www.bis.gov.in

उत्पाद मैनुअल
वस्त्रादि चिकित्सीय/सर्जिकल गाउन और चिकित्सीय/सर्जिकल ड्रैप — विशिष्टि

IS 17334: 2025 के अनुसार

PRODUCT MANUAL
Textiles — Medical/Surgical Gowns and Medical/Surgical Drapes — Specification
ACCORDING TO IS 17334: 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 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 17334: 2025
	शीर्षक **Title**	:	Textiles — Medical/Surgical Gowns and Medical/Surgical Drapes — Specification
	संशोधनों की संख्या **No. of amendments**	:	NIL
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	The manufacturer shall declare the material used by them for manufacturing the Medical/Surgical Gowns and Medical/Surgical Drapes as well as the details of the supplier of material. In case of change of material supplier, manufacturer shall get the product/material tested and submit conforming report to BIS before marking the product. Biocompatibility evaluation shall be done on raw material at design stage for all levels. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product. The Conformity of raw materials to the standard may be established through supplier's test certificate, test report of BIS recognized/empanelled lab or any other NABL accredited lab

			or through in house testing. Note: This section indicates the requirements for raw material(if specified in the IS)for which compliance is to be established during Grant of Licence/Change in Scope of Licence/Factory Surveillance.
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Please refer Annex-A
c)	**नमूने का परिमाण** **Sample Size**	:	5 pcs. 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 किए जाने वाले पैरामीटर** **Parameters to be Declared in Test Request**		i. Variety ii. Material iii. Performance requirement iv. Type v. Sterility 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-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**		
	(i) Workmanship and Finish (ii) Impact penetration (iii) Particle release (iv) Tensile strength (dry & wet) (v) Bursting strength (dry & wet) 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 17334: 2025 with the following scope:		
	Name of the product		Textiles — Medical/Surgical Gowns and Medical/Surgical Drapes

	Variety	• Medical/Surgical Gowns • Medical/Surgical Drapes
	Material	• Woven- To be declared • Non-woven- To be declared
	Performance requirement	Level 1/Level 2/Level 3/Level 4
	Type	Single use/Reusable
	Sterility	Sterilie/Unsterile

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN,9, BAHADUR SHAH ZAFAR MARG,
NEW DELHI-110002

ANNEX-A

GROUPING GUIDELINES

Following grouping guidelines shall apply while defining the scope of the licence in case of application for grant of licence or application for change in scope of licence:

(i) Separate samples for each performance level of Medical/Surgical Gowns and Medical/Surgical Drapes to be drawn.

(ii) If a sample of a particular performance level of Medical/Surgical Gowns is tested, same performance level of Medical/Surgical Drapes may also be covered in the scope of licence.

(iii) Separate samples for each type of Medical/Surgical Gowns and Medical/Surgical Drapes to be drawn & tested to be included in the scope of licence.

(iv) If a sample of sterilized Medical/Surgical Gowns is tested, unsterilized Medical/Surgical Gowns may also be covered in the scope of licence. Similarly, if a sample of sterilized Medical/Surgical Drapes is tested, unsterilized Medical/Surgical Drapes may also be covered in the scope of licence.

(v) The manufacturer shall declare the material used by them for manufacturing the Medical/Surgical Gowns and Medical/Surgical Drapes, and the samples of each type of material shall be tested.

(vi) Scope of licence shall be restricted based on the manufacturing and testing facilities available.

(vii) During operation of licence, samples of each variety covered in the scope of licence, shall be tested in rotation, to the extent possible.

ANNEX – B

List of Test Equipment

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sr. No.	**Test used in with clause reference**	**Test Equipment**
1.	Impact penetration, Clause 6.2	- Distilled water or water of equivalent purity, at (27 ± 1)°C - Impact Penetration Tester - White textile blotting paper - Laboratory balance
2.	Hydrostatic resistance (cmwc), Clause 6.2	- Water, grade 3 water in accordance with ISO 3696 - Fabric clamp - Manometer - Mechanism for measuring the increase in water pressure. - Atmosphere for conditioning and testing
3.	Blood penetration resistance, Clause 6.2	- Penetration test cell - Retaining screen - Air pressure source - Stopwatch - Balance - Vessel, or graduated cylinder or vessel - Thickness gauge
4.	Viral penetration resistance, Clause 6.2	- Thickness gauge - Retaining screen - Air pressure source - Incubator - Water bath - Balance - Vortex mixer - Refrigerator - Autoclave - Stopwatch - Orbital shaker - pH meter - Inoculating loop - Torque wrench, - Spectrophotometer - Centrifuge - Petri dishes - Pipettes - Test tubes - Test tube rack - Glass bottles - Micropipettes

5.	Particle release, Clause 6.2	- Lamina flow hood - Flexing unit (modified Gelbo Flex) - Flexing chamber and air collector - Particle counter - Glue - Gloves
6.	Tensile strength (dry and wet) , Clause 6.2	- Tensile testing machine - Clamps
7.	Bursting strength (dry and wet), Clause 6.2	- Bursting tester - Test area of 50 cm1 - A safety cover - Damping device
8.	Cleanliness-microbial (for unsterile gown), Clause 6.2	- Suitable culture media, incubation equipment etc. (Specific apparatus/reagents depends on the method chosen for characterization and determination of bioburden)
9.	Resistance to microbial penetration — Dry (CFU), Clause 6.2	- 50 g ± 0,5 g of talc - Spores of Bacillus subtilis - TGE agar plates - Pneumatic ball vibrator - Thick stone plate/marble plate - Compressed Air Flow Meter - Six Stainless Steel Containers - Stainless Steel Plate with 6 retaining holes - Stopwatch. - rubber stoppers
10.	Resistance to microbial penetration —Wet (IB), Clause 6.2	- Biosafety cabinet class II - Incubators - Refrigerator - Water bath - Bacterial strain suspension - Purified water - Peptone water - TGE agar (TGEA) - Petri dishes - Donor material - Cover film - Reference material - Pipettes - Micropipettes - Sterile dilution tubes - Rake - Test apparatus as per Annex B of IS 16549 - Cylindrical object of stainless steel or other appropriate material suitable for sterilization - Conical Steel Rings - Dynamometer

11.	Biocompatibility evaluation, Clause 6.2	**Cytotoxicity test** - Closed containers for extraction of sample Extraction vehicle - pH meter - Water bath - Incubator (37±1°C) humidified 5% CO2/air. - Microscope - Laminar flow cabinet (Biological hazard standard). - Shaker for microstate plates. - Cell counter or hemacytometer. Weighing Balance, - Air conditioner - Petri dishes - Pipetting aid. - Pipettes (8-channel pipettes, dilution block) - Cryotubes. - Tissue culture flasks (80 cm2, 25 cm 2) – - -Well tissue culture microtitre plates - -Culture medium to prevent absorption - -Cell lines - -Negative control material (High-density polyethylene) - Positive control material. (Sodium Lauryl Sulphate (SLS) - -Reference materials - Dulbecco's Modification of Eagle's Medium (DMEM), - without Lglutamine - Newborn calf serum (NBCS) - Phosphate - -Buffered saline (PBS), without Ca2+ and Mg2+ (for trypsinization) - Phosphate - -Buffered saline (PBS), with Ca2+ and Mg2+ (for rinsing). - -HEPES(4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid) - Dimethyl sulfoxide (AR Grade). - L-glutamine (200 mM), - Trypsin/EDTA solution. - Nutrient agar - Cell culture media - Penicillin/streptomycin solution - Mouse fibroblasts - Agarose overlay - Neutral red - Ethanol (AR Grade). - Glacial acetic acid (AR Grade) - Distilled water **Tests for Irritation and Skin Sensitization** - Rotary evaporator - pH meter - Pipetting aid - Weighing Balance - Shaker - Flasks - Incubators - Petri dishes

		- Pipetting aid

		- Air conditioner - Pulverizing or grinder apparatus - Extraction vial (borosilicate glass tubes with caps) - Absorbent gauze patch (non-occlusive dressing) - Marker with permanent ink. - Extract vehicle Full - Spectrum lighting source - Soft catheter or blunt -Tipped cannula - Occlusive chamber containing a gauze pad. - Vernier caliper - Non-irritating dressing - Non-irritating tape - Gauze pad - Spectrophotometer - Bandage (semi-occlusive or occlusive) - Water or non-irritant solvent - Methanol - Acetone - Physiological saline -Vegetable oil - Ethylene oxide - Freund's complete adjuvant (FCA) - Cytotoxic marker chemicals (Sodium dodecyl sulphate) -Vital dyes - Tissue culture medium - Distilled or Deionized water - NaCl (0.9 %) - MTT Sol. (0.3 mg/ml to 1 mg/ml) - Isopropanol - Olive oil - Dimethylsulfoxide (DMSO) - n-hexane - Ethanol - Heptane - Lubricant - Positive control (Sodium Lauryl Sulphate (SLS) - Negative control (Non-irritant, Absorbent gauze)
12.	Breathability test (water vapour transmission rate), Clause 6.2	- Conditioning Chamber - test dish - Burette - triangular sample support - adhesive - cover ring - Adhesive tape - Turntable - Weighing balance (capable of measuring up to an accuracy of 0.001g)

ANNEX C

SCHEME OF INSPECTION AND TESTING

1. QUALITY ASSURANCE PLAN

1.1 It is expected that manufacturers (licensees/applicants) will implement a Quality Assurance Plan 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 defining the control unit (i.e. lot/batch etc.) and the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and submit the same to BIS Branch Office for information. The manufacturer shall comply with the same and maintain test records in accordance with para 2.4.

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

1.3.1 For the guidance of manufacturers, the recommended definition of control unit is: For the purpose of this scheme, entire quantity of (Medical/Surgical Gowns)/(Medical/Surgical Drapes) having same performance level (1/2/3/4) & same type (single/multiple use), manufactured from the same consignment of material and produced under similar conditions of manufacturing in a day.

1.3.2 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in **Table 1**.

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. Alternatively, the manufacturer has the option of adherence to the quality plan as per levels of control recommended in column 3 of Table 1.

1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

2. ENSURING COMPLIANCE THROUGH TESTING- It is expected that manufacturers (licensees/applicants) will establish a suitably equipped and staffed in house laboratory (In house testing facility) for testing at least those parameters of the Indian Standard which require routine testing for ensuring quality of the product. This includes in-process controls as may be defined and put in place by the manufacturer and testing parameters/requirements which can only be performed in the factory.

2.1 For the guidance of manufacturers, Table 1 giving the recommended levels of control is given below. Column 2 of Table 1 indicates routine tests where test equipment is required in house as “R” or other tests which can be subcontracted as “S”. Subcontracting is permitted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.2 For MSME manufacturers, the requirement of maintaining a laboratory/in-house testing facility for routine tests (indicated as “R” in Column 2 of Table 1) is also optional.

2.2.1 MSME manufacturers may utilize common cluster based facilities as per guidelines for the utilization of cluster based test facilities by MSMEs or the provisions of Sharing of testing facilitiesor get testing done from BIS recognized/empaneled laboratory or any other laboratory having validNABL accreditation as per IS/ISO/IEC 17025.

2.3 **Large Scale manufacturers shall maintain an in-house laboratory equipped at least withtest facilities for routine tests (indicated as "R" in Column 2 of Table 1)**, where different testsgiven in the specification shall be carried out in accordance with the method given in the specification**.** They shall also implement a calibration plan for the in-house test equipment.

2.3.1 Alternatively, in lieu of an in-house laboratory, large scale manufacturers can also utilize the provisions of Sharing of testing facilities as per the Guidelines for Grant of Licence available on BIS website www.bis.gov.in. (Under Conformity Assessment>Product Certification Process). Even for subcontracted tests, provisions for sharing of testing facilities can be utilized.

2.4 **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 laboratoryor any other laboratory having valid NABL 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 incorporated legibly and indelibly on each Medical/Surgical Gowns, Medical/Surgical Drapes and on its package, 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 Each product or package, containing medical/surgical gowns, medical/surgical drapes, having a critical area shall be prominently labeled identifying the areas with different performance levels and the performance level of the relevant area(s).

3.3 **Additional Marking requirements**: The material shall also be marked with the following additional requirement on each pack of Medical/Surgical Gowns and Medical/Surgical Drapes:

a) Any other requirement not specified in the Indian Standard

4. REJECTION - All 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

LEVELS OF CONTROL

(1)				(2)	(3)		
Test Details				Test equipment requirement R: required (or) S: Sub-contracting permitted	Levels of Control		
Clause	Requirement	Test Method			No. of Samples	Frequency	Remarks
		Clause	Reference				
4	Workmanship and finish	4	IS 17334	R	Adequate visual inspection for cleanliness and hygiene to be ensured		
6.2	Impact penetration	-	IS 17375	R	One	Each control unit	-
-do-	Hydrostatic resistance (cmwc)	-	IS 391	R	One	Each control unit	-
-do-	Blood Penetration Resistance	-	IS 16546	S	One	Once in 3 months	-
-do-	Viral Penetration Resistance	-	IS 16545	S	One	Once in 3 months	Only for Surgical Gowns
-do-	Particle Release	-	IS 15891 (Part 10)	S	One	Once in 3 months	-
-do-	Tensile Strength (dry and wet)	-	IS 15891(Part 3)/IS 1969 (Part 1)	R	One	Each control unit	-
-do-	Bursting Strength (dry and wet)	-	IS 1966	R	One	Each control unit	-
-do-	Cleanliness-microbial	-	IS 11737	R	One	Each control unit	-
-do-	Resistance to Microbial Penetration – Dry (CFU)	-	IS 16548	S	One	Once in 3 months	-

-do-	Resistance to Microbial Penetration – Wet (IB)	-	IS 16549	S	One	Once in 3 months	-
-do-	Biocompatibility evaluation 1) Cytotoxicity Test 2) Irritation and 3) Skin Sensitization	- - -	IS/ISO 10993 (Part 5) IS 17932 (Part 6) IS 17932 (Part 7)	S	The manufacturer shall declare the material used by them for manufacturing the surgical gowns and drapes as well as the details of the material supplier and also whenever there is any change in the same. In case of change of material supplier, manufacturer shall get the product/material tested and submit conforming report to BIS before marking the product. Biocompatibility evaluation for Cytotoxicity and Irritation and skin sensitization shall be done on each type of material at design stage for all levels. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material for manufacturing the product.		
-do-	Breathability test	Annex-F	IS 16390	R	One	Each Control Unit	