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उत्पाद मैनुअल

**MEDICAL TEXTILES — PERMEABLE
NONWOVEN SURGICAL ADHESIVE
TAPE — SPECIFICATION IS 16948: 2018
के अनुसार**

**PRODUCT MANUAL
FOR MEDICAL TEXTILES —
PERMEABLE NONWOVEN SURGICAL
ADHESIVE TAPE — SPECIFICATION
ACCORDING TO IS 16948: 2018**

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 16948: 2018
	शीर्षक Title	:	MEDICAL TEXTILES — PERMEABLE NONWOVEN SURGICAL ADHESIVE TAPE — SPECIFICATION
	संशोधनों की संख्या No. of amendments	:	NIL
2.	नमूना दिशानिर्देश Sampling Guidelines		
a)	कच्चा माल Raw material	:	<i>No Specific Requirements</i> 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	:	i. Permeable nonwoven surgical adhesive tape of maximum width shall be tested to cover all the declared widths in the scope of licence. ii. Permeable nonwoven surgical adhesive tape with perforations shall be tested separately to be included in the scope of licence.
c)	नमूने का परिमाण Sample Quantity	:	10 Roll 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	:	– Optional Requirements – Width 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 to Annex-A
4.	निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing	:	Please refer to Annex-B
5.	एक दिन में संभावित परीक्षण Possible tests in a day		
	All tests are possible to be carried out in a day except Water vapour permeability, provided that the conditioned samples are available. 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 16948: 2018 with the following scope:		
	Name of the product		MEDICAL TEXTILES — PERMEABLE NONWOVEN SURGICAL ADHESIVE TAPE
	Widths		To be declared
	Optional Requirement		With/Without perforations

ANNEX–A

LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests Used In With Clause Reference	Test Equipment/Chemical
1.	Weight of backing material, Clause 5.1 & Table 1	– Analytical Electronic Balance – Measuring Scale/ Measuring Tape – Hot Air Oven – Sieve having aperture of 106 micrometer – Paper Cutter/Scissor – Petroleum spirit (boiling range- 40-60°C) – Chloroform – Acetic Acid
2.	Weight of adhesive mass, Clause 5.1 & Table 1	– Analytical Electronic Balance – Measuring Scale/ Measuring Tape – Hot Air Oven – Sieve having aperture of 106 micrometer – Paper Cutter/Scissor – Petroleum spirit (boiling range- 40-60°C) – Chloroform – Acetic Acid
3.	Water vapour permeability, Clause 5.1 & Table 1	– Analytical Electronic Balance – Measuring Scale/ Measuring Tape – Electrically Heated Humidity Cabinet (Conditioning Chamber) – Non-corrodible Box in accordance with clause 6.9.1.1 of IS 14944 – Paper Cutter/Scissor – Anhydrous Calcium Chloride – Absorbent Cotton
4.	Adhesiveness, Clause 5.1 & Table 1	– Analytical Electronic Balance – Measuring Scale/ Measuring Tape – Universal Testing Machine – Hot Air Oven – Stainless Steel Plates – Roller – Stopwatch
5.	Width of the tape, Clause 5.1 & Table 1	– Measuring Scale/ Measuring Tape

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: Permeable Nonwoven Adhesive Tapes of particular width (with/without perforations) manufactured under similar conditions of production 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 pack, 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 pack:

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

4. HYGIENIC CONDITIONS – The manufacturing and preparation of the adhesive tapes shall be conducted under proper 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)		
Test Details				Test equipment requirement R: required (or) S: Sub- contracting permitted	Levels of Control		
Clause	Requirements	Test Method			No of Sample s	Frequency	Remarks
		Clause	Ref.				
5.1 & Table 1	Weight of backing material	6.4	IS 14944	R	One	Each Control Unit	
5.1 & Table 1	Weight of adhesive mass	6.4	IS 14944	R	One	Each Control Unit	
5.1 & Table 1	Water vapour permeability	6.9	IS 14944	R	One	Each Control Unit	
5.1 & Table 1	Adhesiveness	6.8	IS 14944	R	One	Each Control Unit	
5.1 & Table 1	Width of the tape	5.1	IS 16948	R	One	Each Control Unit	
5.1 & Table 1	Perforations (optional)	5.1	IS 16948	R	One	Each Control Unit	