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उत्पाद मैन्युअल
DISPOSABLE ARTIFICIAL INSEMINATION GLOVES — SPECIFICATION
7180:2025 के अनुसार

PRODUCT MANUAL
FOR DISPOSABLE ARTIFICIAL INSEMINATION GLOVES — SPECIFICATION
According to IS 7180:2025

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 underScheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations,2018 for variousproducts. The document may also be used by prospective applicants desirous of obtaining BIS certification.

1.	**मानक संख्या** **IS No.**	:	IS 7180:2025
	शीर्षक **Title**	:	Disposable Artificial Insemination Gloves
	संशोधनों की संख्या **No. of amendments**	:	NIL
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	Raw material shall be in accordance with clause 3.1 of IS 7180: 2025. Note: This section indicates the requirements for raw material (if specified in the IS) for which compliance is to be establishedduring Grant of Licence/Change in Scope of Licence / Factory Surveillance.
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Each type of Disposable Artificial Insemination Gloves are to be drawn and tested to be included in the scope of licence.
c)	**नमूने का परिमाण** **Sample Quantity**	:	50 pieces. Note: This section indicates the quantity of the sample of the product and/or the raw material (if applicable), required to be sent to the laboratory for testing, for the purpose of Grant of Licence/Change in Scope of Licence/ Factory Surveillance (in case of market surveillance, effort may be made to procure the required quantity of product sample, as far as possible since raw material sample may not be available in market)
d)	**परीक्षण अनुरोध में घोषित**		• Name of the product • Type

	किए जाने वाले पैरामीटर **Parameters to be Declared in Test Request**		Note: Apart from the above, any other requirements/parameters may also be declared as per the standard, as applicable.
3.	**परीक्षण उपकरणों की सूची** **List of Test Equipment**	:	Please refer ANNEX-A
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	Please refer ANNEX-B
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**		
	All tests are possible to be carried out in a day. Note: This section is for the guidance of BIS Certification Officers/Technical Auditors of BIS Authorized Outside Surveillance Agencies (OSAs) during factory inspection to provide ready reference regarding the tests which can be witnessed during the inspection in the factory by the officer/auditor.		
6.	**लाइसेंस का दायरा /Scope of the Licence:**		
	Licence is granted to use Standard Mark as per IS 7180:2025 with the following scope:		
	Name of the product	Disposable Artificial Insemination Gloves	
	Type	Men/Women	

ANNEX – B

LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests used in with Clause Reference	Test Equipment
1	Dimensional Requirements, Clause 3.2.1	- Vernier Caliper - SS scale
2	Thickness, Clause 3.2.2	- Micro meter - Digital Thermohygrometer
3	Tensile Strength, Clause 3.4	- Tensile testing machine - Loading scale - SS scale - Measuring tape - Conditioning chamber - Digital Thermohygrometer
4	Elongation at Break, Clause 3.5	- Tensile testing machine - Loading scale - SS scale - Measuring tape - Conditioning chamber
5	Density, Clause 3.6	- dreschsel bottle - water bath - burette - Pipette - Specific Gravity Bottle - Weighing balance Reagents - Distilled water
6	Reaction to Aqueous Extract, Clause 3.8	- Weighing balance - Glass beaker - PH strip - Ethyl Alcohol - Phenolphthalein Indicator - Methyl Orange Indicator
7	Seam Test, Clause6.1	- Water bucket

ANNEXURE-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 differenttests as per the Indian Standard) and declare the arrangement for testing i.e. whether in-house or subcontracting/sharing for each applicable test 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: All gloves of the same type(Men/Women) manufactured under similar condition of manufacturing using same raw material.

1.3.2 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommendedlevels 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 requirementsof the Indian Standard for which they may have in-house test facilities. 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 shall maintain test records for the tests carried out (either in-house or at a sub-contracted or at shared test facility) to establish conformity of the product to the Standard for operation of licence. For the tests being subcontracted or conducted at a shared test facility, test results issued by the laboratories or test facilities, shall be made available for inspection by BIS.

3. PACKING AND MARKING - The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each pack of gloves, provided always that the material so marked conforms to each requirement of the specification.

3.1 Packing and Marking shall be done as per the Indian Standard.

3.2 **Additional Marking requirements**: Additionally, the following shall also be marked on each pack of gloves:

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

4. TEST CERTIFICATE- Each consignment of gloves shall be supplied with a certificate to the effect that the units being supplied have been tested as per the requirements of the specification and found suitable for use.

5. REJECTION - The production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark. 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

(Recommended Levels of Control by BIS - For Guidance Only)

Test Details (1)				Levels of Control (2)		
Cl.	**Requirement**	**Test Methods**		**No. of Samples**	**Frequency**	**Remarks**
		Clause	**Reference**			
3.1	Raw Material	--	IS 14500	One	Each Consignment	
3.2	Dimensions & thickness	3.2	IS 7180	One	Each control unit	
3.3	Appearance	3.3	-do-	One	Each control unit	
3.4	Tensile strength	Annex A	do-	One	Each control unit	
3.5	Elongation at break	Annex A	do-	One	Each control unit	
3.6	Density	Annex B	do-	One	Each control unit	
3.7	Color	3.7	do-	One	Each control unit	
3.8	Reaction to Aqueous Extract	3.8	do-	One	Each control unit	
6.1	Seam test	6.1	do-	One	Each control unit	