING TO IS 15354(Part 1):2018**

*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.	<b>Product</b>	:	IS 15354 (Part 1):2018
	<b>Title</b>	:	Single-Use Medical Examination Gloves-Gloves Made from Rubber Latex or Rubber Solution
	<b>No. of Amendments</b>	:	NIL
2.	<b>Sampling Guidelines:</b>		
a)	<b>Raw material</b>	:	As per Cl. 4 of IS 15354 (Part 1):2018
b)	<b>Grouping guidelines</b>	:	Please refer <a href="#">ANNEX – A</a>
c)	<b>Sample Size</b>	:	24 pairs for all tests
3.	<b>List of Test Equipment</b>	:	Please refer <a href="#">ANNEX – B</a>
4.	<b>Scheme of Inspection and Testing</b>	:	Please refer <a href="#">ANNEX – C</a>
5.	<b>Possible tests in a day :</b>		
	(i) Dimensions as per Cl. 6.1 (ii) Tensile Properties before accelerated ageing as per Cl. 6.3.2 (iii) Watertightness as per Cl. 6.2		
6.	<b>Scope of the Licence :</b>		
	“Licence is granted to use Standard Mark as per IS 15354 (Part 1):2018 with the following scope:		
	Name of the product	Single-Use Medical Examination Gloves- Gloves Made from Rubber Latex/Rubber Solution	
	Type	Type 1/ Type 2	
	Size	X-S, S, M, L, X-L	

**ANNEX A**

**Grouping Guidelines**

1. The parameters as given below shall be considered for grouping of Single-Use Medical Examination Gloves- Gloves Made from Rubber Latex or Rubber Solution as per IS 15354(Part 1):2018 for GoL/CSoL:
  - i. Type of gloves- Type 1 / Type 2
  - ii. Glove size- X-S, S, M, L, X-L
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*

<b>Sl. No.</b>	<b>Tests used in with Clause Reference</b>	<b>Test Equipment</b>
1.	Dimensions as per Cl. 6.1	a) Vernier Caliper b) Measuring Scale c) Micrometer d) Thickness gauge
2.	Watertightness as per Cl. 6.2	a) Watertightness apparatus set
3.	Tensile properties before and after accelerated ageing as per Cl. 6.3	a) Thickness gauge b) Hot Air Oven c) Tensile Testing Machine d) Dumb bell Die cutter

*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 15354 (Part 1):2018.

**4. CONTROL UNIT** – Entire quantity of Single-Use Medical Examination Gloves made from Rubber Latex or Rubber Solution of the same type and finish 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**

<b>(1)</b>				<b>(2)</b>	<b>(3)</b>		
<b>Test Details</b>				<b>Test equipment requirement</b> R: required (or) S: Sub-contracting permitted	<b>Levels of Control</b>		
Cl.	Requirement	Test Methods			No. of Sample	Frequency	Remarks
		Clause	Reference				
4	Materials	4	IS 15354 (Part 1)	–	–	Each consignment	#
6.1	Dimensions	6.1 & Table 2	IS 15354 (Part 1)	R	5 pairs of each size	Each Control Unit	
6.2	Watertightness	6.2 & Annex-A	IS 15354 (Part 1)	R	3 pairs of each size	Each Control Unit	
6.3	Tensile Properties before and after accelerated ageing	6.3.2, 6.3.3 & Table 3	IS 15354 (Part 1)	R	3 pairs	Each Control Unit	

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

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.