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उत्पाद मैन्युअल

Medical Textiles – Underpad – Specification

IS 17786: 2022 के अनुसार

PRODUCT MANUAL
FOR Medical Textiles – Underpad – Specification
ACCORDING TO
IS 17786:2022

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 17786:2022
	शीर्षक **Title**	:	Medical Textiles – Underpad - Specification
	संशोधनों की संख्या **No. of amendments**	:	NIL
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	The raw material shall be conforming to the requirements specified in clause 4 of IS 17786: 2022. The Conformity of raw materials to the standard may be established through supplier's test certificate, test report of BIS recognized/empanelled lab or any other NABL accredited lab or through in house testing. 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**	:	*Please refer to Annex-A*
c)	**नमूने का परिमाण** **Sample Quantity**	:	*50 Pieces* 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**	**:**	i) Type ii) Size iii) Optional Requirements 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-B
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	Please refer to Annex-C
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**		
	Following tests are possible to be carried out in a day, provided that the conditioned samples are available: i. Types & Sizes ii. Manufacture, workmanship and finish iii. pH Value iv. Minimum Absorption Capacity 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 17786: 2022 with the following scope:		
	Name of the product	Medical Textiles – Underpad	
	Type	Single use / Re-useable	
	Size	Small / Medium /Large / X Large	
	Optional requirements	With/Without Biocompatibility Evaluation	

Annex-A
Grouping Guidelines

1. Underpads may be of two types:
   i) Single use
   ii) Re-useable

2. Further, four sizes of underpads have been defined in the Standard:
   iii) Small
   iv) Medium
   v) Large
   vi) X Large

3. In addition to above, optional requirement of Biocompatibility Evaluation has also been defined in the Standard.

4. Considering the above, following grouping guidelines have been prepared for GOL/CSOL:

i) Sample of each type of underpads (Single/Re-useable) shall be drawn and tested to be covered in the scope of licence.

ii) Sample of underpads of any size may be drawn and tested to cover all the sizes of particular type in the scope of licence

iii) To cover optional requirements of Biocompatibility evaluation in the scope of licence, sample shall be tested for the optional requirements additionally.

iv) If underpads with optional requirements are tested, then underpads without optional requirements may also be covered in the scope of licence.

v) If underpads having dimensions other than those specified in Table 1 (Dimensions of Underpad) of IS 17786: 2022 are intended to be covered in the scope of licence, the same shall be declared by the manufacturer.

vi) The scope of the license shall be restricted based on the manufacturing and testing facilities available.

vii) During operation of the license, samples of each variety covered in the scope of license shall be tested in rotation to the extent possible.

ANNEX–B

LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests Used In With Clause Reference	Test Equipment/Chemical
1	**Sizes,** Clause 5 & Table 1	- Vernier caliper - Steel scale
2	**pH Value**, Clause 8.1	**Reagents:** - Distilled or deionized water - Potassium chloride sol. (0.1mol/l) - Buffer solutions (Having pH around 4, 7 or 9) **Apparatus:** - pH-meter (with glass electrode, capable of measuring to at least 0.1pH units) - Mechanical shaker - Weighing Balance (accurate to 0.01 g) - Beakers (150ml) - Volumetric flasks(1L) - Stoppered glass or polypropylene flasks - Thermometer
3	**Minimum Absorption Capacity**, Clause 8.2 & Table 2	- Test liquid, *c*(NaCl) = 9.0 g/l, prepared at 23°C ± 2°C, comprising grade 3 distilled water as specified in ISO 3696, containing 9.0 g/l sodium chloride as specified in ISO 6353-2 - Reservoir, of dimensions not less than the length and width of the urine-absorbing containing test liquid to a depth of 100 mm (Internal dimensions of 900 mm × 600 mm × 150mm) - Drainage screen (made of rods of 3 mm + 0,25 mm diameter welded together to form a square grid with 25 mm + 1 mm between rod centres) of length and width 20 mm less than the internal dimensions of the reservoir - Drainage material of the same length and width as the drainage screen and of minimum internal depth 25 mm - Balance, capable of measuring the dry mass of the urine-absorbing aid under test to the nearest 0.1 g - Balance, capable of measuring the mass of the tared drainage tray and the wet urine-absorbing aid under test to the nearest 1 g - Conditioning Chamber
4	**Absorption Time,** Clause 8.2 & Table 2	- Stainless Steel Dosing Ring - Total Weight, 315 to 320 g, total height:4.2 inch. - Inner Diameter, 1.9-inch, outer diameter

		(top):2.00 inch. - Test Solution, of 0.9 percent NaCl solution (37 + 1°C) of pH 6.0 to 7.0 - Pipette, of 30 ml volume to accurately adjust the volume of fluid for the test. - Stop Watch - Separating Funnel - Conditioning Chamber
5	**Retention Capacity,** Clause 8.2 & Table 2	- Cylindrical copper wire basket - 80mm high & 50mm in diameter - Fabricated from wire of diameter 0.4mm - Mesh aperture of 15-20mm - Basket shall weigh 2.4-3.0g - Conditioning Chamber
6	**Bacterial and Fungal Bioburden**, Clause 8.3.1	**Reagents:** - Plate count agar (PCA) - Sabouraud chloramphenicol agar (SCA) - Sodium chloride (0.85%) **Apparatus:** - Autoclave - Hot air oven, - Incubator (30-350°C) - Incubator (20-250°C) - pH meter - Water bath - Colony counter - Laminar Air Flow - Mechanical Shaker - Petri dishes - Flasks/bottles Test tubes
7	**Test for Common Skin Pathogen—Staphylococcus Aureus,** Clause 8.3.2	**Reagents:** - Cooked salt medium - Baird Parker medium - Blood agar - Citrated Rabbit plasma - Nutrient agar - Normal saline water - Gram's Stain kit, **Apparatus:** - Autoclave - Hot air oven, - Incubator (370°C) - pH meter - Water bath, - Laminar Air Flow - Microscope - Mechanical shaker - Petri dishes - Glass Slide - Test Tubes (Narrow) - Straight nichrome wire

8	**Biocompatibility Evaluation - Cytotoxicity, Irritation and Skin Sensitization (optional),** Clause 8.4	**<u>Cytotoxicity Test</u>** - Closed containers for extraction of sample - Extraction vehicle - pH meter - Water bath - Incubator (37±1°C) humidified 5% CO_2/air. - Microscope - Laminar flow cabinet (Biological hazard standard). - Shaker for microstate plates. - Cell counter or hemacytometer. - Weighing Balance - Air conditioner - Petri dishes - Pipetting aid. - Pipettes (8-channel pipettes, dilution block) - Cryotubes. - Tissue culture flasks (80 cm^2, 25 cm^2) - 96-Well tissue culture microtitre plates. - Culture medium to prevent absorption - Cell lines - Negative control material (High-density polyethylene) - Positive control material (Sodium Lauryl Sulphate (SLS) - Reference materials - Dulbecco's Modification of Eagle's Medium (DMEM), without L- glutamine - Newborn calf serum (NBCS) - Phosphate-buffered saline (PBS), without Ca2+ and Mg2+ (for trypsinization) Phosphate-buffered saline (PBS), with Ca2+ and Mg2+ (for rinsing) - HEPES(4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid) - Dimethyl sulfoxide (AR Grade). - L-glutamine (200 mM) - Trypsin/EDTA solution - Nutrient agar - Cell culture media - Penicillin/streptomycin solution - Mouse fibroblasts - Agarose overlay - Neutral red - Ethanol (AR Grade) - Glacial acetic acid (AR Grade) - Distilled water **<u>Tests for Irritation and Skin Sensitization</u>** - Rotary evaporator - pH meter - Pipetting aid - Weighing Balance - Shaker,

		- Flasks - Incubators - Petri dishes - Pipetting aid - Air conditioner - Pulverizing or grinder apparatus - Extraction vial (borosilicate glass tubes with caps) - Absorbent gauze patch (non-occlusive dressing) - Marker with permanent ink. - Extract vehicle - Full-spectrum lighting source - Soft catheter or blunt-tipped cannula - Occlusive chamber containing a gauze pad. - Vernier caliper - Non-irritating dressing - Non-irritating tape - Gauze pad - Spectrophotometer - Bandage (semi-occlusive or occlusive) - Water or non-irritant solvent - Methanol - Acetone - Physiological saline - Vegetable oil - Ethylene oxide - Freund's complete adjuvant (FCA) - Cytotoxic marker chemicals (Sodium dodecyl sulphate) - Vital dyes - Tissue culture medium - Distilled or Deionized water - NaCl (0.9 %) - MTT Sol. (0.3 mg/ml to 1 mg/ml) - Isopropanol - Olive oil - Dimethylsulfoxide (DMSO) - *n*-hexane - Ethanol - Hapten - Lubricant - Positive control (Sodium Lauryl Sulphate (SLS) - Negative control (Non-irritant, Absorbent gauze)

ANNEX-C

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 Underpads of particular type, size & shape with/without optional requirements produced using same raw material & under similar conditions of manufacture 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 of underpads, 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 of underpads:

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

4. HYGIENIC CONDITIONS (if applicable) – The underpads shall be manufactured under good hygienic conditions. The general guidelines for good manufacturing practice to maintain hygiene requirements at a manufacturing facility are given in Annex D of IS 17786:2022.

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**		
Cl.	Requirement	Test Methods			No. of Sample	Frequency	Remarks
		Clause	Reference				
4	Material	4	IS 17786	S	One	Each Consignment	
5	Type & Sizes	5	IS 17786	R	Firm to have adequate in-process controls to check compliance of this parameter as per the requirements specified in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity.		
6	Workmanship & Finish	6	IS 17786	R			
8.1	pH	--	IS 1390	R	One sample	Each control unit	
8.2	Minimum Absorption Capacity	--	ISO 11948	R	One sample	Each control unit	
-do-	Absorption Time	Annex-B	IS 17786	R	One sample	Each control unit	
-do-	Retention Capacity	Annex-C	IS 17786	R	One sample	Each control unit	
8.3	**Hygiene Testing Requirement**						
8.3.1	Bacterial and Fungal Bioburden	8.3.1	IS 17786 & IS 11737 (Part 1)	S	The manufacturer shall perform the hygiene testing for the final product every quarter for monitoring purpose and whenever there is a change in the raw material, manufacturing premises, and the supplier of the raw material.		
8.3.2	Test for Common Skin Pathogen – Staphylococcus Aureus	8.3.2	IS 17786 & IS 5887 (Part 2)	S			
8.4	Biocompatibility Evaluation - Cytotoxicity, Irritation and Skin Sensitization (optional)	8.4	IS/ISO 10993 Part 5, IS/ISO 10993 Part 10 & ISO 10993 Part 12	S	The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material for manufacturing the product (if applicable).		