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उत्पाद मैनुअल
चिकित्सीय वस्त्रादी - दंतचिकित्सीय
बिब / नैपकिन - विशिष्टि
IS 17354: 2020 के अनुसार

PRODUCT MANUAL
FOR Medical Textiles – Dental
Bib/Napkins – Specification
ACCORDING TO IS 17354: 2020

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.	मानकसंख्या IS No.	:	IS 17354: 2020
	शीर्षक Title	:	Medical textiles – Dental bib/Napkins – Specification
	संशोधनोंकीसंख्या No. of amendments	:	01
2.	नमूनादिशानिर्देश Sampling Guidelines		
a)	कच्चा माल Raw material	:	The dental bib/napkins shall be made from suitable material that is not prohibited for use for the purpose under any applicable law/regulation in force so that the product made out of this meets the requirements specified in this standard. Further, manufacturer of dental bib/napkins shall submit a declaration identifying the materials being used to make the product and stating that no material that is prohibited for use for the purpose under any applicable law/ regulation has been used. 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)	समूहीकरणदिशानिर्देशGrouping Guidelines	:	Please refer to Annex-A
c)	नमूनेकापरिमाणSample Quantity	:	1 pack containing at least 20 bibs/napkins (multiple packs may be sent in case pack contains less than 20 bibs/napkins) 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	परीक्षणउपकरणोंकीसूचीList of Test Equipment	:	Please refer to Annex-B
4.	निरीक्षणऔरपरीक्षणकीस्कीमScheme of Inspection and Testing	:	Please refer to Annex-C
5.	एक दिन में संभावित परीक्षणPossible tests in a day Workmanship and Finish (Cl. 5.1), Tensile Strength, Water proofness and absorption (Table 1) may be tested in a day if 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.	लाइसेंसकादायरा/Scope of the Licence: “Licence is granted to use Standard Mark as per IS 17354: 2020 with the following scope:		
	Name of the product		Medical textiles – Dental bib/Napkins
	Type		Disposable and/or Reusable
	Sizes/Shapes		As declared by the manufacturer
	Material		As declared by the manufacturer for each type as applicable i.e. Material for Disposable Dental bib/Napkins – Material for Reusable Dental bib/Napkins –

ANNEX-A

GROUPING GUIDELINES

The following grouping guidelines shall apply for Grant of Licence (GoL)/Change in Scope of Licence (CSoL):

1. The manufacturer shall declare the types of materials being used to manufacture dental bibs/napkins (for both types i.e. disposable and reusable) as well as the sizes/shapes of the dental bibs/napkins being manufactured.
2. The manufacturer shall declare the types i.e. disposable and/or reusable Dental bib/Napkins to be covered in the scope of licence. Separate samples of disposable and reusable napkins shall be tested. Absorption is applicable in case of disposable dental bib/napkin only.
3. Samples of each type of material and of any of the sizes/shapes of dental bibs/napkins being manufactured and intended to be covered in the scope of licence, shall be tested.
4. Scope of licence shall be restricted based on the manufacturing and testing facilities available.
5. During the operation of licence, samples of each variety covered I the scope of licence 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	Size and Shape, Cl. 4	Measuring tape, Vernier calipers
2	Water proofness, Cl. 5.2	Apparatus for waterproofness test (See IS14944), conditioning chamber
3	Cleanliness – Microbial, Cl. 5.2	Apparatus, materials, reagents, culture media and incubators as per ISO 11737-1 : 2018 (Sterilization of Health Care Products — Microbiological Methods Part 1 Determination of a Population of Microorganisms on Products) based on the method selected
4	Tensile Strength, Cl. 5.2	Tensile Testing Machine
5	Absorption, Cl. 5.2	<u>Liquid Absorbency Time</u> Cylindrical wire basket, Container for liquid, Specified liquid as per IS 15891 (Part 6) <u>Liquid absorptive capacity</u> Wire gauze test piece support, Dish, Suitable weighing glass with cover, Balance, capable of determining mass to an accuracy of ± 0.01 g, Stopwatch, Specified liquid,

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: entire quantity of dental bib/napkins of the same type (disposable/reusable), size, shape and made from the same consignment of raw material 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/empaneled 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 the dental bib/napkins 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 the dental bib/napkins:

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

4. HYGIENIC CONDITIONS (if applicable) – The manufacture and preparation of the dental bib/napkins shall be conducted under proper hygienic conditions. The manufacturer shall implement a system of maintaining hygienic conditions in the factory and maintain records of activities for maintaining hygienic conditions according to the system.

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 Clause Reference			No. of Sample	Frequency	Remarks
4	Manufacture(Material)	4	IS 17354	-			
5.1	Workmanship and Finish	5.1	IS 17354	R	The manufacture shall put in place adequate inspections/process controls to ensure that the dental bib/napkins are clean and free from substances liable to cause tendering during storage The manufacturer shall also ensure that manufacture and preparation of the dental bib/napkins is conducted under proper hygienic conditions. The manufacturer shall implement a system of maintaining hygienic conditions in the factory and maintain records of activities for maintaining hygienic conditions according to the system		
5.2	Performance requirements						
i)	Water proofness		IS 14944	R	One	Each control unit	
ii)	Cleanliness – Microbial		ISO 11737-1	R	One	Once in a month	
	Tensile Strength (dry and wet)		IS 15891 (Part 3)	R	One	Each control unit	
iv)	Absorption a) Liquid absorbency time b) Liquid absorptive capacity		IS 15891 (Part 6)	R	One	Each control unit	Absorption is applicable incase of disposable dental bib/napkin only.