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उत्पाद मैन्युअल
चिकित्सकीय वस्त्रादि — अवशोषक सूती जालीदार कपड़ा — विशिष्टि
IS 758: 2023 के अनुसार

PRODUCT MANUAL FOR
Medical Textiles — Absorbent Cotton Gauze – Specification
ACCORDINGTO IS 758: 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 758: 2023
	शीर्षक **Title**	:	Medical Textiles — Absorbent Cotton Gauze — Specification
	संशोधनों की संख्या **No. of amendments**	:	01
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	Fibre - material of gauze cloth shall be cotton fibre Yarn - cotton yarn used in the manufacture of gauze shall conform to the requirements specified in IS 171. (no testing required if yarn is ISI Marked) Cloth – Cloth shall conform to the requirements of Cl. 3.2 of IS 758:2023 Conformity of raw materials to the requirements specified in the standard may be established through test certificate of suppliers, or test report from BIS recognized/empanelled lab or any other lab having valid accreditation, or through 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**	:	In case sterilized Absorbent Cotton Gauze is intended to be covered in the scope of licence, manufacturer shall provide suitable evidence of sterility to BIS.
c)	**नमूने का परिमाण** **Sample Quantity**	:	20 m + 1 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)
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**		
	Count of yarn, Threads/dm, Mass, length, width, pH value of aqueous extract, Scouring loss, Freedom from optical whitener 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 758 :2023 with the following scope:		
	उत्पाद का नाम Name of the product	Medical Textiles — Absorbent Cotton Gauze	
	Sterilization	Sterilized/Not Sterilized	

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ANNEX – A
LIST OF TEST EQUIPMENTS
(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests Used In With Clause Reference	Test Equipment/Chemical
1	Threads/dm, 4.2	• Canvas cloth (slightly bigger than 25 cm (in length) × full width of the gauze cloth) • Metal plate measuring approximately 25 cm × 2 cm and weighing approximately 75 g • Adhesive tape • Means for suspending the whole assembly in the vertical position • glass plate • Steel Scale • Thermometer to determine atmospheric temperature • Hygrometer • Vernier calliper • 5. Measuring tape • Low Power Microscope/Counting glass • Clamps- As per clause 6.1.1 of IS 1963:1981 • Forceps • Table (At least 4 m of length) • Marker Chalk/Pencil
2	Mass, 4.2	• Horizontal, flat smooth table • Graduated Steel Scale • Balance capable of weighing up to an accuracy of 0.005 g • T-square (for over-dry method)
3	Length, 4.2	• Calibrated Steel Rule, 2 m min. • Table with smooth surface, 4 m min. Conditioning Chamber
4	Width, 4.2	
5	Absorbency, 4.2	• Wide-Bore Glass Tube, open at both ends • Glass Plunger, solid or closed at the bottom • Glass Trough, of suitable size, preferably 20 × 15 × 50 cm. • Retort Stand, with a clamp. • Stop-Watch, reading correct to 0.1 second. • Two Glass Plates, 10 × 10 cm and 0.75 cm thickness. • A Pair of Forceps • Measuring Cylinder • Analytical Balance, with a resolution of 0.1 mg. • Distilled Water,

6	*p*H value of aqueous extract, 4.2	Reagents: • Distilled or deionized water, of at least grade 3 as defined in ISO 3696, having a pH between 5,0 and 7,5. • Potassium chloride solution, 0,1 mol/l • Buffer solutions, which may be prepared as specified in Annex A of IS 1390, or obtained commercially, having a pH similar to that being determined, for calibration of the pH-meter before measurement. Apparatus: • Stoppered glass or polypropylene flasks, chemically resistant • Mechanical shaker, • Beakers, chemically resistant, with a capacity of 150 ml • Rods, chemically resistant • pH- meter, with a glass electrode, with a resolution of at least 0,01 pH-units • Balance, with a resolution of at least 0,01 g. □ 1 l volumetric flasks, of grade A quality.
7	Scouring loss, 4.2	Reagents: • Resizing Enzyme – diatase or other suitable enzyme • Sodium Chloride – Solid • Caustic soda solution 2% m/v containing 1% turkey red oil grade 2 conforming to IS 1044 • Acetic Acid Solution 1% • Chloroform Apparatus: • Soxhlet Apparatus • Drying Oven capable of maintaining a temperature of 105±3°C • Weighing Balance capable of weighing to an accuracy of 0.001 g
8	Freedom from optical whitener, 4.2	Source of Ultraviolet Light
9	Cleanliness– Microbial/Bioburden Test	Reagents: • Plate count agar (PCA) • Sabouraud chloramphenicol agar (SCA) • Sodium chloride (0.85%) Apparatus: • Autoclave

		• Hot air oven, Incubator (30-35 °C) • Incubator (20-25 °C) • pH meter • Water bath • Colony counter • Laminar Flow hood • Mechanical Shaker • Petri dishes • Flasks/bottles • Test tubes

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**

For the guidance of manufacturers, the recommended definition of control unit is: the entire quantity of the cotton gauze bleached and processed at a time.

1.3.1 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in **Table 1**.

1.3.2 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 the label of each Packet, 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

3.3 "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 Clause Reference**			**No. of Sample**	**Frequency**	**Remarks**
3.1	Yarn		IS 171	S	One	Each consignment	If consignment is accompanied by test certificate for conformity or is ISI marked, no further testing is required
3.2	Cloth	3.2	IS 758	S	One	Each consignment	If consignment is accompanied by test certificate for conformity or no further testing is required
4.1	Fibre Identification		IS 14944	S	One	Each consignment	If consignment is accompanied by test certificate for conformity or no further testing is required
4.2	Requirements of Absorbent Cotton Gauze						
i)	Count of yarn (for guidance only)		IS 758	R	Three if the control unit consists of 25 pieces or less and 5 otherwise	Each Control unit	
ii)	Threads/dm	Annex B	IS 758	R	Three if the control unit	Each Control unit	

					consists of 25 pieces or less and 5 otherwise		
iii)	Mass		IS 1964	R	Three if the control unit consists of 25 pieces or less and 5 otherwise	Each Control unit	
iv)	Length		IS 1954	R	5	Each Control unit	
v)	Width	Annex B	IS 758	R	5	Each Control unit	
vi)	Absorbency		IS 2369	R	2	Each Control unit	
vii)	pH value of aqueous extract		IS 1390	R	2	Each Control unit	
viii)	Scouring loss		IS 1383 (mild method)	R	2	Each Control unit	
ix)	Freedom from optical whitener		IS 758	R	2	Each Control unit	
4.3	Cleanliness– Microbial/Bioburden Test		IS/ISO 11737 (Part 2) or IS/ISO 11737 (Part 1)	S	The manufacturer shall perform the hygiene testing for the final product once in 03 months for monitoring purpose and whenever there is a change in the raw material, manufacturing premises, and the Supplier of the raw material.		