



उत्पाद मैनुअल
रैन्फोर्सिंग के बिना अस्पताल रबड़ शीटिंग — विशिष्टि
IS 8164: 2023 के अनुसार

PRODUCT MANUAL FOR
HOSPITAL RUBBER SHEETING WITHOUT REINFORCING FABRIC
SPECIFICATION ACCORDING TO IS 8164: 2023

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 8164:2023
	शीर्षक Title	:	HOSPITAL RUBBER SHEETING WITHOUT REINFORCING FABRIC
	संशोधनों की संख्या No. of amendments	:	01
2.	नमूना दिशानिर्देश Sampling Guidelines		
a)	कच्चा माल Raw material	:	Materials shall conform to the requirements of Cl. 3.1 of IS 8164:2023. Conformity shall be established through supplier's test certificates, or test reports issued by BIS recognized/empaneled labs or any other accredited lab, or in house testing, or combination thereof. 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	:	Not applicable (standard does not classify the product into any varieties)
c)	नमूने का परिमाण Sample Quantity	:	5 meters' length in Full width 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 to Annex- A देखें
4.	निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing	:	Please refer to Annex- B देखें
5.	एक दिन में संभावित परीक्षण Possible tests in a day		
	Workmanship & Finish, Length and Width, thickness 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 readyreference 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:		
	8164:2023 के अनुसार मानक मुहर का उपयोग करने के लिए लाइसेंस निम्नलिखित कार्यक्षेत्र के लिए प्रदान किया जाता है “ Licence is granted to use Standard Mark as per IS 8164:2023 with the following scope:		
7.	उत्पाद का नाम Name of the product		HOSPITAL RUBBER SHEETING WITHOUT REINFORCING FABRIC

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)

Major test equipment required to test as per requirements of Indian Standard.

Sl. No.	Tests used in with Clause Reference	Test Equipment
1	Thickness (Clause 3.1.3)	- Thickness Gauge
2	Workmanship & Finish (3.2)	- Inspection Table
3	Mass (I of Table 1)	- Weighing balance - Scale - Humidity Chamber
4	Tensile Strength (Sl. No. ii of Table 1) & Elongation at Break (Sl. No. iii of Table 1)	- Tensile Testing Machine - Dumb-bell Die & cutting machine
5	Tension Set at 250% elongation and 15mm recovery time (Sl. No. iv of Table 1)	- Tensile Testing Machine or Straining device as per IS 3400 (Part 13) - Die and cutting machine for cutting strip test pieces with enlarged end - Oven with air flow - Scale
6	Hardness (Shore A) (Sl. No. v of Table 1)	- Durometer of appropriate types (A, AO, D, AM) as per IS 3400 (Part 23/Sec 1) : 2018
7	Accelerated ageing at 70 °C for 168 hours in air oven (Sl. No. vi of Table 1) a) Change in tensile strength b) Change in elongation	- Ageing Oven with hour meter & Digital Thermometer - Tensile Testing Machine
8	Water Proofness under 300mm Head of water (Sl. No. vii of Table 1)	- Hydrostatic Test Arrangement with means to measure water pressure (manometer/pressure gauge)
9	Colour fastness to washing (Sl. No. viii of Table 1)	- Suitable mechanical laundering device - Balance accurate to ± 0.01 g - Mechanical stirrer minimum $16,667 \text{ s}^{-1}$ (1000 r/min.), Stainless steel balls - Hot plate - Reagents and materials (soap solution, sodium carbonate, adjacent fabrics etc.)

10	Colour fastness to light (Sl. No. ix of Table 1)	- Blue wool reference materials, humidity-test control fabric, - Laboratory exposure devices
11	Autoclave test (Sl. No. x of Table 1) a) Change in Tensile Strength b) Change in elongation c) Change in Hardness (Shore	- Autoclave with means to determine steam pressure level (i.e. pressure gauge) - Tensile Testing Machine - Durometer of appropriate types (A, AO, D, AM) as per IS 3400 (Part 23/Sec 1) : 2018
12	Reaction of aqueous extract (Sl. No. xi of Table 1)	- Weighing balance - Chemically resistant glass flask - Water cooled reflex condenser with ground glass connection, measuring cylinder - Heating mantle/Hot plate - Methyl orange and phenolphthalein
13	Resistance to detergents and disinfectants (Sl. No. xii of Table 1)	- Phenol - Ammonia Solution - Soap Solution - Thermometer - Hot plate
14	Heavy metals (Sl. No. xiii of Table 1) a) Pb b) Hg c) Cr d) As e) Cd	- ICP-OES spectrometer as per ISO 19050 : 2015
15	Polycyclic aromatic Hydrocarbon (Sl. No. xiv of Table 1) a) Benzo(a) pyrene (BaP), b) Sum of PAH	- GC/MS as per EN 16143
16	N-Nitrosamines (Sl. No. xv of Table 1)	<u>Reagents:</u> Sodium Hydrogen Carbonate, Sodium Chloride, Potassium Carbonate, Sodium Nitrite, Hydrochloric Acid Solution — 0.1 M, 6 Sodium Hydroxide Solution — 0.1 M, n-Hexane, Hydrochloric Acid Solution, Sodium Hydroxide Solution, Purified Nitrogen, Anti-Bumping Granules, Sintered Glass Frits for Columns, Acetone, or other suitable solvent., Standard Solutions of N-Nitrosamines, Internal standard solution of N-Nitrodiisopropylamine (NDiPA), free from other N-Nitrosamines, 200 ng/ml in the acetone or other suitable solvent, Anhydrous Sodium Sulphate, (granular) or suitable Whatman phase separating filter. Ammonia Solution, Sand, Acid Washed and Calcined <u>Apparatus:</u> Normal Laboratory Apparatus, Oven, maintained at a

		temperature of $40 \pm 2^{\circ}\text{C}$, Glass Column with Outlet and PTFE Stopper, Kuderna - Danish (K-D) Evaporative Flask and Concentrator, Water Bath, capable of maintaining temperatures in the range 40°C to 60°C, Ampoules, Sealing Tongs for the Ampoules, Glass Wool, Washed with the, Dichloromethane, Separating Funnel, 200 ml, Separating Funnel, 100 ml, Chemiluminescence Detector, of adequate sensitivity (Thermal Energy Analyzer), Gas Chromatograph (GC) See Annex G of IS 3565
17	Length and Width	- Table of min. 5 meter length and width of 50mm more than specified width - Steel scale

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: all the finished sheeting manufactured from same batch of raw material vulcanized under similar conditions 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 piece of rubber sheeting, 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 piece of rubber sheeting:

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

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
(ONLY FOR GUIDANCE PURPOSE)

(1)				(2)	(3)		
Test Details				Test equipment requirement R: required (or) S:Sub-contracting permitted	Levels of Control		
Cl.	Requirement	Test Methods			No. of Sample	Frequency	Remarks
		Clause	Reference				
3.1	Material	3.1, 3.1.1	IS 8164	S	One	Each consignment	No testing required if accompanied by supplier's test certificates
3.1.2	Colour	3.1.2	IS 8164	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.		
3.1.3	Thickness	3.1.3	IS 8164	R	3	Each Control unit at equal intervals	
3.2	Workmanship & Finish	3.2	IS 8164	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.		
3.3 & Table 1	Requirements for Hospital Rubber Sheeting Without Reinforcing Fabric						
-do-	i) Mass	--	IS 7016 (Part 1/Sec 1)	R	1	Each control unit	-
-do-	ii) Tensile Strength	--	IS 3400 (Part 1)	R	1	Each control unit	The thickness of the test specimen shall be same as single thickness of the product.
-do-	iii) Elongation at break, percent, Max	--	IS 3400 Pt 1	R	1	Each control unit	

-do-	iv) Tension set at 250 percent elongation and 15 min recovery time, percent, Max	--	IS 3400 (Part 13),	R	1	Once in a month	Using strip test pieces with enlarged ends and of thickness same as single thickness of the product.
-do-	v) Hardness (Shore A)	--	IS 3400 (Part 23/ Sec 1)	R	1	Each control unit	
-do-	vi) Accelerated ageing at 70 °C for 168 hours in air oven a) Change in tensile strength from original, percent Max Change in elongation at break from original percent, Max	--	IS 3400 (Part 4)	R	1	Once in a month	
-do-	vii) Waterproofness under 300mm head of water	--	IS 7016 (Part 7)	R	1	Each control unit	
-do-	viii) Colour fastness to washing	--	IS/ISO 105C10	S	1	Once in six months	Also whenever there is a change in the material and/or the supplier
-do-	ix) Colour fastness to light	--	IS/ISO 105 : B01	S	1	Once in six months	
-do-	x) Autoclaving test a) Change in tensile strength from original, percent Max b) Change in elongation at break from original percent, Max c) Change in Hardness (Shore A)	--	Annex A of IS 8164, IS 3400 (Part 4)	R	1	Once in a week	
-do-	xi) Reaction of aqueous extract	Annex B	IS 8164	R	1	Once in a month	
-do-	xii) Resistance to detergents and disinfectants	Annex C	IS 8164	R	1	Once in a month	

-do-	xiii) Heavy metals, ppm, Max a) Pb b) Hg c) Cr d) As Cd	--	ISO 19050	S	1	Once in six months	Also whenever there is a change in the material and/or the supplier
-do-	xiv) Polycyclic aromatic hydrocarbon a) Benzo(a) pyrene (BaP) b) Sum of PAH2),	--	EN 16143	S	1	Once in six months	
-do-	xv) N-Nitrosamines,	Annex G	IS 3565	S	1	Once in six months	
3.4	Length & Width	3.4	IS 7016 Pt 1	R	3	Each Control unit at equal intervals	Length on each roll Width – three times
3.5	Preservation	3.5	IS 8164	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.		