उत्पाद मैन्युअल
आई एस 15354 (PART 1):2023 के अनुसार
एकल-उपयोग चिकित्सा परीक्षण दस्ताने-रबर लेटेक्स या रबर समाधान से बने दस्ताने
दस्तावेज़ संख्या – पी एम/आई एस 15354 (Part 2)/ 2/ दिसंबर 2023

भारतीय मानक ब्यूरो की स्कीम-I (अनुरूपता मूलयांकन) विनियम, 2018 के तहत यह उत्पाद मैन्युअल प्रमाणीकरण के प्रचालन में रीति और पारिशिता की सुसंगतता सुनिश्चित करने के लिए सभी क्षेत्रीय/शाखा कार्यालयों और लाइसेंसी द्वारा संदर्भ सामग्री के रूप में उपयोग किया जाएगा। बीआईएस प्रमाणीकरण लाइसेंस/ प्रमाणपत्र प्राप्त करने के इच्छुक भावी आवेदकों द्वारा भी इस दस्तावेज़ का उपयोग किया जा सकता है ।

PRODUCT MANUAL FOR
Single-Use Medical Examination Gloves-Gloves Made from Rubber Latex or Rubber Solution
ACCORDING to
15354 (Part 1):2023
Document No.- PM/ IS 15354 (Part 1)/ 2/ Dec 2023

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.

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PRODUCT MANUAL FOR SINGLE-USE MEDICAL EXAMINATION GLOVES- GLOVES MADE FROM RUBBER LATEX OR RUBBER SOLUTION ACCORDING TO IS 15354(Part 1):2023

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 15354 (Part 1):2023
	Title	:	Single-Use Medical Examination Gloves-Gloves Made from Rubber Latex or Rubber Solution
	No. of Amendments	:	0
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	As per Cl. 5 of IS 15354 (Part 1):2023
b)	**Grouping guidelines**	:	Please refer ANNEX – A
c)	**Sample Size**	:	24 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**	:	Please refer ANNEX – D
6.	**Scope of the Licence :**		
	"Licence is granted to use Standard Mark as per IS 15354 (Part 1):2023 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
	Finish		Textured surface over part or all of the gloves / Smooth surface / Powdered surface / Powder-free surface
	Size		X-S, S, M, L, X-L

ANNEX A

Grouping Guidelines

1. Single-Use Medical Examination Gloves- Gloves Made from Rubber Latex or Rubber Solution as per IS 15354 (Part 1):2023 are classified based on the following:

   i. Type of gloves- Type 1 / Type 2
   ii. Finish - Textured surface over part or all of the gloves / Smooth surface / Powdered surface / Powder-free surface
   iii. Glove size- X-S, S, M, L, X-L

2. Gloves with different sizes shall be considered as one group, provided the type and finish remains the same.

3. Gloves of any Glove size from each Type of Gloves shall be tested to cover all the sizes of gloves in that group.

4. Gloves of each finish of any size shall be tested to cover the particular type of finish. However, if gloves with complete textured surface is tested, gloves with Textured surface over part and Smooth surface may be considered.

5. In addition to the samples of varieties drawn for independent testing as per the above guidelines, factory test reports of all other varieties intended to be covered in scope of license, shall also be submitted by the manufacturer

6. The Firm shall declare the Types and Sizes of various gloves they intend to cover in the Licence. The Scope of Licence may be restricted based on the Manufacturing and Testing capabilities of the Manufacturer.

7. 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

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Finish as per Cl. 4	Electronic weigh bridge
2.	Dimensions as per Cl. 7.1	Vernier Caliper Measuring Scale Micrometer Pressure-thickness gauge
3.	Water tightness as per Cl. 7.2	Watertightness apparatus set
4.	Tensile properties before and after accelerated ageing as per Cl. 7.3	Hot Air Oven with timer Tensile Testing Machine 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 – Gloves shall be marked as per CL. 9 of IS 15354 (Part 1):2023. The Standard Mark as given in the Schedule of the licence shall also be printed legibly and indelibly marked on the drums.

3.1 In addition to the above, the licence no. CM/L- ……and details of BIS website shall be marked on each drums as follows: "For details of BIS certification please visit www.bis.gov.in"

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

(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	Materials	5	IS 15354 (Part 1)	_	_	Each consignment	No further testing is required, if accompanied with the Test Certificate or ISI Marked
4.3	Finish	4.3	IS 15354 (Part 1)	R	Firm to have adequate in-process controls to check compliance of this parameter as per the tolerances given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		
7.1	Dimensions	7.1 & Table 2	IS 15354 (Part 1)	R			
7.2	Water tightness	7.2 & Annex-A	IS 15354 (Part 1)	R	3 pairs of each size	Each Control Unit	
7.3	Tensile Properties before and after accelerated ageing	7.3.2, 7.3.3 & Table 3	IS 15354 (Part 1)	R	3 pairs	Each Control Unit	
7.4	Sterility	7.4	IS 15354 (Part 1)	R	Firm to have adequate in-process controls to check compliance of this parameter as per the tolerances given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity.		

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.

Annex – D

Possible tests in a day

(i) Finish as per Cl 4.3

(ii) Dimensions as per Cl. 7.1

(iii) Water tightness as per Cl. 7.2

(iv) Tensile Properties before accelerated ageing as per Cl. 7.3.2