उत्पाद मैन्यूअल
एकल-उपयोग रोगाणुमुक्त रबड़ सर्जिकल दस्ताने — विशिष्ट
आईएस 13422: 2024 / आईएसओ 10282: 2023 के अनुसर

PRODUCT MANUAL FOR
Single-Use Sterile Rubber Surgical Gloves — Specification
as per IS 13422: 2024 / ISO 10282: 2023

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो) अनुरूपता मूल्यांकन (विनियम, 2018 की योजना -I के तहत प्रमाणन के संचालन में एकरूपता और पारदर्शिता के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता है।

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity 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.

1.	**मानक संख्या** **IS No.**	:	IS 13422: 2024 / ISO 10282: 2023
	शीर्षक **Title**	:	Single-Use Sterile Rubber Surgical Gloves — Specification
	संशोधनों की संख्या **No. of amendments**	:	None
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	To be declared by the manufacturer as per Cl. 5.1 of IS 13422
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Please refer **ANNEX – A**
c)	**नमूने का परिमाण** **Sample Quantity**	:	100 Nos
d)	**परीक्षण अनुरोध में घोषित किए जाने वाले पैरामीटर** **Parameters to be**	:	As per Scope of the licecne (See Sl. No. 6)

	Declared in Test Request		
3.	**परीक्षण उपकरणों की सूची List of Test Equipment**	:	Please refer **ANNEX – B**
4.	**निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing**	:	Please refer **ANNEX – C**
5.	**एक दिन में संभावित परीक्षण Possible tests in a day**	:	All tests
6.	**लाइसेंस का दायरा /Scope of the Licence:**		

"License is granted to use Standard Mark as per ***IS 13422: 2024 / ISO 10282: 2023*** with the following scope:

Name of the product	Single-Use Sterile Rubber Surgical Gloves — Specification
Material	To be declared by the manufacturer as per Cl. 5.1 of IS 13422
Type	Type – 1 / Type – 2
Design	Gloves with straight fingers / Gloves with fingers curved in the palmar direction
Cuff Termination	Cut / Rolled Rim
Finish	Textured surface over part or the entire glove / Smooth surface / Powdered surface / Powder-free surface
Sizes	5 / 5.5 / 6 / 6.5 / 7 / 7.5 / 8 / 8.5 / 9 / 9.5

ANNEX -A

Grouping Guidelines

1. Single-Use Sterile Rubber Surgical Gloves as per IS 13422 are classified based on the following:

Material	To be declared by the manufacturer as per Cl. 5.1 of IS 13422
Type	Type – 1 / Type – 2
Design	Gloves with straight fingers / Gloves with fingers curved in the palmar direction
Cuff Termination	Cut / Rolled Rim
Finish	Textured surface over part or the entire glove / Smooth surface / Powdered surface / Powder-free surface
Sizes	5 / 5.5 / 6 / 6.5 / 7 / 7.5 / 8 / 8.5 / 9 / 9.5

2. For considering GoL/ CSoL, Single-Use Sterile Rubber Surgical Gloves of lowest and highest size from each type of raw material, type of gloves, design, cuff termination and finish shall be tested to cover all other sizes of Single-Use Sterile Rubber Surgical Gloves in the scope of licence.

3. Firm shall declare the varieties of Single-Use Sterile Rubber Surgical Gloves that they intend to be covered in the Licence. The Scope of Licence may be restricted based on the Manufacturing and Testing capabilities of the Manufacturer.

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

Note: The firm shall declare the following:

a) Type of surface treatment it intends to carry out
b) Process of Sterility

ANNEX- B
LIST OF TEST EQUIPMENTS
(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Dimensions as per Cl. 7.1 and Table 2	Thickness gauge Scale
2.	Watertightness as per Cl. 7.2	Test set up as per Annex B Volume / flow meter Stop watch Temperature Sensor
3.	Tensile Strength and Elongation at Break as per Cl. 7.3.2 and Cl. 7.3.3	Thickness gauge Scale Universal Testing Machine Dumb bell Die cutter
4.	Accelerated Ageing	Hot Air Oven with timer

ANNEX C
Scheme of Inspection and Testing

1. QUALITY ASSURANCE PLAN

1.1 It is expected that during operation of BIS licence, manufacturers will implement a Quality Assurance Plan (QAP) i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.

1.2 The manufacturers shall define a Quality Assurance Plan (QAP) defining the control unit (i.e. lot/batch etc.), the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and declare the arrangement for testing i.e. whether in-house or subcontracting/sharing and submit the same to BIS Branch Office for information. The manufacturer shall comply with the QAP and maintain test records in accordance with Para 2.1.

1.3 **RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT**:

1.3.1 For the guidance of manufacturers, the recommended definition of control unit is: *Intravascular Over-Needle Peripheral Catheters of same size manufactured in a day under similar process condition from the same consignment of raw materials* shall constitute a control unit.

1.3.2 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in **Table 1**. Manufacturer has the discretion of declaring their own levels of control or accept the levels of control given in this document.

1.3.3 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan.

2. ENSURING COMPLIANCE THROUGH TESTING - manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard. However, there is no obligation to maintain in-house laboratory. Licensee may use alternative arrangements for tests of the production as per the declared QAP. Various alternatives are available for operation of BIS certification as given below and the relevant guidelines for availing such relaxations by the manufacturers, as amended from time to time, are to be referred:

i. Shared testing resources like common facility,

ii. Cluster based testing facility,

iii. Sub-contracting to outside laboratories which may either be:

   a. BIS recognised/empanelled laboratories, or

   b. Any accredited laboratory as per ISO/IEC 17025

2.1 TEST RECORDS- The manufacturers maintaining an in-house laboratory or utilizing common cluster based facilities or shared test facilities shall maintain test records for the tests carried out to establish conformity. For the tests being subcontracted to BIS recognized/empanelled laboratory or any other laboratory having valid accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

3. PACKING AND MARKING - The Standard Mark as given in the Schedule of the licence shall be marked legibly and indelibly on the packaging of *Single-Use Sterile Rubber Surgical Gloves* provided always that the gloves so marked conforms to each requirement of the specification.

3.1. Marking on Single-Use Sterile Rubber Surgical Gloves shall be done as per designation specified at Cl. 9 of IS 13422: 2024 / ISO 10282: 2023.

3.2 **Additional Marking requirements**: The packaging of Single-Use Sterile Rubber Surgical Gloves shall also be marked with the following additional requirement on each packing:

a) "For BIS certification details please visit www.bis.gov.in"

3.3 All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark.

4. HYGIENIC CONDITIONS (if applicable) – NA.

5. REJECTION - 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)		
Test Details				Levels of Control		
Cl.	Requirement	Test Methods		No. of Sample	Frequency	Remarks
		Clause	Reference			
5	Material	5.1 to 5.3	IS 13422	One	Each Consignment of raw material	No further testing is required if accompanied with TC or ISI marked
5.4	Bio-compatibility		ISO 10993	One	Once in every three years	Whenever there is change in any aspect as specified in Cl. 4.9 of IS 17932 (Part 1)
7.1 Table 2	Dimensions	Annex A	IS 13422		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	
7.2	Watertightness	Annex B	IS 13422	One	Each Control Unit	
7.3	Tensile Properties					
7.3.2 Table 3	***Force at break and elongation at break before accelerated ageing***		ISO 37 IS 3400 (Part 1)	One	Each Control Unit	
	Min Force at break Min Elongation at break Maximum force required to produce 300 % elongation					
	Force at break and elongation at break after accelerated ageing		ISO 37	One	Once in a month	
	Min Force at break Min Elongation at break					