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उत्पाद मैन्युअल
चिकित्सीय वस्त्रादि - बिना बुने हुए वाइप्स - विशिष्टि

IS 17787:2021 के अनसार

PRODUCT MANUAL
FOR Medical Textiles — Nonwoven Wipes — Specification
ACCORDINGTO IS 17787:2021

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 17787:2021
	शीर्षक **Title**	:	Medical Textiles — Nonwoven Wipes — Specification
	संशोधनों की संख्या **No. of amendments**	:	NIL
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	The non-woven fabric used for manufacture of wipes shall confirm to IS 17788 : 2021. (Cl. 4) Conformity may be established through test certificate of supplier or test report from BIS recognized/empanelled lab or any other accredited lab or in –house testing or combination thereof. No testing is required if fabric is ISI marked. 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**	:	Samples of any length and width may be tested to cover the entire range of length and width being manufactured, provided facilities exist. In case anti-bacterial properties are intended to be claimed and covered in scope, samples shall be tested for anti-bacterial activity.
c)	**नमूने का आकार Sample Size**	:	15 packets (70-80 wipes per packet) 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**		
	Seal Leakage test, Length and Width and pH. 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 17787:2021 with the following scope:		
	Name of the product		Medical Textiles — Nonwoven Wipes
	Sizes (Length and Width)		
	Antibacterial Activity (optional)		*With or without*

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN,9, BAHADUR SHAH ZAFAR MARG,
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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.	Length and width, mm	6.1	• Measuring scale with L.C. 1 mm
2.	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
3.	Total viable Count	6.1	• General Apparatus, Equipment and media used in microbiological labs as per Cl. 3.2 of IS 14648 • Colony Counter. • *Neutralizing Diluents* (Fluid casein digest — soy lecithin — polysorbate 20 medium (SCDLP 20 broth)/Eugon LT 100 broth/D/E neutralizing broth/Modified Latheen broth/Inactivating Diluent. It is generally recommended to use a universal neutralizing agent, for example, D/E neutralizing broth) • *Diluents* (Peptone broth/neutrient broth) • *Culture Media* [For Total Microbial Count - Soyabean casein digest medium (Trypticase Soy agar/TSA) & for yeast & mould count – Sabourauds Dextrose agar/Potato Dextrose agar. • Incubator (30 – 35 Deg C) • Incubator (20 – 28 Deg C) • Refrigerator

4.	Pseudomonas Aeruginosa	6.1	• General Apparatus, Equipment and media used in microbiological labs as per Cl. 3.2 of IS 14648 • *Diluents & Culture media* *[* (a) Enrichment broth — Eugon LT 100 broth or any other validated neutralizing enrichment medium, b) Selective agar for isolation — Cetrimide agar medium, and c) Selective agar for confirmation — Pseudomonas agar medium for detection of pyocyanin and pyorubin. • *Strains of microorganism* [For validation of the test conditions, Pseudomonas aeruginosa ATCC 9027 standard indicator test strain shall be used]. • Incubator (30 – 35 Dec C) • Sterile loop • *Confirmation of Pseudomonas Aeruginosa* [Gram's Stain, Oxidase Test and Culture on PA medium for detection of pyocyanin].
5.	Staphylococcus aureus	6.1	• General Apparatus, Equipment and media used in microbiological labs as per Cl. 3.2 of IS 14648 • *Diluents and Culture Media* [a) Enrichment broth — Eugon LT 100 broth/ Fluid soyabean casein digest medium/D/E neutralizing broth/Modified latheen broth. b) Selective agar medium for isolation of Staphylococcus aureus — Baird Parker Agar/ Mannitol salt agar medium/Vogel Johnson agar medium] • *Strains of Micro-Organisms* [For validation of the test conditions, Staphylococcus aureus ATCC 6538/6538P standard indicator test strain shall be used. • Incubator (30 – 35 Deg C) • Baird Parkar Agar.

6.	Candida albicans	6.1	• General Apparatus, Equipment and media used in microbiological labs as per Cl. 3.2 of IS 14648 • *Diluents and Culture Media* [a) Enrichment broth — Eugon LT 100 broth/ Fluid soyabean casein digest medium/ Modified latheen broth/Glucose and peptone added lecithin polysorbate medium/D/E neutralizing broth/Soyabean casein digest lecithin polysorbate 80 medium. b) Selective agar medium for isolation of C. albicans — Sabouraud dextrose chloramphenicol agar/Potato dextrose agar with antibiotics/BIGGY Agar. c) Selective agar medium for identification of C. albicans — Corn meal agar with 1 percent polysorbate 80. • *Strains of micro-organisms* [For validation of the test conditions, Candida albicans ATCC 10231 standard indicator test strain shall be used].

7.	E-Coli	6.1	• General Apparatus, Equipment and media used in microbiological labs as per Cl. 3.2 of IS 14648 • *Diluents and Culture Media* [a) Enrichment broth — Eugon LT 100 broth/ Fluid lactose medium with neutralizing and dispersing agents/Fluid lactose medium/ Modified letheen broth/D/E neutralizing broth/Soyabean casein digest lecithin polysorbate 80 medium. b) Selective agar for isolation — MacConkey agar medium. c) Selective agar for confirmation — Levine Eosin — Methylene Blue agar medium] • *Strains of Micro-Organisms* [For validation of the test, use Escherichia coli ATCC 8739 standard indicator test strain. • Incubator (30 0 35 Deg C)
8.	Anti-bacterial activity (optional), absorption method	6.1	• Inoculation loop • Petri dish • Incubator • Refrigerator • Nutrient broth/Tryptone Soya broth • Erlenmeyer Flask (100 ml) • Weighing Balance of LC 0.01 g • spectrophotometer or McFarland's nephelometer. • Glass Rod • Vials with cap • Autoclave • Aluminium Foil
9.	Seal Leakage Test	6.3	• leakage test apparatus with vacuum pump. • pressure measuring device. • Stopwatch.

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 wipes made from the same consignment of raw material under similar conditions in one 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 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 theprovisions 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 legibly and indelibly on each packet containing wipes 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 additionalrequirement on each packet containing wipes:

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

4. HYGIENIC CONDITIONS – Hygienic conditions shall be maintained while producing nonwoven wipes.

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	One	Each Consignment	Conformity may be established through test certificate of supplier or test report from BIS recognized/empanelled lab or any other accredited lab or in – house testing or combination thereof. No testing is required if fabric is ISI marked.
5	Workmanship & Finish	IS 17787	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		
6.3	Seal Leakage Test	IS 17787	R	Ten	Each Control unit	
6.1	Length and Width	IS 17787	R	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		
6.1	pH	IS 1390	R	One	Each Control unit	
6.1	Total Viable Count	IS 14648	R	One	Once in a week	
6.1	Pseudomonas aeruginosa	IS 14648	R	One	Once in a week	
6.1	Staphylococcus aureus	IS 14648	R	One	Once in a week	
6.1	Candida albicans	IS 14648	R	One	Once in a week	
6.1	E. Coli	IS 14648	R	One	Once in a week	
6.1	Anti-Bacterial Activity (Optional)	IS/ISO 20743	S	As agreed between purchaser and supplier		