PM/17788/1
Jan 2024

www.bis.gov.in

उत्पाद मैन्युअल
चिकत्सीय वस्त्रादि - वाइप्स के लिए बिना बुना हुआ कपड़ा

IS 17788:2021 के अनसार

PRODUCT MANUAL
FOR Medical Textiles — Nonwoven Fabric for Wipes — Specification ACCORDINGTO IS 17788:2021

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 various products. The document may also be used by prospective applicants desirous of obtaining BIS certification.

1.	**मानक संख्या** **IS No.**	:	IS 17788:2021
	शीर्षक **Title**	:	Medical Textiles — Nonwoven Fabric for Wipes — Specification
	संशोधनों की संख्या **No. of amendments**	:	NIL
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	The non-woven fabric (spunlace or spunbond or combination of both) shall be manufactured from cotton or viscose or blends of cotton, viscose, bamboo, polyester and polypropylene fibres. Manufacturer shall submit a declaration confirming compliance to the above clause 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**	:	The manufacturer shall declare each unique blend composition of fabric (e.g. 100% cotton or 20% cotton, 80% polyester blend) and one sample of each such unique blend composition shall be tested
c)	**नमूने का आकार Sample Size**	:	350 grams 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)
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 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 17788:2021 with the following scope:		
	Name of the product	Medical Textiles — Nonwoven Fabric for Wipes	
	Blend composition	(e.g. 100% cotton or 20% cotton, 80% polyester blend, etc.)	

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

ANNEX – A

LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests used in with Clause Reference		Test Equipment
	Tests	**Cl. Ref.**	
1.	Fibre Identification	6.1	Relevant methods to be used for quantitative analysis as per IS 667
2.	Weight per square meter	6.1	• Apparatus for cutting the test pieces (Die, at • least 50 000 mm sq. / Template • Steel rule • Razor blade • Weighing Balance
3.	Absorption Test (a) Sinking Time (b) Water Holding Capacity	6.1	• Cylindrical wire basket (as per IS 15891(Part 6): 2012) • Stopwatch. • Container for liquid • Weighing Balance (LC – 0.01 g) • Wire gauze test piece support (at least 120 mm x 120 mm, with a metal frame and 2 mm nominal mesh size in accordance with ISO 565) • Clips • Dish, for containing the wire gauze • weighing glass, with cover • Specified liquid (as per agreement)
4.	Breaking strength (dry and wet)	6.1	• Tensile testing machine • Clamps and jaw faces • Non-ionic wetting agent (for wet testing)
5.	pH	6.1	• pH-meter with a glass electrode (LC-0.01 pH-units) • Stoppered glass or polypropylene flasks, Beakers (150 ml) • Weighing Balance (LC – 0.01 g) • Mechanical shaker • Glass Rods • 1 L Volumetric Flasks

ANNEX B

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: Entire quantity of non-woven fabric of the same blend manufactured under similar conditions from the same consignment of raw materials 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 facilities or get testing done from BIS recognized/empaneled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.3 **Large Scale manufacturers shall maintain an in-house laboratory equipped at least with test facilities for routine tests (indicated as "R" in Column 2 of Table 1)**, where different tests given 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 laboratory or 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 roll of non-woven fabric 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**: The material shall also be marked with the following additional requirement on each roll of non-woven fabric:

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

4. HYGIENIC CONDITIONS - Nonwoven Fabric for Wipes shall be produced under hygienic conditions.

5. 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
(ONLY FOR GUIDANCE PURPOSE)

(1)			(2)	(3)		
Clause	**Requirements**	**Test Method**	**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**No of Samples**	**Frequency**	**Remarks**
4	Material	IS 17788	R	Firm to have adequate in-process controls to check compliance of this parameter as per the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		
5	Workmanship and Finish	IS 17788	R	Firm to have adequate in-process controls to check compliance of this parameter as per the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		
6.1	Fibre Identification	IS 667	R	One	Each Consignment	
6.1	Weight per square meter	IS 15891 (Part 1)	R	One	Each Control unit	
6.1	Absorption (Sinking time)	IS 15891 (Part 6)	R	One	Each Control unit	
6.1	Absorption (Water holding capacity)	IS 15891 (Part 6)	R	one	Each Control unit	
6.1	Breaking Strength (Dry)	IS 15891 (Part 18)	R	Once	Each Control unit	
6.1	Breaking Strength (Wet)	IS 15891 (Part 18)	R	One	Each Control unit	
6.1	pH	IS 1390	R	One	Each Control unit	