www.bis.gov.in

उत्पाद मैन्युअल
चिकित्सीय वस्त्रादि - जूते के कवर – विशिष्टि
IS 17349: 2020 के अनुसार

PRODUCT MANUAL
FOR Medical Textiles – Shoe Covers – Specification
ACCORDINGTO IS 17349:2020

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.	**मानक संख्या** **IS No.**	:	IS 17349:2020
	शीर्षक **Title**	:	चिकित्सीय वस्त्रादि - जूते के कवर Medical Textiles – Shoe Covers – Specification
	संशोधनों की संख्या **No. of amendments**	:	01
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	The shoe cover 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. This may be established through the material supplier's test certificate/declaration and/or the declaration of the shoe cover manufacturer 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 Annex - A
c)	**नमूने का परिमाण** **Sample Quantity**	:	20 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 of Material ii. Sizes/Dimensions 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**		
	Manufacture (Cl. 4), Workmanship and Finish (Cl. 5.1), Tensile Strength and Bursting Strength – after conditioning (Cl. 5.2) 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:**		
	IS 17349: 2020 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 17349:2020 with the following scope:		
	उत्पाद का नाम Name of the product	Medical textiles – Shoe covers	
	Type of Material		
	Sizes/Dimensions		

ANNEX-A

GROUPING GUIDELINES

For the purpose of Grant of Licence (GoL)/Change in Scope of Licence (CSoL), the following grouping guidelines shall apply:

Manufacturer shall declare the types of material (e.g. nylon, polypropylene, polyester etc.) used to make shoe covers and the sizes/dimensions of shoe covers.

Shoe covers of each type of material and any size/dimension shall be tested to cover the types of material, and sizes/dimensions being manufactured in the scope of licence.

In case a licensee intends to add new sizes/dimensions in the scope of licence, they are only required to inform BIS regarding the same based on which BIS shall endorse the same in the scope of licence.

Scope of the licence shall be restricted based on the manufacturing and testing facilities available. During the operation of licence, each variety covered in the scope of licence shall be drawn and tested in rotation, to the extent possible.

Scope of licence shall be restricted based on the manufacturing and testing facilities available.

During operation of licence, samples of each variety covered in 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	Cleanliness – Microbial , Cl. 5.2, Table 1 S No (i)	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
2	Tensile Strength, Cl. 5.2, Table 1 S No (ii)	Tensile Testing Machine
3	Bursting Strength, Cl. 5.2, Table 1 S No (iii)	Burst Tester

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 shoe covers made from the same consignment of raw material, and of the same size, manufactured 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 pack of shoe covers 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 shoe covers:

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

4. HYGIENIC CONDITIONS – Shoe covers shall be produced under 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**		
Cl.	**Requirement**	**Test Methods Clause Reference**			**No. of Sample**	**Frequency**	**Remarks**
4	Manufacture	4	IS 17349:2020	R	Manufacturer shall ensure adequate inspections/in process control to ensure conformity to these requirements		Conformity of material to the requirements may be established through the material supplier's test certificate/declaration and/or the declaration of the shoe cover manufacturer.
5.1	Workmanship and Finish	5.1	IS 17349:2020	R	Manufacturer shall ensure adequate inspections/in process control to ensure workmanship and finish is as per the requirements specified		
5.2	Performance Requirements						
i)	Cleanliness – Microbial (CFU/100 cm2)		IS/ISO 11737-1	S	One	Once in a month	
ii)	Tensile strength (Dry and wet)		Nonwoven IS 15891 (Part 3), Woven 1969 (Part 1)	R	One	Each control unit	
iii)	Bursting strength (Dry and wet)		IS 1966 (Part 1)	R	One	Each control unit	