



उत्पाद मैनुअल
Medical Textiles – Surgical Face Masks

IS 16289:2014 के अनुसार

PRODUCT MANUAL FOR
Medical Textiles — Surgical Face Masks
According to IS 16289:2014

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना- I के तहत प्रमाणन के संचालन में अभ्यास और पारदर्शिता के संचालन में पारदर्शिता सुनिश्चित करने 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 लाइसेंस/प्रमाणपत्र 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 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.	उत्पाद Product	:	IS 16289:2014
	शीर्षक Title	:	Medical Textiles – Surgical Face Masks
	संशोधनों की संख्या No. of amendments	:	0
2.	नमूना दिशानिर्देश Sampling Guidelines		
a)	कच्चा माल Raw material	:	No specific requirement
b)	समूहीकरण दिशानिर्देश Grouping Guidelines	:	Please refer ANNEX -A
c)	नमूने का आकार Sample Size	:	30 pieces
3.	पराक्षण उपकरणों का 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		
	Materials and Construction, Design, Differential Pressure, Splash resistance and Sub micron particulate filtration efficiency (provided conditioned samples are available, conditioning of 6 h required)		
6.	लाइसेंस का दायरा /Scope of the Licence:		
	Licence is granted to use Standard Mark as per IS 16289:2014 with the following scope:		
	Name of the product	Medical Textiles – Surgical Face Masks	
	Class	Class 1/Class 2/ Class 3	

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ANNEX A
Grouping Guidelines

IS 16289:2014 covers three classes of face masks based on performance

- Class 1
- Class 2
- Class 3

If a sample of Class 3 is drawn and tested, Classes 1,2 and 3 can be considered for grant of licence/addition in scope on that basis. Similarly, if Class 2 sample is drawn and tested, Classes 1 and 2 can be considered for grant of licence/addition in scope. However, if Class 1 sample is tested, Class 1 may only be considered for for grant of licence/addition in scope

However, it shall be ensured that the firm has the requisite manufacturing and testing facilities to produce the varieties intended to be covered in the scope of licence

During operation of licence, samples of all varieties shall be drawn and tested by rotation.

ANNEX B
List of Test Equipment

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests used in with Clause Reference	Test Equipment
1	Bacterial filtration efficiency CI 4.2 Table 1 SI No (i)	Apparatus: • Autoclave, capable of maintaining temperature of 121-123 °C. • Incubator, capable of maintaining temperature of 37 + 2 °C. • Analytical Balance capable of weighing 0.001 g • Vortex Mixer, capable of mixing the contents of 16 mm × 150 mm test tubes • Orbital Shaker, capable of achieving 100 - 250 rev/min. • Refrigerator, capable of maintaining 2-8 °C. • Six stage viable particle cascade impactor • Vacuum Pump, capable of 57 litre/min • Air Pump/Compressor, capable of 1.1 kg/cm². • Peristaltic Pump, capable of delivering 0.01 ml/min • Nebulizer, capable of delivering mean particle size of 3.0 micrometer and a challenge level of 2 200 particles per test • Glass Aerosol Chamber, 60 cm × 8 cm diameter tube. • Colony Counter, manual or automatic, capable of counting upto 400 colonies per plate • Automatic Pipetor, capable of delivering 1.0 + 0.05 ml • Flow Meters, capable of 28.3 litres/min. • Pressure Gauges, capable of 35 + 1 kPa • Air Regulator Reagents: • Staphylococcus Aureus, ATCC#6358 • Tryptic soy Agar (TSA) 6 • Tryptic soy broth (TSB) 6 • Peptone Water <i>Test method reference : IS 16288:2014</i>

2	Differential Pressure CI 4.2 Table 1 SI No (ii)	Apparatus for measuring air resistance with a Flow Meter, capable of measuring an air flow of 8 litre/min, Manometers, Electric Vacuum Pump and Needle valve <i>Test method reference: Annex C of IS 16289:2014</i>
3	Splash resistance CI 4.2 Table 1 SI No (iii)	• Splash resistance test apparatus: A suitable test apparatus to dispense a specified volume of synthetic blood through a small diameter canula (1.27 cm long with an internal diameter of 0.084 cm and length more than 30.5cm) over a controlled amount of time at a specimen mask a set distance away. The test apparatus consists of a specimen holding fixture, a targeting plate, a pressurized fluid reservoir, a pneumatically actuated valve with interchangeable canula and a valve controller. The test apparatus includes a base for more convenient mounting of the components and a hood or other components to contain or control the splash. • Synthetic Blood • Isopropanol, laboratory grade, for cleaning the apparatus. • Talcum Powder, Pipette capable of dispensing 0.1 ml, Stop Watch <i>Test method reference: Annex D of IS 16289:2014</i>
4	Sub-micron particulate filtration efficiency	Aerosol test system consisting of clean, dry compressed air supply, HEPA filters, aerosol generator, charge neutralizer, humidifier, test filter holder and duct assembly, pressure drop measuring device, air flow rate measuring device, temperature and humidity detectors and optical particle counters, Latex Suspension, Oscilloscope. <i>Test method reference: Annex E of IS 16289:2014</i>
5	Conditioning	Conditioning chamber to condition at 21 ± 5 °C, $85 \pm 5\%$ RH for test at SI No 1 and at 27 ± 2 °C, $65 \pm 2\%$ RH for tests at SI No 3 and 4 Barometer
Note: The above list is indicative only and may not be treated as exhaustive.		

ANNEXURE-C

SCHEME OF INSPECTION AND TESTING FOR Medical Textiles — Surgical Face Masks ACCORDING TO IS 16289:2014

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.

The manufacturer shall prepare and implement 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. PACKING AND MARKING- The Standard Mark as given in the schedule of the licence shall be indelibly marked on the mask and its packages along with the other marking details as required by the standard. Packing and Marking shall be done as per the provisions of the Indian Standard. The following shall be marked in (addition -

a) The BIS licence number

b) The phrase 'Please see www.bis.gov.in for BIS certification details'. *

**In case of space constraints, (b) may be marked only on the package*

4. TEST CERTIFICATE- Each consignment of surgical face masks 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. CONTROL UNIT – For the purpose of this scheme, all surgical masks of the same class and produced in one day shall be considered as a control unit.

6. 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.

6.1 All the production which conforms to the Indian Standard and covered by the licence should be marked with Standard Mark.

7. 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
LEVELS OF CONTROL**

Test Details (1)				(2)	Levels of Control (3)		
Cl.	Requirement	Test Methods		Test equipment requirement R: required (or)S: Sub-contracting permitted	No. of Samples	Frequency	Remarks
		Clause	Reference				
4.1	Materials, construction and Design	4.1	IS 16288	R	Based on lot size as per column 3 of Table 2 of IS 16289	Every 7 th control unit	
4.2	Bacterial Filtration Efficiency	4.2	IS 16288	S	5	Each 15 th control unit	
-do-	Differential Pressure	Annex C	IS 16289	R	5	Every 7 th control unit	
-do-	Splash Resistance	Annex D	-do-	R	5	-do-	
-do-	Sub-micron particulate filtration efficiency at 0.1 μ	Annex E	-do-	S	5	Each 15 th control unit	
Note 1: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empaneled by the Bureau. Note 2: 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 to BO head.							