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BUREAU OF INDIAN STANDARDS

AGENDA

Technical Textiles for Medtech Applications Sectional Committee, TXD 36 **26th Meeting**

Date	Time	Venue
15 April 2024 (Monday)	1030 h	Video Conference through CISCO Webex

CHAIRMAN: **Dr. Prakash Vasudevan, Director**
The South India Textile Research Association, Coimbatore

MEMBER SECRETARY: **Shri Dharmbeer, Scientist D/Joint Director, 'Textiles'**
Bureau of Indian Standards, New Delhi

Item 0 WELCOME & INTRODUCTORY REMARKS

Item 1 CONFIRMATION OF THE MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the 25th meeting of the TXD 36 committee held on 05 January 2024 through CISCO Webex videoconferencing was circulated vide our reference TXD 36/A 2.25 email dated 20 January 2024.

1.1.1. The committee may **REVIEW** and **APPROVE** the minutes as circulated.

Item 2 SCOPE AND COMPOSITION OF TXD 36

2.1 The present scope and composition of the committee is given at **Annex 1 (Pages 7-9).**

The comments were received from Shri N.K. Kansara, Ex-DDG, BIS vide email dated 18 March 2024 which are provided as follows:-

'Technical Committee TXD 36 is for Technical Textiles for Medtech Applications and is having scope as "To formulate Indian Standards for terminology, testing and specifications for technical textiles for medtech applications such as healthcare and hygiene textile products, implantable and non-implantable and extra corporeal textile products."

From the above, it appears that the scope of the Committee per say does not cover "Medical Devices" but for technical textile which could be used as raw materials for a no. of medical devices. However, there are a no. of product standards which listed as being established by this Committee. This may please be reviewed either from the point of view of the scope of Committee as to whether it covers Medical Devices or whether the scope needs to be reworded to cover such products.

Further, although the title of many standards start as Medical textiles - Barrier Face Covering, Medical Textiles - Hydrocolloid Dressing, Medical Textiles - Bandage Plaster of Paris, Medical Textiles - Zinc Oxide Self-Adhesive Plaster, the standard IS 18266 has its title as

Textiles - Medical Respirator. It may be examined whether the product is simply an ordinary textile or a Medical Textile.

2.1.1 The Committee may **REVIEW**.

2.2 Shri Abhijit Mondal, Bisonlife India Private Limited, Bengaluru has requested for membership in TXD 36. He has 18+ years of experience in Technical Textile, Safety Product Development and Research and Development (R&D), specializing in Product Commercialization and Regulatory Certification.

2.2.1 The Committee may **DECIDE.**

2.3 Shri Venkatesh A, Viridian Testing Laboratories LLP has requested for membership in TXD 36. He has done B.Sc in Chemistry and have 18+ years of experience in laboratory testing, quality management system**,** factory technical audit, certification audit, calibration, research & development in textiles filed.

2.3.1 The Committee may **DECIDE.**

Item 3 ISSUES ARISING OUT OF PREVIOUS MEETING OF TXD 36

3.1 Summary of actions taken on the various decisions of the 25th meeting is given at **Annex 2 (Pages 10-11).**

3.1.1 The Committee may **NOTE**.

Item 4 DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

4.1 IS 17334 : 2019, Medical Textiles — Surgical Gowns and Surgical Drapes — Specification

In the 23rd meeting of TXD 36, it was requested that following stakeholders shall send samples to SITRA for testing of dry and wet bacterial penetration test: -

a) Dr. Sanjiiv Rehlan, FICCI/PWMAI (Shalex Overseas), New Delhi
b) Shri Sumit Marwah, Dispoline India Private Limited, Bengaluru
c) Shri Khalil Khan, Surya Textech, Chandigarh
d) Shri Apurva Ranka, Alpha Foam Private Limited, Pune

The test report/test results are yet to be received.

The updated draft revision has been given in **Annex 3 (Pages 12-23).**

4.1.1 The Committee may **DECIDE.**

4.2 IS 16111 : 2013, Elastic bandage

In the 22nd meeting of TXD 36, the committee requested Shri T. Balaji, KOB Medical Textiles and Dr. Manish Sabharwal, Dr. Sabharwal Wound Care, Baddi to review the requirement of GSM, Stretch Length and Extensibility due to wider range and provide their inputs. The technical inputs received from KOB Medical Textiles Pvt. Ltd. has been given in **Annex 4 (Pages 24-27).**

The technical comments from Dr. Sabharwal Wound Care are yet to be received.

The updated draft revision has been given in **Annex 5 (Pages 28-33).**

4.2.1 The Committee may **DECIDE.**

4.3 Medical Textiles – Nonwoven Gauze (Sterile and Non-Sterile) – Specification

In the 22nd meeting of TXD 36, the committee decided that M/s Ginni Filaments, M/s Welspun India and M/s Alpha Foam Pvt. Ltd. shall share their inhouse test report for non-woven gauze on performance parameter mentioned in table 1 including the tensile strength [IS 15891 (Part 3) : 2011/ISO 9073-3:1989] and breaking strength [IS 15891 (Part 18) : 2017/ISO 9073-18:2007] for dry and wet condition in machine and cross-direction to decide the final value.

The technical inputs received from M/s Ginni Filaments, M/s Welspun India have been given in **Annex 6 (Pages 34-47).**

The technical comments from M/s Alpha Foam Pvt. Ltd. are yet to be received.

The updated draft standard has been given in **Annex 7 (Pages 48-52).**

4.3.1 The Committee may **DECIDE.**

4.4 Medical Textiles -Scrub Suit – Specification

In the 23rd meeting of TXD 36, the committee decided that the following information shall be included in the draft standard :-

i) The foreword of the subject (including need and importance)
ii) The value and test method for physical performance parameters like tensile strength, tear strength, bursting, seam strength, pilling and abrasion resistance test (where applicable) are to be mentioned in existing draft. The values suggested shall be supported by inhouse test report/third party report/International Practice.
iii) Patient gown are to be excluded from draft specification.
iv) Requirement and test method for cleanliness microbial cleanliness is to be included instead of hygiene testing.
v) The information on method of sterilization and re-processing may be included.
vi) Any other technical information

The committee requested the following stakeholders to share their technical inputs: -

a) Ms. Shivani Swamy, Livinguard Mumbai
b) Shri Abhijit, Knya Med, Mumbai
c) Dr. Sanjiiv, PWMAI/FICCI, New Delhi
d) Mr. Apurva Ranka/Mr. Rajiv Ranka, Alpha Foam Ltd, Pune
e) Shri Khalil Khan, Surya Textech, Chandigarh

The technical inputs received from Ms. Shivani Swamy, Livinguard Mumbai has been given in **Annex 8 (Pages 53-61).**

The technical comments from other stakeholders are yet to be received.

The updated draft standard has been given in **Annex 9 (Pages 62-74).**

4.4.1 The Committee may **DECIDE.**

4.5 Medical Textile — Sterilization Wraps — Specifications

In the 23rd meeting of TXD 36, the committee decided that the following information shall be included in the draft standard :-

i) The foreword of the subject (including need and importance)
ii) The value and test method for performance parameters are to be mentioned in existing draft. The values suggested shall be supported by inhouse test report/third party report/International Practice.
iii) The equivalent IS/ISO or a separate Annexure is to be provided for EN/ASTM/AATCC test method.
iv) The specific information for sampling, packing, labelling and marking shall be provided.
v) Any other technical information.

The committee requested the following stakeholders to share their technical input: -

a) Shri D. Veerasubramanian, SITRA
b) Shri Dhaval Ghuge, Medline Healthcare Industries Pvt. Ltd, Pune
c) Shri Sumit Marwah, Dispoline India Pvt. Ltd., Bengaluru
d) Amit Kumar, Surgeine Healthcare (India) Private Limited, Sonipat

The technical inputs received from Shri D. Veerasubramanian, SITRA has been given in **Annex 10 (Pages 75-76).**

The technical comments from other stakeholders are yet to be received.

The updated draft standard has been given in **Annex 11 (Pages 77-84).**

4.5.1 The Committee may **DECIDE.**

Item 5 COMMENTS ON PUBLISHED STANDARDS

5.1 IS 17509 : 2021, Disposable Baby Diaper — Specification

In the last meeting of TXD 36, the committee decided that the following manufacturers/stakeholders shall send atleast 5 samples (wood pulp or superabsorbent polymer or combination in absorbent core) any size/lot of baby diaper for testing of pH test as per IS 1390 : 2022/ISO 3071 : 2020 and Rate of absorption per gush (s) to each lab i.e Testtex, SASMIRA and SITRA separately for testing:-

i) Shri Prashant Jadhav, P & G, Mumbai
ii) Shri Kamal Johari, Nobel Hygiene, Mumbai
iii) Shri Rohit Shrivastava, Unicharm India, Gurgaon

The technical inputs received comments received from Unicharm India, Soother Healthcare, P &G, Mumbai, Bella premium and SITRA are given at **Annex 12 (Pages 85-95).**

5.1.1 The Committee may **DECIDE.**

5.2 IS 18266 : 2023, Textiles — Medical Respirator — Specification

The comments were received from Shri N.K. Kansara, Ex-DDG, BIS vide email dated 18 March 2024 which are given at **Annex 13 (Pages 96-97).**

5.2.1 The Committee may **DECIDE.**

5.3 In the last meeting of TXD 36, the committee decided that Dr. Manish Sabharwal, Dr. Sabharwals Woundcare, Baddi shall provide the requirement and test method for Bioburden level or objective criteria for establishing conformity to sterility test on the following standards :-

i) **IS 863 : 2023, Medical Textiles - Cotton bandage cloth - Specification (third revision)**
ii) **IS 758 : 2023, Medical Textiles — Absorbent Cotton Gauze — Specification (Fifth Revision)**

The technical inputs from Dr. Sabharwals Wound care are yet to be received.

It has been observed that the Cleanliness microbial / Bioburden for unsterile products as per International standards on Medical Textiles such as Surgical Drape , gown, clean air suit are ≤ 100 (CFU/100 cm^2)

5.3.1 The Committee may **DECIDE.**

Item 6 NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD

6.1 Chitosan Haemostatic Dressings

Shri Brijesh P, Axio Bio-Solutions Private Limited has requested BIS for formulation of standard on Chitosan Haemostatic Dressings, however the technical inputs/working draft is yet to be provided.

6.1.1 The Committee may **DECIDE.**

Item 7.1 REVIEW OF PRE-2000 STANDARDS/DUE FOR REVIEW

As per procedure of BIS, standards which were published/reaffirmed five years ago or earlier are required to be reviewed to assess adequacy of the requirements specified. Review is carried out keeping in view the changes in technology, current industrial practices and the needs/expectations of the consumers/users so as to decide regarding further reaffirmation/revision/withdrawal/amendment of the standards under

The list of standards due for 5 year review are given at **Annex 14 (Pages 98-99).**

The list of pre-2000 standards are given at **Annex 15 (Page 100).**

7.1 The Committee may **DECIDE.**

Item 8 DATE AND PLACE OF NEXT MEETING

Item 9 ANY OTHER BUSINESS

ANNEX 1
(Item 2.1)

Scope and Composition of Technical Textiles for Medtech Applications, TXD 36

Scope: To formulate Indian Standards for terminology, testing and specifications for technical textiles for medtech applications such as healthcare and hygiene textile products, implantable and non-implantable and extra corporeal textile products.

Meeting(s) held	**Date & Place**
24th Meeting	07 November 2023 (Through VC)
25th Meeting	05 January, 2024 (Through VC)

SL NO.	ORGANIZATION REPRESENTED	NAME OF THE REPERESENTATIVE PRINCIPAL/(ALTERNATE)	ATTENDANCE
1.	**Director, SITRA**	**Dr. Prakash Vasudevan** (Chairman)	2/2
2.	3 M India Limited New Delhi	Shri Kulveen Singh Bali (Smt. Prabha Hegde)	2/2
3.	Alpha Foam Ltd., Pune	Shri Rajiv Ranka (Shri Apurva Ranka)	2/2
4.	Association of Indian Medical Device Industry (AiMeD), New Delhi	Shri Amit Kumar (Smt. Rama Venugopal)	2/2
5.	All Indian Institute of Medical Sciences, New Delhi	Dr. Vijaydeep Siddharth (Dr. Anoop Daga) (Dr. Sidhartha Satpathy)	1/2
6.	Business Coordination House New Delhi	Shri Kanav Gupta Smt. Ritika Gupta	1/2
7.	Cologenesis Healthcare Pvt. Ltd, Salem	Shri R Krishana Kumar Shri K. Ramprasad	2/2
8.	Defence Research & Development Establishment (DRDE), Gwalior	Dr. Vikas B. Thakre (Shri Suraj Bharati)	2/2
9.	DGAFMS, Ministry of Defence, New Delhi	Surg Capt S.S Dalawayi (Surg Lt Cdr Kotian V. Gopal)	2/2
10.	DGQA (Ministry of Defence), New Delhi	Shri S.S. Kashyap (Shri Arnab Das)	2/2
11.	Dima Products, Mumbai	Shri Nirav Mehta (Shri Raghavan Adiyodi)	2/2

12.	Director General of Health Services, New Delhi	Dr. Naresh Panchal (Dr. B. S. Charan)	2/2
13.	Dispoline India Private Limited, Bangalore	Shri Sumit Marwah	2/2
14.	DMSRDE, Kanpur	Dr. Mukesh Kumar Sinha	2/2
15.	Dr. Sabharwals Manufacturing Labs Pvt Ltd Panchkula	Shri Manish Sabharwal (Shri Dhruv Sabharwal)	2/2
16.	Federation of Indian Chambers of Commerce & Industry, New Delhi	Dr. Sanjiiv Rehlan (Ms Tulsi)	2/2
17.	Ginni Filaments Limited NOIDA	Shri Pramod Sharma	2/2
18.	Indian Council of Medical Research, New Delhi	Dr. Sadhana Srivastav	2/2
19.	Indian Institute of Technology, New Delhi	Prof Ashwini Agarwal (Prof Bipin Kumar)	1/2
20.	Indian Technical Textile Association	Dr. Anup Rakshit (Shri Mahesh Kudav)	2/2
21.	JNTL Consumer Health (India) Pvt Ltd. (Kvenue), Mumbai	Smt. Monika Sathe (Ms. Roocha Khedkar)	2/2
22.	KOB Medical Textiles Pvt Ltd, Palladam	Shri Arun Buchade (Shri T. Balaji)	2/2
23.	Livinguard Technologies Pvt. Ltd., Mumbai	Ms. Shivani Swamy (Shri Shashank Morje)	2/2
24.	Maulana Azad Medical College, New Delhi	Dr. Pawanindra Lal (Dr. Kirti Nath/Dr Lalit Gupta)	2/2
25.	Medline Healthcare Industries Pvt. Ltd, Pune	Mr. Anothony D' Costa (Shri Dhaval Ghuge)	2/2
26.	Ministry of Textiles (NTTM), New Delhi	Shri Ajay Pandit	1/2
27.	National Physical Laboratory, New Delhi	Dr. Suraj Khanna	1/2
28.	Nobel Hygiene, Mumbai	Shri Joy Devassy (Smt. Sneha Gupta)	2/2
29.	Office of the Drug Controller (CDSCO), Delhi	Dr. Aseem Sahoo (Ms. Shyamni Sasidharan)	2/2
30.	PGIMER, Chandigarh	Dr. Pankaj Arora (Dr. Vijay Tadia)	2/2
31.	Procter and Gamble Co., Mumbai	Shri Prashant Jadhav (Shri Girish Parhate)	2/2

32.	South India Textile Research Association, Coimbatore — 641014	Shri S. Sivakumar (Dr. E. Santhini)	2/2
33.	Surya Textech, Chandigarh	Shri Khalil Khan (Shri Yogesh Yadav)	2/2
34.	Textiles Committee Mumbai	Shri Kartikeyan Dhanda (Dr. P. Ravichandran)	2/2
35.	The Pad Project (NGO), India	Smt. Tanya Mahajan	2/2
36.	The Synthetics & Art Silk Mills Research Association, Mumbai	Dr Manisha Mathur (Mrs. S. S. Dongre)	2/2

ANNEX 2
(Item 3.1)

SUMMARY OF ACTIONS TAKEN ON THE MINUTES OF 25th MEETING OF TXD 36

Item No.	Decision	Action taken
2.1	Certain modifications were suggested in the composition of the committee.	Updated composition is given in **Annex 1**
4.1	**RESEARCH AND DEVELOPMENT PROJECT** **4.1** New Subject - Surgical Sutures (absorbable and non-absorbable) The committee finalized the Term of Reference for surgical sutures'	The finalized ToRs has been uploaded on BIS website for seeking proposals for R & D. The last date of proposal for R & D proposal is **30 April, 2024.**
5.1	**COMMENTS ON PUBLISHED STANDARDS** **IS 5405: 2019, Sanitary Napkins — Specification (second revision) and IS 17514 : 2021, Reusable Sanitary Pad / Sanitary Napkin / Period Panties — Specification** The committee finalized the amendments in IS 5405 :2019, IS 17514 : 2021	The amendments were published.
5.2	**COMMENTS ON PUBLISHED STANDARDS** **IS 17509: 2021, Disposable Baby Diaper — Specification** The committee finalized the amendment in IS 17509 : 2021.	The amendment was published.
5.3	**COMMENTS ON PUBLISHED STANDARDS** **IS 17508: 2020, Disposable Adult Incontinence Diaper – Specification** The committee finalized the amendment in IS 17508 : 2020.	The amendment was published.
5.4	**COMMENTS ON PUBLISHED STANDARDS** **IS 17354: 2020, Medical Textiles — Dental Bib / Napkins — Specification**	The amendment was published.

	The committee finalized the amendment in IS 17354 : 2020.	
5.5	**COMMENTS ON PUBLISHED STANDARDS** **IS 863: 2023, Medical Textiles - Cotton bandage cloth - Specification (third revision)** The committee decided that Dr. Manish Sabharwal, Dr. Sabharwals Manufacturing Labs Pvt Ltd, Panchkula shall provide the requirement and test method for Bioburden level or objective criteria for establishing conformity to sterility test.	Coming up for discussion in agenda item

ANNEX 3
(Item 4.*1*)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDRADS

Draft for comments only Doc No.: TXD 36 (XXXXX)
XXXXX 2024

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भारतीय मानक मसौदा

चिकित्सीय वस्त्रादि — चिकित्सीय एवं सर्जिकल गाउन एवं सर्जिकल ड्रैप — विशिष्ट

(IS 17334 का *पहला पुनरीक्षण*)

Draft *Indian Standard*

Medical Textiles — Medical and Surgical Gowns and Surgical Drapes — Specification

(*First Revision* of IS 17334)

ICS 11.140;

59.080.01

Technical Textiles for Medtech Applications Sectional Committee, TXD 36

last date for receipt of comments is XXXX 2024

FOREWORD

(Formal clauses will be added later)

This standard was originally published in 2019. The present revision has been made in the light of experience gained since its first adoption and to incorporate the following major changes:

i) Amendment has been incorporated in this standard.
ii) Title of the standard has been modified and changed in this standard.
iii) Comments has been incorporated.

Surgical gowns and surgical drapes are intended to be used to minimize the transmission of infective agents between patients and clinical staff during the surgical and other invasive procedures.

This standard addresses the performance of surgical gowns and surgical drapes designed to protect against exposure of healthcare workers to blood, body fluids, and other potentially infectious materials during surgery and other healthcare procedures. This standard defines testing and reporting performance requirements levels for surgical gowns and surgical drapes manufacturers in order to provide information to end users that can be used in making informed decisions in the selection and purchase of surgical gowns and surgical drapes according to the anticipated exposures.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2:2022 'Rules for rounding off numerical values (*second revision*).' The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1 SCOPE

1.1 This standard specifies requirements for single use and reusable surgical gowns and surgical drapes intended for medical use.

1.2 This standard is intended to be used primarily by manufacturers of surgical gowns and surgical drapes in qualifying, classifying, packaging, labelling, and sterilization of surgical gowns and surgical drapes, so that healthcare workers can make more informed decisions of selection of right surgical gown and surgical drape in accordance with the protection level and risk involved in the procedure.

1.3 This standard does not include universal procedure packs designed for specific procedures, however, contents of customized procedure packs shall be manufactured in accordance with this standard.

2 REFERENCES

The standards listed in Annex A contain provisions which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated are valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards.

3 TERMS AND DEFINITIONS

For the purposes of this standard, the following terms shall apply:

3.1 Barrier Properties — Ability of a protective material to resist the penetration of liquids and resistance to airborne and liquid borne microorganisms at different state (*see* **3.9** and **3.24**).

3.2 Biocompatibility — The ability to be in contact with a living system without producing an adverse effect.

3.3 Blood-borne Pathogen — Infectious microorganisms including virus carried in blood or other body fluids.

3.4 Body Fluids — Any liquid produced (secreted/ excreted) by body.

3.5 Colony Forming Unit (CFU) — Unit by which culturable number of microorganisms is expressed.

3.6 Cleanliness–microbial — Freedom from population of viable microorganism on a product and/ or a package.

3.7 Cleanliness–particulate Matter — Freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact.

3.8 Critical Product Area — Product area with a greater probability to be involved in the transfer of infective agents to or from the wound, for example, front and sleeves of surgical gowns.

3.9 Dry Microbial Penetration — Migration of microorganisms through a barrier material in dry state.

3.10 Infective Agent — Microorganism that has been shown to potentially cause infections.

3.11 Invasive Surgical Procedure — Surgical procedure penetrating skin or mucosa

3.12 Less Critical Product Area — Product area where direct contact with blood, body fluids, and other potentially infectious materials (OPIMs) is less likely to occur.

3.13 Liquid Penetration — Migration of liquid(s) through the material.

3.14 Manufacturer — Means processing of raw material or inputs in any manner that results in emergence of a new product having a distinct name, character and use. The term "manufacturer" shall be construed accordingly.

3.15 Microbial Penetration — Migration of microorganisms, from one side of the material through the other.

3.16 Particle Release — Particle release from fiber fragments and other particles during mechanical stress.

3.17 Performance Level — Discrete standard defined to classify products according to the performance requirements of this standard.

3.18 Reusable Product — Product intended by the manufacturer to be reprocessed and reused.

3.19 Single-use Product — Product intended by the manufacturer to be used only once.

3.20 Sterile Field — An area created by placing sterile surgical drapes around the patient's surgical site and on the stand that will hold sterile instruments and other items needed during surgery.

3.21 Surgical Gown — Protective clothing that is intended to be worn by healthcare workers during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate matter.

3.22 Surgical Drape — A covering for the patient for the prevention of transfer of infective agents, such as microorganisms, body fluids and particulate material. "Surgical drapes are used during surgery to prevent contact with unprepared surfaces and to maintain the sterility of environmental surfaces, equipment and the patient's surroundings".

3.23 Synthetic Blood — Mixture of red dye/surfactant, thickening agent, and distilled water having a surface tension and viscosity representative of blood and other body fluids and the colour of blood.

3.24 Wet Microbial Penetration — Migration of microorganisms through a barrier material in wet state.

4 WORKMANSHIP AND FINISH

4.1 A manufacturing and processing specification shall be designed and validated for the product, including visual and hygienic cleanliness. The validation shall include all steps involved in manufacturing and processing.

4.2 The key manufacturing and processing variables shall be identified, monitored and recorded. The type and frequency of routine monitoring shall be documented.

4.3 During manufacturing and processing, the control of decontamination, disinfection procedures and the traceability of sterilization shall be maintained.

'NOTE — The requirements given in 4.1 to 4.3 are for guidance of the manufacturer. Reference may also be made to the Medical Devices Rules 2017.'

5 GENERAL REQUIREMENTS

5.1 Product (s) shall meet all the requirements specified in this standard throughout their useful life. If the manufacturer does not specify critical and/or noncritical area of a product, the product shall meet at least level "0" performance requirements as given in Table 1 and Table 2.

5.2 Manufacturing and Processing Requirements and Documentation

The manufacturer shall establish a formal quality management system including requirements for the product development, design, production, testing, packaging, labeling, distribution and provision of related services as per medical device rules, 2017 for surgical gown and surgical drape. The quality management system shall include a risk management procedure where inputs for product realization shall include the outputs from risk management.

For reusable products, processing and lifecycle control shall be included in the quality management system. The requirements specified in this standard shall be met and documented that the fitness for the intended purpose has been established for each use, both for single-use and reusable surgical gowns and surgical drapes.

Microbiological monitoring (as per ISO 14698-1), air monitoring of clean room (as per ISO 14644-1), sterilization (as per IS/ISO 11135), packaging [as per IS/ISO 11607 (Part 1 and Part 2)], validation [as per IS/ISO 11137 (Part 1 and 2), ISO 11138-t 7] and residual sterility (IS/ISO 10993-7) shall be maintained by the manufacture.

'NOTE — The requirements given are for guidance of the manufacturer. Reference may also be made to the Medical Devices Rules 2017.'

5.3 Barrier Properties

The final performance requirement level shall be based on the performance of the critical zone component. The classification of the product shall indicate the performance of the critical zone component having the lowest barrier performance. The information for principle of critical area for guidance has been given in Annex B.

The performance of seams between and within critical zones shall meet the requirements of this standard. The performance of seams between critical and less critical zones shall meet at least the requirements of the adjacent less critical zone. Non-critical areas of the surgical gowns and surgical drapes can have one level less as compared to the standard earmarked for the surgical gowns and surgical drapes.

The performance requirements of reusable products shall have to be met after declared wash cycle.

6 PERFORMANCE REQUIREMENTS

6.1 The manufacturer shall ensure the maintenance of required performance level after sterilization of the material and testing shall be performed on the finished product. If the product is intended to be used after sterilization, testing shall be carried out on products after sterilization with the exception of microbial cleanliness.

Test specimens shall be taken from different products of the same lot. If multiple tests are to be performed (for example, the critical zone consists of more than one component, such as the base material, a seam, and a point of attachment), then test specimens for each component may be taken from the same product.

If the test area of the finished product is too small to perform the test, a representative sample of the same material may be used. The representative sample shall be treated in the same way as the finished product.

During manufacture and processing, testing shall be carried out within a formal quality system.

6.2 Surgical gowns and surgical drapes shall conform to the requirements specified when tested according to the method given in Table 1 and Table 2 respectively.

6.3 The general guidelines/recommendations to use different levels of surgical gown/surgical drape for healthcare application and surgeries in hospitals have been given in Table 3.

7 MARKING

7.1 Each pack of surgical gown/surgical drape shall be legibly and indelibly marked with following information:

a) Name of the product ;

b) Dimension /size of the product;

c) Manufacturer’s name, initials or trade-mark, if any;

d) Month and year of manufacture, batch /lot number;

e) Sterilized or un-sterilized (or) it can be sterile or unsterile;

f) Method of sterilization and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization;

g) An indication that the device has been specified by the manufacturer for single-use only;

h) If the product is multiple use, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of reuses. Where products are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the device will still comply with “the essential principles of safety and performance of medical devices”;

j) Performance level; and

k) Any other statutory requirement as required by the law in force.

Table 1 Performance Requirements for Surgical Gowns

(*Clauses* **5.1, 6.2, 8.1.1, 8.2.2** and **9.1**)

Sl No.	Characteristics		Requirement				Method of Test,
			Level 1	Level 2	Level 3	Level 4	
(1)	(2)		(3)	(4)	(5)	(6)	(7)
i)	Impact penetration (g)		≤ 4.5	NA	NA	NA	ISO 18695
ii)	Hydrostatic resistance (cmwc)		NA	≥ 20	≥ 50	NA	ISO 811
iii)	Blood resistance		NA	NA	NA	Pass	IS 16546
iv)	Viral resistance		—	—	—	Pass	IS 16545
v)	Particle release [log10 (lint count)]		≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0	IS 15891 (Part 10)
vi)	Tensile strength (dry and wet) (N)		≥ 20	≥ 20	≥ 20	≥ 20	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)
vii)	Bursting strength (dry and wet) (kPa)		≥ 40	≥ 40	≥ 40	≥ 40	IS 1966 (Part 1)
viii)	Cleanliness– microbial (CFU/100 cm^2)		≤ 300	≤ 300	≤ 300	≤ 300	ISO 11737-1
ix)	Resistance to microbial penetration — Dry (CFU)		NA	≤ 300	≤ 300 (for less critical zones)	NA	IS 16548
x)	Resistance to microbial penetration — Wet (I_B)		NA	NA	2.8 (for critical zones)	—	IS 16549
xi)	*Biocompatibility Evaluation	Cytotoxicity	None	None	None	None	IS/ISO 10993-5
		Irritation and skin sensitization	Non-irritant and nonsensitizer	Non-irritant and nonsensitizer	Non-irritant and nonsensitizer	Non-irritant and nonsensitizer	IS 17932 (Part 6)
xii)	Moisture vapour transmission rate (*Max.*) (optional)		NA	NA	NA	40 m^2 Pa/W	ISO 11092
*Remarks: Confirm the biocompatibility of raw material at designed stage for all levels. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product.							

Table 2 Performance Requirements for Surgical Drapes
(*Clauses* **5.1, 6.2, 8.1.1** and **8.2.2**)

Sl No.	Characteristics		Requirement				Method of Test,
			Level 1	Level 2	Level 3	Level 4	
(1)	(2)		(3)	(4)	(5)	(6)	(7)
i)	Impact penetration (g)		≤ 4.5	NA	NA	NA	ISO 18695
ii)	Hydrostatic resistance (cmwc)		NA	≥ 20	≥ 50	≥ 100	ISO 811
iii)	Blood resistance		NA	NA	NA	Pass	IS 16546
iv)	Particle release [log10 (lint count)]		≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0	IS 15891 (Part 10)
v)	Tensile strength (dry and wet) (N)		≥ 20	≥ 20	≥ 20	≥ 20	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)
vi)	Bursting strength (dry and wet) (kPa)		≥ 40	≥ 40	≥ 40	≥ 40	IS 1966 (Part 1)
vii)	Cleanliness– microbial (CFU/100 cm^2)		≤ 300	≤ 300	≤ 300	≤ 300	ISO 11737-1
viii)	Resistance to microbial penetration — Dry (CFU)		NA	≤ 300	≤ 300 (for less critical zones)	NA	IS 16548
ix)	Resistance to microbial penetration — Wet (I_B)		NA	NA	2.8 (for critical zones)	—	IS 16549
x)	*Biocompatibility Evaluation	Cytotoxicity	None	None	None	None	IS/ISO 10993-5
		Irritation and skin sensitization	Non-irritant and nonsensitizer	Non-irritant and nonsensitizer	Non-irritant and nonsensitizer	Non-irritant and nonsensitizer	IS 17932 (Part 6)
* Remarks: Confirm the biocompatibility of raw material at designed stage for all levels. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product.							

Table 3 General Guidelines/Recommendations for Use of Different Levels of Surgical Gowns/Surgical Drapes
(*Clause* 6.3)

Performance Level	Anticipated risk of exposure
Level 1	• Minimal risk to the patient independent of anesthesia • Minimally invasive procedures with little or no body fluid loss

	• Often done in an office setting with the operating room principally for anesthesia and monitoring
Level 2	• Minimal to moderately invasive procedure • Mild body fluid loss • Mild risk to patient independent of anesthesia
Level 3	• Moderate to significantly invasive procedure • Moderate body fluid loss • Moderate risk to patient independent of anesthesia
Level 4	• Highly invasive procedure • High body fluid loss • Major/critical risk to patient independent of anesthesia • Usual post-operative ICU stay with invasive monitoring

Each product or package, containing surgical gowns, surgical drapes, having a critical area shall be prominently labeled identifying the areas with different performance levels and the performance level of the relevant area(s).

Labelling and marking requirements shall be followed as per Medical Device Rules, 2017.

7.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 Lot

All the surgical gowns or surgical drapes of the same material and dimensions produced under similar conditions of manufacture and sterilization shall constitute a lot.

8.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

NOTES

1 For level 0, 1, 2 and 3 surgical gowns, the conformance of the performance requirements as given in Table 1 may be accepted at fabric stage (except cleanliness microbial, resistance to blood and resistance to viral) for a product if desired by buyer/ user. In such cases, the traceability certificate for conformance of the performance requirement of fabric shall be maintained by the product manufacturer for each lot.

2 Similarly, for level 0, 1, 2 and 3 surgical drapes, the conformance of the performance requirements as given in Table 2 may be accepted at fabric stage (except cleanliness microbial and resistance to blood) for a product if desired by buyer/user. In such cases, the traceability certificate for conformance of the performance requirement of fabric shall be maintained by the product manufacturer for each lot.

8.1.2 The number of surgical gowns or surgical drapes to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 1, 2 and 4 of Table 4.

8.1.3 These surgical gowns/ surgical drapes shall be selected at random from the lot as per procedure given in IS 4905.

8.2 Number of Tests and Criteria for Conformity.

8.2.1 All the surgical gowns/surgical drapes as per column 2 of Table 4 shall be examined for workmanship and finish (**4.1** to **4.3**).

8.2.1.1 Any surgical gowns/ surgical drapes failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 3 of Table 4. Otherwise, the lot shall be rejected.

Table 4 Number of Surgical Gown/ Surgical Drape to be selected
(*Clauses* **8.1.2, 8.2.1, 8.2.1.1, 8.2.2** and **8.2.3)**

Sl No.	**Lot Size**	**Non-destructive Testing**		**Destructive Testing**	
		No. of Gown/Drape to be Selected	Acceptance Number	No. of Gown/Drape to be Selected	Acceptance Number
	N	N	a	n_1	a_1
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 50	5	0	2	0
ii)	51 to 150	8	0	3	0
iii)	151 to 280	13	1	3	0
iv)	281 to 500	20	2	3	0
v)	501 to 1 200	32	3	5	0
vi)	1 201 to 3 200	50	5	5	0
vii)	3 201 and above	80	7	5	0

8.2.2 Out of the sample already found satisfactory according to **8.2.1.1**, a sub-sample as per column 4 of Table 4 shall be taken. This sub-sample shall be further tested for the remaining requirements as given in Table 1 and Table 2.

8.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective surgical gowns/ surgical drapes found in the sample (as per **8.2.2**) is less than or equal to the acceptance number as given in column 5 of Table 4.

9 MOISTURE VAPOUR TRANSMISSION RATE (OPTIONAL TEST FOR SURGICAL GOWN)

Moisture vapour transmission is the ability of water vapour to pass through a material. This attribute has a significant effect on comfort, because materials without the ability to allow moisture transmission are generally uncomfortable. This test is recommended to be performed for level 3 surgical gowns as given in Table 1, as level 3 gowns are being used in high risk surgeries with prolonged duration where the doctors/ healthcare personnel are subjected to heat stress due to which they may feel uncomfortable.

10 EDUCATION

The manufacturer may provide technical information and/or training explaining the performance level classification system and its implications for the end user. Thereafter, the end-user is responsible for making judicious selections of products according to:

a) the performance level of the product, and

b) the anticipated degree of exposure of health care personnel to blood, body fluids, and OPIM during a given procedure or activity.

'NOTE — The requirements given are for guidance of the manufacturer and user.'

10.1 Information on Critical and Less Critical Areas

The manufacturer shall differentiate between the critical and less critical areas of the product, if applicable, and identify the different areas.

11 PACKAGING AND STERILIZATION

For packaging of the products, requirements as per IS/ ISO 11607-1 and 2 shall be followed.

For packaging and sterilization, the Medical Device Rule, 2017 shall be followed.

Validation of sterilization process shall be done as per IS/ISO 11135, IS/ISO 11137 -1 and 2, ISO 11138-7 and, IS/ISO 10993-7 standards.

ANNEX A
(*Clause* **2**)

LIST OF REFERRED STANDARDS

IS/Other Publication	*Title*
IS 4905: 2015	Random Sampling And Randomization Procedures (*First Revision*)
IS 15891 (Part 3): 2011	Textiles — Test Methods For Nonwovens: Part 3 Determination Of Tensile Strength And Elongation
IS 15891 (Part 10): 2017	Textiles — Test Methods For Nonwovens: Part 10 Lint And Other Particles Generation In Dry State
IS 1966 (Part 1) : 2022 /ISO 13938-1 : 2019	Textiles — Bursting Properties of Fabrics Part 1 Hydraulic Method for Determination of Bursting Strength and Bursting Distension (*Third Revision*)

IS 1969 (Part 1) : 2018 /ISO 13934-1 : 2013	Textiles — Tensile Properties Of Fabrics: Part 1 Determination Of Maximum Force And Elongation At Maximum Force Using The Strip Method (*Fourth Revision*)
IS 17932 (Part 6) : 2023	Biological Evaluation of Medical Devices Part 6 Tests for Skin Sensitization
IS/ISO 10993-5: 2009	Biological Evaluation Of Medical Devices: Part 5 Tests For In Vitro Cytotoxicity
IS/ISO 10993-7: 2018	Biological Evaluation of Medical Devices Part 7 Ethylene Oxide Sterilization Residuals
IS/ISO 11137-1: 2006	Sterilization Of Health Care Products — Radiation: Part 1 Requirements For Development, Validation And Routine Control Of A Sterilization Process For Medical Devices
IS/ISO 11137-2: 2013	Sterilization Of Health Care Products — Radiation: Part 2 Establishing The Sterilization Dose
IS/ISO 11135: 2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
IS/ISO 11607-1: 2019	Packaging for Terminally Sterilized Medical Devices Part 1 Requirements for Materials, Sterile Barrier Systems and Packaging Systems (*First Revision*)
IS/ISO 11607-2: 2019	Packaging for Terminally Sterilized Medical Devices Part 2 Validation Requirements for Forming, Sealing and Assembly Processes (*First Revision*)
IS 391 : 2020/ISO 811 : 2018	Textile Fabrics — Determination of Resistance to Water Penetration — Hydrostatic Pressure Test (*Second Revision*)
IS 16545 : 2016/ISO 16604 : 2004	Clothing For Protection Against Contact With Blood And Body Fluids — Determination Of Resistance Of Protective Clothing Materials To Penetration By Blood-Borne Pathogens — Test Method Using Phi-X174 Bacteriophage
IS 16546 : 2016/ISO 16603 : 2004	Clothing For Protection Against Contact With Blood And Body Fluids — Determination Of The Resistance Of Protective Clothing Materials To Penetration By Blood And Body Fluids — Test Method Using Synthetic Blood
IS 16548 : 2016/ISO 22612 : 2005	Clothing For Protection Against Infectious Agents — Test Method For Resistance To Dry Microbial Penetration
IS 16549 : 2020/ISO 22610 : 2018	Surgical Drapes, Gowns and Clean Air Suits, Used as Medical Devices, for Patients, Clinical Staff and Equipment — Test Method to Determine the Resistance to Wet Bacterial Penetration (*First Revision*)
IS 17376 : 2020/ISO 11092 : 2014	Textiles — Determination of Physiological Effects — Measurement of Thermal and Water-Vapour Resistance under Steady-State Conditions (Sweating Guarded-Hot Plate Test)
IS 18469 (Part 7) : 2023 /ISO 11138-7 : 2019	Sterilization of Health Care Products — Biological Indicators Part 7 Guidance for the Selection Use and Interpretation of Results
IS 17375 : 2020/ISO 18695 : 2007	Textiles — Determination of Resistance to Water Penetration — Impact Penetration Test
ISO 14698-1: 2003	Cleanrooms and associated controlled environments — Bio contamination control — Part 1: General principles and Methods
ISO 14644-1: 2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration

ANNEX B
(*Clause* **5.3**)

B-1 PRINCIPLES OF THE CRITICAL ZONE

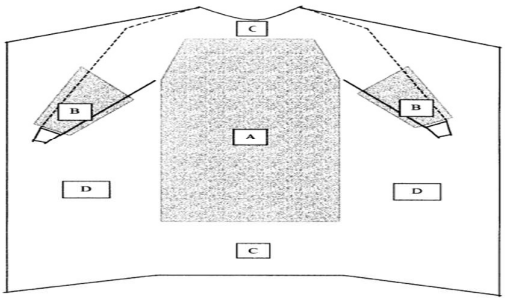
The critical zone can be described as an area approximately 12 inches around the fenestration of a drape where it is thought that reinforcement is needed to resist the penetration and strike through of fluids. Additionally, the critical zone (see Fig. 1) on surgical gown encompasses the front area from mid-chest to waist and the sleeves to 2 inches above the elbows.

However, there are two important factors as related to the critical zone. Fluid is often not always contained in the proximity of the critical zone. For example, during an arthroscopic procedure a large amount of fluid can be used during the procedure and is not contained within the critical zone of the arthroscopic drape.

Specialty drapes, such as extremity drapes, may have a reinforced critical zone (*see* Fig. 2). However, due to the amount of fluids that may be encountered and/or manipulation of the body parts the surgical team should consider draping reinforcement of the areas outside of the critical zone. For example, during a hip arthroplasty, the leg is placed through several maneuvers to initially dislocate the joint, facilitate bone excision and placement of the prostheses, put the joint back into place, and further maneuvers to test the prostheses prior to closing the surgical wound. This calls for draping reinforcement of the entire leg and foot in order to prevent an SSI.

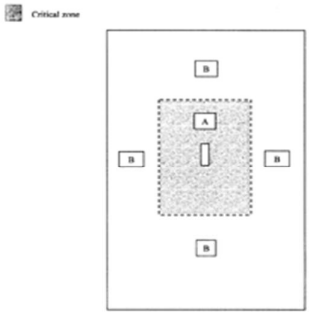
In this situation, it may be considered that the critical zone should be further expanded outside of the manufacturers region of reinforcement around the fenestration, thus further suggesting that the critical zone is a fluctuating zone that dependent on the procedure to be performed.

The final performance requirement level of the product shall be based on the performance of the critical zone component.



A and B - Critical zone
C and D - Less critical zone

FIG. 1 SURGICAL GOWN



A - Critical zone
B - Less critical zone

FIG. 2 SURGICAL DRAPE

ANNEX 4
(Item 4.*2*)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

COMMENTS OF KOB MEDICAL TEXTILES PVT. LTD, COIMBATORE
IS 16111:2013 standard revision:

Reason for revision:
As a part of review of published standards it was decided in the 22nd Meeting of Sectional Committee, TXD 36 of Technical Textiles for Medtech Applications dated 9th Jun 2023 to review the standard IS 16111 and revise suitably.

What are all the changes:

- **Changes in**
  - Inclusion of 3 amendments
  - FOREWARD statement
  - Scope part
  - Definition
  - Dimension and tolerance
  - Material composition
  - Requirements
  - Procedure

Manufacturers:

- M/s. KOB Medical Textiles Pvt Ltd.,
- Other manufactures throughout India

Users :

- **Elastic Bandages –** An elastic bandage is intended to provide support and immobilize dressings covering the wounds besides the function of compression and support for orthopedic purposes. To be used in intact skin only.
- Being used in hospitals and directly used by common patients based on physician reference.

International standard:
DIN 61634 – standard for Elastic immobilising bandage – this DIN standard is the basic reference for the Elastic bandages. Based on the input from this, IS 16111 standard was developed.

FORMAT FOR SENDING COMMENTS ON BIS DOCUMENTS

NAME OF THE COMMENTATOR/ORGANIZATION: **KOB Medical Textiles Pvt .Ltd.**

Standard : IS 16111 : 2013

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Specific Proposal (Draft clause to be add/amended)	Remarks	Technical References on which (2), (3), (4) are based
(1)	(2)	(3)	(4)	(5)
Foreword	Foreword in existing version of standard	Foreword modified as per mentioned in draft standard	Forword in align with changes made	Amendments of IS 16111 standard and

			in the proposed revision and in align with Indian MDR 2017	Indian MDR 2017.
1 : Scope	This standard covers the dimension and other requirement for Elastic bandages	Scope shall be as "Elastic bandages are Medical Devices categorized as Class A. This standard covers the dimensions and other requirement for elastic bandages"	Updation in align with CDSCO' medical device classification guideline.	MDR 2017 – medical device classification guideline
3.1 Elastic bandages	An elastic bandage is intended to provide support and immobilize dressings covering the wounds besides the function of compression and support for orthopedic purposes.	Additionally the text "To be used in intact skin only" shall be added.	Updation in align with CDSCO' medical device classification guideline.	MDR 2017 – medical device classification guideline
5 Dimensions and Tolerances	Amendment No. 3	Amendment No. 3 shall be incorporated	Incorporation of amendment No.3	As per amendment
6 Material	6.1 Elastic bandages shall be cellulosic / non -cellulosic yarn or combination of both yarn with following composition 6.1.1 hydrophilic / cellulosic fibre content, minimum 35 percent [See IS 189 (part 1)]. 6.2 Filament yarns made from partially oriented yarn (POY) of polyester, polyamide, polypropylene or equivalent material. 6.3 It consist of a core made of height stretch spandex, lycra, polyurethane ,rubber	**Clause title shall be modified as 6 MATERIAL COMPOSITION :** **6.1 Elastic bandages** Shall be with cellulosic/non cellulosic yarn or combination of both yarn with following composition 6.1.1 Elastic bandages shall have minimum 35 % of hydrophilic / Cellulosic fiber content. [See IS 1889 (part 1)] **6.2 Raw material :**	**a)** Elastic bandages shall have minimum 35 % hydrophilic content. Existing version of standard narrates the above requirement with ambiguity and misinterpreted as every yarn shall have minimum 35 % of hydrophilic content. b) for better clarity,	Modification shall be done to avoid any potential ambiguity.

	or similar material and covered/wrapped with synthetic filament yarn or grey/bleached/dyed cotton and /or viscose/rayon.	Cellulosic yarns; Non Cellulosic Filament yarn made from polyamide, polyester, polypropylene or equivalent materials; Core made of high stretch polyurethane or rubber or other similar material and covered/wrapped with synthetic filament yarn or grey/bleached/dyed cotton and/or viscose/rayon.	bandage and raw material requirement shall be classified separately	
7.1 Weight	7.1.1 The weight of elastic bandage determined by weighing the whole bandage divided by the stretched surface area per width gives the weight per unit area.	7.1.1 The weight of elastic bandage determined by weighing the whole bandage divided by the stretched surface area per width gives the weight per unit area. **(text 'per width' shall be removed)**	Correct 'definition for measuring the weight per meter' is mentioned.	As per actual definition.
7.2 Stretched length and extensibility	1) The extensibility of elastic bandage shall be 65 to 220 percent.	1) The extensibility specification shall be modified as 55 to 270 percent 2) This part shall be updated with Elastic bandage's category wise Extensibility %	1)To include the elastic bandages manufactured with short extensibility through woven technology and with high extensibility through knitting technology. 2) To have the scope of specific bandage	1)Have the scope to include more elastic bandages from woven and knitting technology. 2) To have better clarity regarding bandages prescription and usage.

		parameters (as per Table 2)	usage for specific indications	
9 TESTS **9.1**	Testing of elastic bandage shall be carried out at 65 +/- 5 relative humidity and temperature 25 +/- 2 C.	Testing of elastic bandage shall be carried out at 65 +/- 5 relative humidity and temperature 27°c +/- 2.	Testing condition shall be revised as mentioned in IS 4605 standard – to make uniform requirement between different bandage standards.	IS 4605 : 1981 standard for Crepe Bandage
10.2 Marking	10.2 Packing The packing shall be marked with the following information a) Name and trade- mark of the manufacturer b) Colour if any c) Width and stretched length d) Batch number	10.2 shall be mentioned as below "The packaging shall be marked as per Medical Device Rule 2017 guidelines"	Updation in align with CDSCO' medical device classification guideline	MDR 2017 – medical device classification guideline
A – 3 **PROCEDURE :**	A- 3.1 Method for measuring of stretched length and extensibility of elastic bandage	1)Shall be updated as per Amendment No. 2 2) Extended condition with specific load duration shall be revised as 60 Seconds from the existing of 30 Seconds	1) Incorporation of amendment No. 2 2) In align with DIN 61634 standard.	1) As per amendment 2) Referred with internal standard.
B-3 **PROCEDURES**	B- 3.1 Method for measuring regain	Shall be updated as per Amendment No 2	Incorporation of amendment No.2	As per amendment

ANNEX 5
(Item 4.*2*)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDRADS

Draft for comments only Doc No.: TXD 36 (22678)
XXXXX 2024

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***भारतीय मानक* मसौदा**
वस्त्रादि — इलास्टिक पट्टी
(आई एस 16111 का *पहला* ***पुनरीक्षण***)

Draft *Indian Standard*
Textiles — Elastic Bandage

(*First Revision* of IS 16111)

ICS: 11.040.20

Technical Textiles for Medtech Applications Sectional Committee, TXD 36

last date for receipt of comments is XXXX 2024

FOREWORD

(*Formal clauses will be added later*)

This standard was originally published in 2013. The present revision has been made in the light of experience gained since its first adoption and to incorporate the following major changes:

i) Title of the standard has been modified and changed.
ii) Amendment has been incorporated.
ii) BIS certification clause is incorporated.
iii) Packing and marking clause is incorporated.
iv) Latest sampling clause is incorporated.
v) References to Indian standards is updated.
vi) Comments has been added.

a) **Amendment 1** Requirement of material and involved processes have been modified.
b) **Amendment 1** Bandage dimension have been added
c) **Amendment 2** Stretched length and extensibility % checking method have been further elaborated
d) **Amendment 2** Regain parameter checking terminology have been redefined
e) **Amendment 3** Bandage dimension and its tolerances have been redefined
f) Bandages different types removed and generally all types are covered.
g) Raw material parts clearly redefined
h) The text ‘to be used in intact skin only’ have been added
i) Testing condition have been redefined
j) Marking as per Medical Device Rule 2017 have been included

An elastic bandage is one continuous strip without joints, of woven/knitted material stretches along its intended to provide support and immobilize dressings covering the wounds besides the function of compression and support for orthopaedic purposes.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2:2022 'Rules for rounding off numerical values (*second revision*).' The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1 SCOPE

Elastic bandages are Medical Devices categorized as Class A. This standard covers the dimensions and other requirement for elastic bandages.

2 REFERENCE

The following standard contains provisions, which, through reference in this text, constitute provision of this standard. At the time of publication, the edition indicated was valid. This standard is subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standard indicated below:

IS No.	*Title*
IS 1889 (Part 1) : 2024/ISO 1833-5 : 2006	Textiles — Quantitative Chemical Analysis — Mixtures of Viscose Cupro or Modal and Cotton Fibres Method Using Sodium Zincate (*second revision*)

3 DEFINITION

For the purpose of this standard, the following definition shall apply.

3.1 Elastic Bandages — An elastic bandage is intended to provide support and immobilize dressings covering the wounds besides the function of compression and support for orthopaedic purposes to be used in intact skin only.

4 TYPES

Elastic bandages can be classified as follows based on type of yarn with their method of manufacturer:

A — woven cellulosic yarn bandage
B — knitted cellulosic yarn bandage
C — woven non-cellulosic yarn bandage
D — knitted non-cellulosic yarn bandage
E — combination of both cellulosic yarn/non-cellulosic yarns woven knitted
F — combination of both cellulosic yarn/non-cellulosic yarns knitted.

5 DIMENSIONS AND TOLERANCES

Description	**Width** (cm)	**Tolerance for width** (cm)	**Stretched Length** (m)	**Tolerance for Stretched Length** (cm)
	2—4	± 0.2	2.0 — 4.0	± 20
			Above 4.0 — 10.0	± 40

			Above 10.0 — 20.0	± 60
Elastic Bandages				
	Above 4 — 12	± 0.5	2.0 — 4.0	± 20
			Above 4.0 — 10.0	± 40
			Above 10.0 — 20.0	± 60
	Above 12— 20	± 0.7	2.0 — 4.0	± 20
			Above 4.0 — 10.0	± 40
			Above 10.0 — 20.0	± 60

6 MATERIAL

6.1 Elastic bandages shall be cellulosic/non-cellulosic yarn or combination of both yarn with following composition.

6.1.1 Hydrophilic/cellulosic fibre content, minimum 35 percent [*see* IS 1889 (Part 1)].

6.2 Filament yarns made from partially oriented yarn (POY) of polyester, polyamide, polypropylene or equivalent material.

6.3 It consist of a core made of high stretch spandex, lycra, polyurethane, rubber or similar material and covered/wrapped with synthetic filament yarn or grey/ bleached/dyed cotton and/or viscose/rayon.

7 MATERIAL COMPOSITION

7.1 Elastic Bandages

Shall be with cellulosic/non cellulosic yarn or combination of both yarn with following composition

7.1.1 Elastic bandages shall have minimum 35 % of hydrophilic / Cellulosic fibre content. [See IS 1889 (part 1)]

7.2 Raw Material

Cellulosic yarns

Non Cellulosic Filament yarn made from polyamide, polyester, polypropylene or equivalent materials;

Core made of high stretch polyurethane or rubber or other similar material and covered/wrapped with synthetic filament yarn or grey/bleached/dyed cotton and/or viscose/rayon.

8 REQUIREMENTS

8.1 Weight

The weight of the elastic bandage shall be 25 to 170 g/m^2.

8.1.1 The weight of elastic bandage determined by weighing the whole bandage divided by the stretched surface area gives the weight per unit area.

8.2 Stretched Length and Extensibility

The extensibility of elastic bandage shall be 65 to 270 percent. Stretched length and extensibility shall be tested as per Annex A.

8.3 Regain

The regain of the test bandage shall be not less than 70 percent when tested as described in Annex B.

9 MANUFACTURE, WORKMANSHIP AND FINISH

9.1 Elastic bandages shall be in woven/knitted bandages containing cellulosic, non-cellulosic yarns or a combination of both with non-fraying closed selvedges /edges and or grey/while/coloured shade.

9.2 Finish

The use of optical brightening agents is prohibited. Under UV lamp no fluorescence shall be observed except for a few brightly illuminated individual fibres.

10 TESTS

10.1 Testing of elastic bandage shall be carried out at 65 ±5 relative humidity and temperature 27°c±2.

10.2 Test for Width

The portion between and including the fast edges of the unstretched bandage.

10.3 Test for Diameter

The distance as measured at the outer circumference while holding the bandage but not pressing the bandage.

11 PACKING AND MARKING

11.1 Packing

The bandage shall be rolled and packed suitably to prevent contamination from dust.

11.2 Marking

The packaging shall be marked as per Medical Device Rule 2017 guidelines.

12 CERTIFICATION MARKING

The elastic bandage may also be marked with the Standard Mark.

12.1 BIS Certification Marking

The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act*, *2016* and Rules and Regulations made there under. The details of the conditions under which the licence for use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

ANNEX A
(*Clause* **8.2**)

METHOD FOR MEASURING OF STRETCHED LENGTH AND EXTENSIBILITY OF ELASTIC BANDAGE

A-1 TEST SPECIMEN

For the purpose of this test, all rolls in the test sample constitute the test specimen.

A-2 APPARATUS

A-2.1 Stretch testing table of marked length 6 m with fixed clamp A at left end and moving clamp B at right end. The table has mechanical and pneumatic arrangement for the loading and un-loading the weights (*see* Fig. 1). The table is attached with a fixed measuring tape arrangement.

A-2.2 Standard weight up to 25 kg in denominations of 1 kg, 2 kg and 5 kg, whichever applicable.

A-3 PROCEDURE

A-3.1 Unwind the bandage on the stretch table and measure its unstretched length L1 immediately. Mark 5 cm on both ends and fix clamp A and clamp B on the bandage at both ends X1 and X2 (5 cm from the ends). Connect the loading pan C weighing 1 kg to the moving clamp B (see Fig. 1). Now apply load of 1 kg for each cm of bandage width. Keep the load applied on the bandage kept in extended condition for 30 s. Measure the distance between two marks and record the stretched length L2 in cm and release the load mechanically or by pneumatic arrangement. To compensate for the clamped part at both ends (that is 5 cm + 5 cm = 10 cm) we need to add correction factor (CF) to this stretched length L2 and derive the final stretched length L3 = L2 + CF.

A-3.1.1 For bandage of stretched length above 5 m, measure the unstretched length L1, mark the centre point by dividing the unstretched length by two. Find the stretched length for the first part and second part separately by the same method.

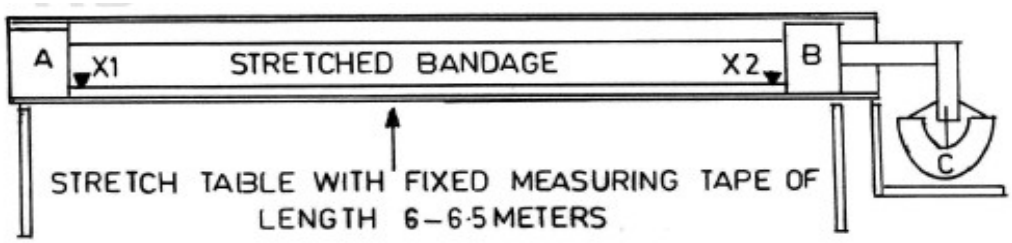


FIG. 1 APPARATUS FOR MEASURING OF STRETCHED LENGTH EXTENSIBILITY OF ELASTIC BANDAGE

A-3.2 Calculate the extensibility percent and correction factor (CF) as follows:

$$\text{Extensibility percent} = \frac{L3 - L_1}{L_1} \times 100$$

NOTES

1 Correction factor, in cm = 10 + (Standard extensibility percent of bandage) / 10
2 Standard extensibility percent of bandage (S)—This standard extensibility percent is determined by measuring one time the stretched length for 100 cm unstretched length. This is added for all subsequent tests for that product.

Find out standard extensibility percent as follows:

$$S = \frac{\text{Stretched length (for 100 cm unstretched length)} - \text{Unstreched length (100 cm)} \times 100}{\text{Unstreched length (100 cm)}}$$

ANNEX B
(*Clause* **8.3**)

METHOD FOR MEASURING OF REGAIN

B-1 TEST SPECIMEN

For the purpose of this test all rolls in the test sample constitute the test specimen.

B-2 APPARATUS

B-2.1 Stretch testing table of marked length 6 m with fixed clamp A at left end and moving clamp B at right end. The table has mechanical and pneumatic arrangement for the loading and un-loading the weights (*see* Fig. 2). The table is attached with a fixed measuring tape arrangement.

B-2.1.1 Standard weight up to 25 kg in denominations of 1 kg, 2 kg and 5 kg, whichever applicable.

B-3 PROCEDURES

B.3.1 Measure the un-stretched length and marked 5 cm at the beginning and at the end of the bandage. In order to determine the regain, the remaining length must be determined. Make a second mark at the beginning of the bandage at a distance of 10 cm from the first mark. Measure the stretched length as per test procedure. Wait for 2 min and in this time the bandage must laying in zig-zag relaxed position (length of about 30 cm). To get the remaining length, measure the length of the marks at the beginning and at the end of the bandage. Add the small part between the first and the second mark. This will give the remaining length.

B-3.2 Calculate the regain in percentage as:

$$\text{Regain in percent} = \frac{\text{Stretched length} - \text{Remaining length}}{\text{Stretched length} - \text{Unstretched length}} \times 100$$

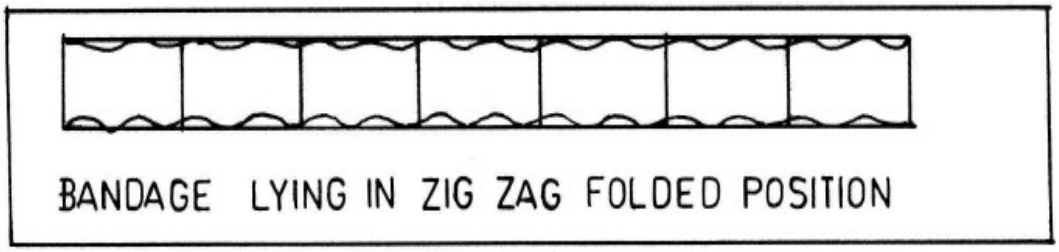


FIG. 2 APPARATUS FOR MEASURING OF REGAIN OF ELASTIC BANDAGE

ANNEX 6
(Item 4.*3*)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

MEDICAL TEXTILES – NONWOVEN GAUZE (STERILE AND NON-STERILE) – SPECIFICATION

A) <u>COMMENTS AND INPUTS FROM GINNI FILAMENTS</u>

TEST REPORT

Test Repot No.	: **C2300145**	Date	**: 17-05-2023**
Our Ref No	;**V/ 3 /E / 121187/23**	No of Sample	**: 2**
Your Ref No	; **20.4.23**	Received on	:**09-05-2023**

To
Ginni Filaments Ltd
Plot No.205-207,GIDC Industrial Estate,
Panoli,Ankleshwar,
Bharuch,Gujarat ,India Pincode : 394116
Contact No(s) : 8929312993

Date (s)of Test Performance :17-05-2023

Dear Sir /Madam,

We are pleased to give our results (enclosed) on your above samples.

Authorised by,
(Kumaran.M)

Test Repot No. : C2300145
Ginni Filaments Ltd

Report Date : 17-05-2023
Reference :20-04-2023

Samples Tested at : R.H. 65% ± 2% and Temp. 21 Degree C ± 1 Degree C

Fabric - Tensile Strength (Zwick/Roell)	**C2300145-2** RAW WHITE. GSM-30. PV3070A2030 30% POLY.70% VISCOSE, APERTURE U MESH REF-GNW/200423-01. WET	**C2300145-3** RAW WHITE, GSM-30, 30% POLY,70% VISCOS REF-GNW200423-0,DRY
Machine Direction Strength (N)	31.3	36.9
Machine Direction Elongation (%)	24.1	19.2
Cross Direction Strength (N)	8.79	9.67
Cross Direction Elongation (%)	84.6	88.0

Note : Rate of traverse 100 mm/min, Specimen Size: 20x 500mm

TEST REPORT

XXVII/P/E/ 22937/23

ULR: TC694423600008445F
Inward / Report No. : P2300127

To,
Ginni Filaments Ltd
Plot No.205-207,GIDC Industrial Estate,
Panoli, Ankleshwar,
Bharuch, Gujarat ,India
Pincode : 394116
Contact No(s) : 8929312993
Email: gurmeet@ginnifilaments.com

Inward Date :06-05-2023
Tested on :**08-05-2023**
Report Date **:08-05-2023**

Dear Sir /Madam,

This has reference to the sample(s) submitted by you for testing vide your letter reference no : **Mail Dt.05.05.2023**.

The results pertaining to your sample(s) are enclosed herewith.

Authorised by,
(D.Veerasubramanian)

Ginni Fliaments Lid, Ref : Mail Dt.05.05.2023 **ULR: TC694423600008445F**

(Sample Tested at: R.H 65% +/- 2% and Temp. 21 Degree C +/- 1 Degree C)

Liquid Absorption Time **IS 15891 (Part 6) : 2012 Reaffirmed 2020**	P2300127-1 Described by the Customer : **30 GSM Product Code:PV3070A2030, Blend-30%Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW1200423-01,Colour-Raw White**
Type of test liquid used	Distilled water
Average liquid absorbency time in sec	1.57
Standard deviation	0.21

Liquid Absorptive Capacity **S 15891 (Part 6) : 2012 Reaffirmed 2020**	P2300127-1 Described by the Customer **: 30 GSM Product Code:PV3070A2030, Blend-30%Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No; GNW/200423-01,Colour-Raw White**
Type of test liquid used	Distilled water
Average liquid absorbency capacity in %	1114.46
Standard deviation	20.75

TEST REPORT

XXVII/P/E/ 22936/23

ULR: TC694423600008444F
Inward / Report No. : P2300128

To,
Ginni Filaments Ltd
Plot No.205-207,GIDC Industrial Estate,
Panoli, Ankleshwar,
Bharuch, Gujarat ,India
Pincode : 394116
Contact No(s) : 8929312993
Email: gurmeet@ginnifilaments.com

Inward Date : 06-05-2023
Tested on : **08-05-2023**
Report Date **: 08-05-2023**

Dear Sir /Madam,

This has reference to the sample(s) submitted by you for testing vide your letter reference no : **Mail Dt.05.05.2023**.

The results pertaining to your sample(s) are enclosed herewith.

Authorised by,
(D.Veerasubramanian)

Ginni Fliaments Lid, Ref : Mail Dt.05.05.2023 **ULR: TC694423600008444F**

(Sample Tested at: R.H 65% +/- 2% and Temp. 21 Degree C +/- 1 Degree C)

Mass per Unit Area **IS 15891-1:2011 Reaffirmed 2019**	**P2300128-1** Described by the Customer : **30 GSM Product Code:PV3070A2030, Blend-30%Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW1200423-01,Colour-Raw White**
Test result of Specimen 1 in g/m^2	34.43
Test result of Specimen 2 in g/m^2	35.37
Test result of Specimen 3 in g/m^2	34.73
Mean value in g/m^2	34.84
Co-officiant of Variation in %	1.38
The conditioning atmosphere used	Teprature:20+/- 2 deg.C and RH:65+/-4

XXVII/P/E/ 22941/23

Report No**. : P2300132**
ULR: TC694423600008449F

To,
Ginni Filaments Ltd

Sample Received on **:08-05-2023**

Plot No.205-207,GIDC Industrial Estate,
Panoli, Ankleshwar,
Bharuch, Gujarat ,India
Pincode : 394116
Contact No(s) : 8929312993
Email: gurmeet@ginnifilaments.com

Inward Date : **08-05-2023**
Tested on **: 09-05-2023**
Report Date **: 09-05-2023**

Dear Sir /Madam,

This has reference to the sample(s) (details given below) submitted by you for testing vide your letter reference no : **Mail Dt.05.05.2023**.

Sample Code	Your Reference
P2300132-1	30 GSM product Code: PV3070, Blend-30% Polyester +70% Viscose. Type : Aperture 16 mesh, Ginni Ref No : GNW/200423-01, Colour-Raw White

The results pertaining to your sample(s) are enclosed herewith.

Authorised by,
(D.Veerasubramanian)

Ginni Filaments Ltd

TEST RESULTS - P2300132 Report Date : 09-05-2023 Ref: Mail Dt.05.5.202

TOTAL LINTING – IS 15891-10

A SIDE

	3.0 Micron	5.0 Micron	10.0 Micron	25.0 Micron	Total
A1	192	146	190	41	569
A2	163	159	166	31	519
A3	262	201	245	72	780
A4	310	299	319	94	1022
A5	292	283	325	87	987
AVG	244	218	249	65	775
C0	0	0	0	0	0
AVG-CO	244	218	249	65	775

B SIDE

	3.0 Micron	5.0 Micron	10.0 Micron	25.0 Micron	Total
B1	408	298	379	81	1166
B2	284	268	290	57	899
B3	157	141	185	110	593
B4	415	380	387	119	1301
B5	501	541	683	132	1857
AVG	353	326	385	100	1163
C0	0	0	0	0	0
AVG-CO	353	326	385	100	1163

	A SIDE	**B SIDE**	**C SIDE**
Total Particles	775	1163	969
Log 10(Lint Count)	2.89	3.07	2.99

TEST REPORT

Test Repot No.: **M2300115**	**URL: TC694423700002196F**	Report Date **: 22-05-2023**
SITRA Ref No: **XXVII/M/E/23058/23**		No of Sample **: 1**
Customer Ref No.: Mail Dt.05-05-2023		Received on : **25-04-2023**

To
Ginni Filaments Ltd
Plot No.205-207, GIDC Industrial Estate,
Panoli, Ankleshwar,
Bharuch, Gujarat ,India
Pincode : 394116
Contact No(s) : 8929312993

Dear Sir / Madam,

This has reference to the sample(s) submitted by you for testing vide your Letter reference no : ***Mail*** **Dt.5.5.23**.

The results pertaining to your sample(s) are enclosed herewith.

Authorised by,
(Dr. R. Radhai)

Test Repot No.: **M2300115** **URL: TC694423700002196F** Report Date : **22-05-2023**
Ginni Filaments Ltd Ref : Mail Dt.**05-05-2023**

Test Name : ISO 11737 -Part -1 -2018 Bio burden testing
Test Condition:

Sample size/ Volume : 1 g
Media used : Nutrient agar, Sabourauds dextrose agar with chloramphenicol
Eluent used : 0.85% Saline with 0.1 % tween 80
Diluent used : 0.85% Saline
Method used to remove Microorganisms : Mechanical shaking
Method of plating : Pour plate method
Inoculum / plate : 1 mL
Incubation conditions : 37°C for 24 h and 25°C for 7 days

Test Parameter	**M2300115-1** Described by the customer : **Nonwoven; 30 GSM Product Code:PV3010A2030, Blend-30% Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW/200423-01,Colour-Raw White**
Total bacterial count	2.1×10^6 CFUL/g
Total fungal count	2.2×10^6 CFUL/g
Result: The samples tested for their bioburden analysis showed 2.1×10^6 CFU/g bacterial growth after 24 h of incubation and 2.2×106 CFU/g fungal growth after 7 days of incubation when tested according to ISO 11737- Part1. The microbial load of the lab environment was within the limit during the test.	

XXVII/PO/E/ 23089/23 **Inward / Report No. : S2300106**

To,
Ginni Filaments Ltd
Plot No.205-207,GIDC Industrial Estate,
Panoli, Ankleshwar,
Bharuch, Gujarat ,India
Pincode : 394116
Contact No(s) : 8929312993
Email: gurmeet@ginnifilaments.com

Inward Date **: 06-05-2023**
Report Date : **23-05-2023**

Dear Sir /Madam,

This has reference to the sample(s) submitted by you for testing vide your letter reference no : **Mail Dt.05.05.2023**.

The results pertaining to your sample(s) are enclosed herewith.

Authorized by.
(L. Amaporpaya Mary)

Ginni Filaments Ltd.	Ref. : Mail Dt. 05-05-2023
pH Values	**S2300106-1** Described by the customer : **30 GSM Product Code:PV3010A2030, Blend-30% Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW/200423-01,Colour-Raw White**
pH	6.40

Water Soluble Substances British Pharmacopocia	**S2300106-1** Described by the customer : **30 GSM Product Code:PV3010A2030, Blend-30% Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW/200423-01,Colour-Raw White**
Percentage	0.17

Ether Soluble Substances EN 14079:2003	**S2300106-1** Described by the customer : **30 GSM Product Code:PV3010A2030, Blend-30% Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW/200423-01,Colour-Raw White**
Percentage	0.11

Fluorescence British Pharmacopocia	**S2300106-1** Described by the customer : **30 GSM Product Code:PV3010A2030, Blend-30% Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW/200423-01,Colour-Raw White**
Result (Percentage /Absent)	Absent

Fibre Identification	**S2300106-1** Described by the customer : **30 GSM Product Code:PV3010A2030, Blend-30% Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW/200423-01,Colour-Raw White**
Fibre Identification	Polyester

EN 14079 : 2003, IS 667 : 1981 RA 2013

Non-woven Gauze is of mesh structure (similar to woven cloth) from viscose (rayon) and polyester staple fibres blended spunlace non-woven fabric with minimum 50 percent viscose (Rayon) content.

Performance Requirements for Nonwoven Gauze Swabs

Sl No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Weight per square metre, g/m2, Min	30	IS 15891 (Part 1)
ii)	Absorbency,		IS 15891 (Part 6)
	Sinking Time, s, Max	10	
	Water Holding Capacity, percent, Min	400	
iii)	Sterilization (optional)	Complies as per the test method	ISO 11737-2
iv)	Tensile strength in machine	20	IS 15891 (Part 3)

	direction (Dry) in N/5cm, Min		
v)	Tensile strength in machine direction (Wet) in N/5cm, Min	20	IS 15891 (Part 3)
vi)	Water soluble substance, %age, Max	1	IS 14944
vii)	Ether soluble substance, %age, Max	1	IS 14944
viii)	Acidity and Alkalinity	6.5 to 8.5	IS 1390:1983
ix)	Fluorescence	6.5 to 8.5	ISO 3071:2005
x)	Cytotoxicity	Absent	IS/ISO 10993-5
xi)	Wet Linting	Value	EN 1644-2:2000

The Manufacturers of Gauze Swabs are the following:

Ginni Filaments Limited Gulshan Vohra – 78386 86633	Sector 5, Plot no 98, SIDCUL U. K, Integrated Industrial Estate, Sector 5, Haridwar, Uttarakhand 249403
Apex Medivision	Gaushala Road, Near Railway Station, Safidon, Haryna-126112

Gurjeet Singh: 81681-78037	
Surgilife Medical Devices Private Limited Lalit Sareen – 98714 51065	448, Patparganj Industrial Area, Patparganj, Delhi, 110092
BIPSON SURGICAL PVT. LTD. Ashish Parikh -93280 44799	Plot No - 14, Industrial Area, Nr. GTS, Sector - 30, Gandhinagar-382030, Gujarat

The Users of Gauze Swabs are the following:

F4 Surgicals Syed Farhat - 09419010073	S.K.Colony, Laizbal, Ananatnag, Kashmir - 192101
Aseem Agencies P Ltd DS Chawla - 98156 07778	778/1, Gurdev Nagar, Ludhiana – 141001, Punjab
Medilivescare Manufacturing Pvt. Ltd. Rajesh Kumar - 78388 60002, 70119 19620	3/9, Ajanta Compound, Site -II, Loni Road Industrial Area, Mohan Nagar, Ghaziabad, (U.P.) - 201007
Reach Global India Pvt Ltd Shreyas Chanekar - 937 078 8855	Plot No. I-22, Gat no 1064, Chordia Industrial Park, Naigaon, Shirwal, Taluka Khandala, Satara, Maharashtra- 412801

Nonwoven wound dressing provides an effective barrier against bacteria

Nonwoven wound dressings can be easily adapted to required specifications

Nonwoven materials used for wound dressing have advantage that they do not trigger coagulating property in blood.

Wound dressings developed from nonwoven materials are particularly effective since the objective of wound care is to facilitate healing and prevent infection. Nonwoven wound dressings and bandages are well-suited for direct contact with the skin, as it helps to cushion the wound and heal faster.

Nonwovens are widely used in medical facilities, to reduce any possibility of infection, contamination or other related concerns and HNI, as human touch is minimised.

Standard	**Description**

ISO 15223-1:2021	Symbols to be used with information to be supplied by the manufacturer
EN ISO 10993-18:2020/A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 9073-10:2004	Textiles - Test methods for nonwovens - Part 10: Lint and other particles generation in the dry state
ISO 9073-6:2000	Textiles Test methods for nonwovens Part 6: Absorption
ISO 9073-3:2023	Nonwovens Test methods Part 3: Determination of tensile strength and elongation at break using the strip method
ISO 9073-1:2023	Nonwovens Test methods Part 1: Determination of mass per unit area
EN 1644-2:2000	Test methods for nonwoven compresses for medical use - Part 2: Finished compresses
EN 1644-1:1997	Test methods for nonwoven compresses for medical use - Part 1: Nonwovens used in the manufacture of compresses
ISO 11737-1:2018	Sterilization of health care products Microbiological methods Part 1: Determination of a population of microorganisms on products
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 13485:2012	Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes

What to consider when choosing gauze sponges

Criteria	Considerations
Absorbency	A sponge requires adequate absorbency to keep an operative field and wound clean and dry. A high-quality sponge that provides good absorption means you will use fewer sponges, saving you both time and money and producing less waste. Absorbency is also key to ensuring patient comfort, as good absorbency helps prevent patients from swallowing blood, saliva and debris.
Thickness	A sponge's fluid absorption rate and retention rate are directly related to its basis weight. Basis weight is a measure of the thickness of the material the sponge is made from. Naturally the more "plies" (layers) in a sponge, whether non-woven or woven, the higher its absorbency. Additional thickness also provides extra cushioning for extraction sites and other wounds.
Linting	Sponge material that tends to shred or fray often leaves small fibers behind on dental instruments or directly in wounds. These fibers can interfere with both treatment and healing, making it important to choose a sponge that does not produce lint. One of the benefits of non-woven sponges is that they are lint-free.
Texture	A sponge with some texture can be useful for cleaning instruments and surfaces. However, a sponge that is made of rough materials can cause pain and irritation when applied to sensitive tissues. A softer sponge that provides little adhesion to the wound is therefore a better choice for extractions and other procedures that create incisions.
Durability	Higher-quality sponges help ensure that you use fewer sponges per procedure. Given the multiple uses for sponges, choosing a more durable brand can result in significant savings.

Versatility	Different procedures and different areas of the mouth require different sizes and shapes of sponges. For example, larger sponges are ideal for cleaning surfaces and instruments, as washcloths for patients' faces and for hemostasis in larger areas of the mouth. Although some types of non-woven sponges can be cut to size, others are best shaped and sized by the manufacturer to suit specific applications. Cutting woven sponges is not recommended, as it can release fibers.
Fiber types	Fiber types are an important point of differentiation between woven and non-woven sponges. While woven sponges are made entirely from cotton, non-woven sponges can be made either entirely from cotton or from blends of polyester and rayon. Cotton fibers are ideal for applications where there is more moisture because cotton fibers get stronger as they get wetter. Polyester, on the other hand, is a non-absorbent fiber, so its strength doesn't change when it gets wet. For that reason, polyester is typically combined with rayon. The two fibers complement each other because whereas polyester is strong, rayon is absorbent. It should also be noted that while both cotton and rayon are biodegradable, polyester is not.
Latex content	Because latex allergies and sensitivities have become more common, sponges that are free of natural rubber latex are generally the safest choice.

B) WELSPUN INDIA

Sl. No.	Characteristic	Method of Test, Ref to	Requirement	V100A4035	NOC100A8035	BCPPSB5743A4035	Woven Gauze
i)	Weight per square metre, g/m2	IS 15891 (Part 1)	30	**35.59**	**37.12**	**37.3**	30
ii)	Absorption:	IS 15891 (Part 6)					Not checked
	a) Sinking time, s, Maxx		<10 .00	1.82	1.17	3	
	b) Water holding capacity, percent, Min		>400.00	1042	974	720	
iii)	Sterilization (optional)	ISO 11737-2	No visible microorganism shall be present	Not visible	Not Visible	Not visible	Not Visible
iv)	Breaking strength in machine direction (Dry), N, Min	IS 15891 (Part 3)	>20.00	52.5	35.3	50.1	-
v)	Breaking strength in machine direction (Wet), N, Min	IS 15891 (Part 3)	>20.00	42.1	33.2	46.3	-
vi)	Water soluble substance (%)	IS 14944	<1.0	<1	<1	<1	<1
vii)	Ether soluble substance (%)	IS 14944	<1.0	<1	<1	<1	<1
viii)	pH value of aqueous extract	IS 1390	6.5 to 8.5	7.2	6.8	7.2	7.1
ix)	Freedom from optical whitener	Viewing under ultra-violet light	No fluorescence (Not more than occasional point of fluorescence visible)	Free	Free	Free	Free

x)	Cytotoxicity	IS/ISO 10993-5	None	None	None	None	Not checked
xi)	Particle release [Log10(lint count)	IS 15891 (Part 10)	≤ 4.0	Dry – 5.18	Dry – 5.58	Dry – 4.79	Dry – 5.00
				Wet - 3.72	Wet - 3.77	Wet - 3.52	Wet - 3.69
i)	Fibre identification	IS 667	Cotton/ viscose/ Modified Cellulosic fibre	Viscose – 100%	Cotton – 100%	Cotton – 57%	Cotton – 100%
						PP – 43%	

ANNEX 7
(Item 4.*3*)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDRADS

Draft for comments only Doc No.: TXD 36(XXXXX)
XXXX 2024

(*Not to be reproduced without permission of BIS or used as Standard*)
***भारतीय मानक* मसौदा**

वस्त्रादि —

Draft *Indian Standard*

Textiles — Medical Textiles – Nonwoven Gauze (Sterile and Non-Sterile) - Specification

ICS:

Technical Textiles for Medtech Applications Sectional Committee, TXD 36

last date for receipt of comments is XXXX 2024

FOREWORD

(*Formal clauses will be added later*)

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*Second Revision*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1 SCOPE

This standard specifies the requirement of Nonwoven Gauze (Sterile and Non- Sterile) intended for medical use.

2 REFERENCES

The standards listed in Annex A contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A.

3 TERMINOLOGY

For the purpose of this standard, the following term shall apply.

3.1 Nonwoven Gauze - It is of mesh structure (similar to woven cloth) made from viscose (rayon) and polyester staple fibers blended spun lace nonwoven fabric with minimum 50 percent viscose (rayon) content.

4 MANUFACTURE, WORKMANSHIP AND FINISH

4.1 The Nonwoven Gauze shall be clean and free from substances liable to cause tendering during storage. The product shall be free from toxic or harmful substances. If the product is to be supplied in sterilized condition, it may be sterilized by any suitable method of sterilization in accordance with IS 10150:1981.

4.2 The manufacture and preparation of the Nonwoven Gauze shall be conducted under proper hygienic conditions

5 MARKING

5.1 Each pack of the Nonwoven Gauze shall be legibly marked with the following information:

a) Generic name (and brand name, if any) of the product. The generic name shall be marked more conspicuously than the brand name;
b) Manufacturer's name, initials or trade-mark, if any;
c) Overall dimensions and quantity;
d) Month and year of manufacture;
e) If sterilized, it shall be described as STERILIZED – Sterility guaranteed unless the pack is opened or damaged, and

Sl No. (1)	**Characteristic** (2)	**Requirement** (3)	**Method of Test, Ref to** (4)
i)	Weight per square metre, g/m^2, *Min*	30	IS 15891 (Part 1)
ii)	Absorbency, Liquid absorption time, s, *Max* Liquid absorptive capacity, percent, *Min*	 10 400	IS 15891 (Part 6)
iii)	Sterilization (optional)	No viable microorganism shall be present	ISO 11737-2
iv)	Tensile strength in machine direction (Dry) in N/5cm, *Min*	20	IS 15891 (Part 3)
v)	Tensile strength in machine direction (Wet) in N/5cm, *Min*	20	IS 15891 (Part 3)
vi)	Water soluble substance, %age, *Max*	1	IS 14944
vii)	Ether soluble substance, %age, Max	1	IS 14944
viii)	pH of the aqueous extract	6.5 to 8.5	IS 1390

ix)	Freedom of Optical Whitener	'No fluorescence or not more than occasional point of fluorescence visible' when viewed under the ultra-violet (UV) light of wavelength 365 nm	
x)	Cytotoxicity	None	IS/ISO 10993-5
xi)	Particle release [log10 (lint count)]	≤ 4.0	IS 15891 (Part 10)
xii)	Fibre identification	at least 50 percent of viscose (rayon) fibre	IS 667

5.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, *2016* and the Rules and Regulations framed thereunder, and the product may be marked with the Standard Mark.

6 SAMPLING AND CRITERIA FOR CONFORMITY

6.1 LOT

All the Nonwoven Gauze of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot.

6.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

6.1.2 The number of packs of Nonwoven Gauze to be selected from the lot shall depend on the size of the lot and shall be in accordance with col 2, col 3 and col 5 of Table 2.

6.1.3 These Nonwoven Gauze shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

Table 2 Number of Nonwoven Gauze to be selected

(*Clause* **6.1.2**)

Sl No.	**Lot size**	**Nondestructive testing**		**Destructive testing**	
		No. of packs of Nonwoven Gauze to be selected	Acceptance Number	No. of packs of Nonwoven Gauze to be selected	Acceptance Number
(1)	N (2)	n (3)	a (4)	n1 (5)	a2 (6)
i)	Upto 280	13 [1]	1	8	0
ii)	281 - 500	20	2	8	0
iii)	501 - 1200	32	3	13	0
iv)	1201 - 3200	50	5	13	0
v)	3201 - 10000	80	7	20	1

[1] Or lot size when less than 13

6.2 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

6.2.1 All Nonwoven Gauze selected as per col 3 of Table 2 shall be examined for manufacture, workmanship and finish (*see* **4.1 to 4.2**).

6.2.1.1 Any Nonwoven Gauze failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in col 4 of Table 2. Otherwise, the lot shall be rejected.

6.2.2 Out of the sample already found satisfactory according to **6.2.1.1**, a sub-sample as per col 5 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

6.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective gauze absorbent found in the sample (*see* **6.2.2**) is less than or equal to the acceptance number as given in col 6 of Table 2.

7 PACKING

The Nonwoven Gauze shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. The wax paper shall not be used for any wrapping as it affects the absorbency of the gauze. If the material is sterilized, it shall be enclosed in a sealed package which is adequate to maintain the sterility of the material up to the time of opening the package. Packaging of the product should be such as to maintain the integrity of the product throughout its shelf life.

ANNEX A
(*Clause* 2)

LIST OF REFERRED INDIAN STANDARDS

IS No.	*Title*
IS 1390 : 2022	Textiles — Determination Of *p*H Of Aqueous Extract (*Third Revision*)
IS 667 : 1981	Methods For Identification Of Textile Fibres (*First Revision*)
IS 4905 : 2015	Random Sampling And Randomization Procedures (*First Revision*)
IS/ISO 11737-2 : 2019	Sterilization Of Health Care Products — Microbiological Methods — Part 2: Tests Of Sterility Performed In The Definition, Validation And Maintenance Of A Sterilization Process
IS 15891 (Part 1) :2011/ISO 9073-1:1989	Textiles — Test Methods For Non-Wovens Part 1 Determination Of Mass Per Unit Area
IS 15891 (PART 6) : 2012/ISO 9073-6 : 2000	Textiles — Test Methods For Nonwovens Part 6 Absorption

The results of the Test “Wet Linting EN 1644-2:200” on various samples, are as follows:

Sl. No	Sample no.	Product	Lint Result Value
1	P2200360	Local make - Woven gauze	2772
2	P2200361	Ginni make - Nonwoven gauze	897
3	P2200362	International make - Sample 1-Non-Woven Gauze sponges-Medline Ref:NON25444	843
4	P2200364	International make - Sample 2- Safe Basics General purpose Non-Woven Sponges-Medicom	1248
5	P2200363	International make - Sample 3-Non-Woven Sponges-Dynarex Corporation Ref:3254	1090

ANNEX 8
(Item 4.*4*)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION
MEDICAL TEXTILES -SCRUB SUIT – SPECIFICATION

Ms Shivani Living Guard Comments

1. Inspection report issued by the mill on the ready for finishing fabric.
2. We run a similar internal inspection of the fabric during intake, so I have also attached that report.
2. Final report after Livinguard treatment for antimicrobial properties and stain repellency.

Unfortunately, we use ASTM and AATCC standards in these, but there should be equivalent IS and ISO standards for each. I am waiting for information on splash resistance and other factors needed for medical scrubs to be clarified from our standards creation process to be able to run further required analysis.

Please note that the other range of scrubs we developed and launched in the US were tested in the US under EPA guidance using a specific EPA protocol. Again here the testing was only to confirm antibacterial efficacy, autoclavability and hydrophobicity of the fabric.

We are yet to come across additional fabric requirements from any market/customer. I believe Dr. Sanjiiv was working on a new draft with requirements as he recommends.

PHYSICAL TEST STANDARDS AND RESULTS FOR COTTON (STRETCH)			
Tests	**Method**	**Unit**	Results
Ends Per Inch	ASTM D 3775		174.00
Picks Per Inch			76.00
Fabric Weight	ASTM D 3776	g/m2	137.50
Overall Width	ASTM D 3774	cms	146.00
Useable Width			143.50
Tensile Strength - Warp	ASTM D 5034	kg	
Tensile Strength - Weft		kg	
Tear Strength - Warp	ASTM D 1424	gm	
Tear Strength - Weft		gm	
Seam Slippage - Warp	ASTM D 434	kg	
Seam Slippage - Weft		kg	
Dimensional Stability L%	AATCC 135	%	-2.10
Dimensional Stability W%			0.00
Bowing	ASTMD 3882	%	
Skew			
Core PH	AATCC 81		6.40
Dp Rating	AATCC 124		

COLOUR FASTNESS TESTS						
Colour Fastness	Method	A/L	Cotton	P	A	W
Washing	AATCC 61-2A	4	3-4	4	4	4
Dry Rub	AATCC 8		4			
Wet Rub	AATCC 8		2-3			

Inward Fabric Q.A report (Bulk) Form: 2A

Test Report No.: TR 944 T.R Date:

31.08.2023Supplier: Fabric Type: Woven

Sample Submitted on: 29.08.2023 Fabric End Use:

Scrub Testing done on: 30.08.2023 Status: To

purchase the fabric

Fabric details: Count- 40,s coton x 97 denier polyester lycra
Color- Air blue ,Construction- 174x76 , Composition- 70 % cotton, 28% polyester2% lycra,Twill 4*2

Test results:

Sr.No. Test Unit Test Results Test Method 1 % Shrinkage % Warpwise - 3%

AATCC 135

Weft wise - 2%

2 pH pH scale 6.4 AATCC 81 3 Absorbency sec 3 sec. AATCC 79 4 Width Cm 148 ASTM D 3774

5 Weight (GSM) gsm 135 ASTM D 3776 6 Rubbing Fastness Rating Dry Rub - 4

AATCC 8

Wet Rub - 3-4

7 Wash fastness Rating 3-4 AATCC 61 8 Perspiration fastness Rating N.A AATCC 15

9 TearStrength Newton N.A ASTM D 1424 10 Tensile Strength Newton N.A ASTM D 5034

Conclusion: Fabric is approved

Introduction

[redacted]HNDM-7 fabric sample – treated with Livinguard 1020 and 3X dry technology was checked for the following:-

I. Antimicrobial activity – ASTM E2149 Method
II. Antiodor property – In-house test protocol for quantitative determination of Iso-valeric acid
III. Water repellent property – AATCC 22 Method

Sample details – 1. HNDM – 7 2. Untreated HNDM	 **Fig 1** : HNDM-7 fabric sample

PART I – Antimicrobial activity of HNDM-7

Procedure

Test Method – ASTM – E2149

Test Organisms – *E.coli* ATCC 25922, *S.aureus* ATCC 6538 & *K.pneumoniae* ATCC 4352

1. Sample was prepared by weighing 1.0 ± 0.1 gm and sterilised by autoclaving.
2. This was then aseptically transferred into separate sterile polypropylene bottles containing 50 ml of Phosphate Buffer.
3. The buffer bottles containing the samples were inoculated with challenge organism to make ~1x 10^6cfu / ml as a final working bacterial dilution.
4. The polypropylene bottles containing the inoculated test samples were closed and placed in a 37° ± 1°C incubator for 1 hour in shaking condition. The sampling for 1 hr contact time was done from the same bottle.
5. The 0 min contact time was immediately analysed after inoculation of test materials.
6. At the end of contact time, all the bottles were shaken for 2 minutes and serial dilution was performed.
7. Every dilution was further analysed by pour plate method.
8. The agar plates (Soyabean Casein Digest Agar) were incubated at 37°C for 24-48 hrs.

Calculation:

Log reduction of bacteria = B - A

Where, A = The Log_{10} of the number of bacteria recovered from the inoculated treated test samples in the jar incubated over the desired contact period.

B = The Log_{10} of the number of bacteria recovered from the inoculated untreated test samples in the jar after the desired contact period.

Observations:

A) Antimicrobial activity against *E.coli* ATCC 25922 At 1 hour of contact time:

The initial count at 0 minute = 2.64 x 10^6 cfu/ml (6.42 log)

Sample Code	Test Culture	Untreated Sample incubated for 1 hour (B)		Sample incubated for 1 hour (A)		Percent Kill (%)
		Cfu/ml	Log Value	Cfu/ml	Log Value	
Untreated Control	*E.coli* ATCC 25922	4.53 x 10^5	5.66	**0.00**	5.66	**0.00**
HNDM – 7	*E.coli* ATCC 25922	-	-	**99.75%**	3.11	**99.71%**

- Remarks: CFU = Colony-Forming Unit, a measure of the number of microorganisms

B) Antimicrobial activity against *S.aureus* ATCC 6538 At 1 hour of contact time:

The initial count at 0 minute = 1.08 x 10^6 cfu/ml (6.03 log)

Sample Code	Test Culture	Untreated Sample incubated for 1 hour (B)		Sample incubated for 1 hour (A)		Percent Kill (%)
		Cfu/ml	Log Value	Cfu/ml	Log Value	
Untreated Control	*S.aureus* ATCC 6538	3.94 x 10^5	5.60	**0.00**	5.60	**0.00**
HNDM – 7	*S.aureus* ATCC 6538	-	-	**99.75%**	3.12	**99.66%**

Remarks: CFU = Colony-Forming Unit, a measure of the number of microorganisms

C) Antimicrobial activity against *K.pneumoniae* ATCC 4352 At 1 hour of contact time:

The initial count at 0 minute = 1.00 x 10^6 cfu/ml (6.00 log)

Sample Code	Test Culture	Untreated Sample incubated for 1 hour (B)		Sample incubated for 1 hour (A)		Percent Kill (%)
		Cfu/ml	Log Value	Cfu/ml	Log Value	
Untreated Control	*K.pneumoniae* ATCC 4352	4.73 x 10^5	5.67	4.73 x 10^5	5.67	**0.00**
HNDM – 7	*K.pneumoniae* ATCC 4352	-	-	1.20 x 10^3	3.08	**99.75%**

Remarks: CFU = Colony-Forming Unit, a measure of the number of microorganisms

Results:

HindMed – Unwashed fabric sample – treated with Livinguard 1020 and 3x dry technology was checked for its antimicrobial activity as per ASTM E2149 Method.

Sample Code	ASTM E2149 – 1 hour		
	***E.coli* ATCC 25922**	***S.aureus* ATCC 6538**	***K.pneumoniae* ATCC 4352**
HNDM – 7	**2.55 (99.71%)**	**2.48 (99.66%)**	**2.59 (99.75%)**

HNDM -7 showed >99% kill for all the organisms.

PART II – Antiodor property of HNDM-7

The build-up and release of odor may become an undesirable feature of some textile items resulting in consumer dissatisfaction. The main physiological contributors to body odor are from eccrine and apocrine sweat glands located in the axillary region, sternum, anogenital area, scalp, feet and hands. Secretions from sebaceous glands, found in many of these same areas, also contribute to odor. All these sources of odor can be unpleasant when transferred to and detected within textiles, sweat related body odor has been reported to be the most common type of odor detected in clothing.Volatile carboxylic acids are a key class of human body odorants.

The main lead substance of sweat odour is isovaleric acid, a short fatty acid of acidic odor and low odor threshold. Quantitative detection of isovaleric acid was done by an Inhouse protocol.

Principle –

The fabric was challenged with the optimum dosage of Isovaleric acid to clearly discern a technology's performance when the challenge odour is at a higher degree. In this detection tube method, isovaleric acid was used as the testing odorant and treated and untreated fabrics were kept in contact with it for one hour. The amount of Isovaleric (gas) remaining in the bottle was quantified using the detector tube & pump.

Observations:

Parameters	Untreated Fabric	Livinguard treated Fabric (HNDM-7)
Weight of fabric	0.3 gms	0.3 gms
(0.1%) Isovaleric acid	300 ul	300 ul
Amount of stroke given	150ml	150ml
Gas detection	Moderate	Negligible

Evaluation of the result:

Results:

The detector tube used for treated HNDM-7 showed negligible amount of gas detection (Isovaleric gas).

PART III – Water Repellent Property of HNDM-7

Test Method – AATCC 22 Water Repellency –

Spray Test

Principle –

Water sprayed against the test surface of a test specimen under controlled conditions produces a wetted pattern whose size depends on the relative repellency of the fabric. Evaluation is accomplished by comparing the wetted pttern with pictures on a standard chart.

Ratings –

100 – No sticking or wetting of upper surface

90 – Slight random sticking or wetting of upper surface

80 – Wetting of upper surface at spray points

70 – Partial wetting of whole of upper surface

50 – Complete wetting of whole of upper surface

0 – Complete wetting of whole upper and lower surfaces

Observations:

Sample Code	AATCC 22 Rating
HNDM – 7	90
Untreated	0

Fig 1 : Untreated Fabric – WR

Fig 2 : HNDM – 7 - WR

Conclusion :

HindMed – HNDM-7 fabric sample – treated with Livinguard 1020 and 3X dry technology demonstrated the following results.

1. Good antimicrobial activity **(>99% microbial kill)** was observed against *E.coli* ATCC 25922, *S. aureus* ATCC 6538 & *K. pneumoniae* ATCC 4352 when tested as per ASTM E2149 method.
2. Negligible amount of gas was detected in treated fabric HNDM-7. It shows good odour capturing activity as compared to untreated fabric.HNDM-7 showed excellent water repellence as per AATCC 22.

ANNEX 9
(Item 4.*4*)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

MEDICAL TEXTILES -SCRUB SUIT – SPECIFICATION

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDRADS

Draft for comments only Doc No.: TXD 36(XXXXX)
XXXX 2024

***भारतीय मानक* मसौदा**
चिकित्सीय वस्त्रादि— स्क्रब सूट — विशिष्टि

Draft *Indian Standard*
Medical Textile — Scrub Suit — Specifications

ICS 11.140; 59.080.01

Technical Textiles for Medtech Applications Sectional Committee, TXD 36

last date for receipt of comments is XXXX 2024

FOREWORD
(Formal clause will be added later)

Scrub suits are intended to be used to minimize the transmission of infective agents and maintain a hygienic environment in medical settings.

Scrub Suit is short-sleeved top and trousers, which is worn during surgery and usually doctors will put on a long-sleeved isolation surgical gown outside the scrub suit to prevent blood from splashing on the body. It is called a scrub suit because every physician before entering the operating room will go through the disinfection action of "scrubbing hands" and most of them wear scrub suit in a sterile environment (scrubbed environment). These scrub suits are made up of disposable non-woven material and are intended for single use only.

Reusable scrub suits are made of more durable, higher-quality materials such as cotton or polyester blends. These materials are designed to withstand multiple wearing and washing cycles without significant deterioration and are thick enough to prevent a patient’s bodily fluids from making direct contact with the wearer’s skin.

Proper laundering and sterilization are critical to maintaining effective infection control with reusable scrub suits. Healthcare facilities must follow strict protocols to ensure that the scrub suits are thoroughly cleaned and sanitized between uses.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2:2022

'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1 SCOPE

1.1 This standard specifies requirements for single use and reusable scrub suits intended for medical use.

1.2 This standard is intended to be used primarily by manufacturers of scrub suits in qualifying, classifying, packaging, labelling, and sterilization of scrub suits, so that healthcare workers can make more informed decisions of selection of right scrub suits in accordance with the protection level and risk involved in the procedure.

2 REFERENCES

The standards given in Annex A contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards.

3 MATERIALS

Scrub suits are clothing typically made from good quality cotton, polyester, polyester/cotton blended fabric, viscose, polyester/viscose blended fabric if meant for reusable purposes to provide comfort, ease of movement and durability when used for external purposes.

Nonwoven SMS or SMMS fabric is used if scrubs are to be worn for single usage such as in intensive surgeries under the surgical gowns for long durations or any other suitable material as agreed mutually between the buyer and seller.

It is recommended that the fabrics used for scrubs suits are manufactured with coatings and/or finishes to enhance the user experience and ensure improved safety and hygiene of the wearer, and reduce the chances of cross contamination between and among patients and healthcare providers - e.g., fluid/ water and blood repellent and environmentally friendly, metal-free antimicrobial finishes. The final fabrics must be breathable and provide Odour-protection for their anticipated long durations of wear.

4 MANUFACTURE, WORKMANSHIP AND FINISH

4.1 Manufacture

Manufacturing of these products must be done by companies holding IS/ISO 9001 and IS/ISO 13485 licenses and must be done following GMP practices.

4.2 Workmanship and finish

The material used in the fabrication of these kinds of medical apparel must be free from lumps and stains, safe for skin contact, and shall not leach harmful chemicals, metal salts and dyes or bleed colour. When visually examined, apparel shall be free from defects, tears or loose stitching. The materials shall be free from odour, smooth to the touch and when worn, shall not chafe or be uncomfortable for the user.

5 SIZES

Size and style of the apparel shall be as agreed to between the buyer and the seller. It is recommended that manufacturers offer a range of sizes from XS - XL to account for different user requirements.

6 WASHING, DRYING AND HANDLING INSTRUCTION

The manufacturer shall provide clear instructions for washing, drying, handling and storage of the product on every packet to ensure proper use and care by the wearer and/or hospitals/ laundry. The reusable scrub suit composed of poly cotton blend shall not be washed above 60 number of washing cycles. For laundering purposes, the higher the water temperature, the shorter the washing cycle required. Despite the water temperature, the use of a chlorine bleach based disinfectant is suggested.

After a load has been washed in low or medium water temperatures, tumble drying and ironing should follow. The water washing temperature shall not be less than 60-66 degrees Celsius followed by proper re-sterilization.

For single use disposable scrub suits clear instructions on proper disposal of the product shall be provided. Reusable scrub suits shall be able to withstand autoclaving (see note).

NOTE— Autoclaving refers to the method of sterilization and involves the use of moist heat under pressure where the scrub suits are exposed to high temperatures of about 121-134 degrees Celsius and steam for a specific duration.

7 GENERAL REQUIREMENTS

The raw material/fabric used for manufacturing of reusable scrub suits shall meet the following requirements as specified in Table 1:

Table 1 Colour Fastness and Dimensional Stability Requirement of Raw Material/Fabric

(*Clause* **7.1**)

Sl No.	**Characteristic**	**Requirement**	**Method of test Ref to**
(1)	(2)	(3)	(4)
i)	Colourfastness to rubbing		IS/ISO 105-X12
	Dry	4 or better	
	Wet	4 or better	

ii)	Colourfastness to perspiration (acidic and alkaline)		IS/ISO 105 E04
	Colour Change	4 or better	
	Staining	4 or better	
iii)	Colourfastness to washing		IS/ISO 105 C06
	Colour Change	4 or better	
	Staining	4 or better	
iv)	Dimensional stability to washing, percentage (Max)		IS 16394
	Warp and Weft Way	$\pm$ 3 %	

8 PERFORMANCE REQUIREMENTS

The scrub suits and patient gowns shall meet the requirements specified herein when supplied in packaged condition.

8.1 Hygiene Testing Requirement

Total viable count (total number of bacteria and fungi) shall not be more than 10 CFU/gm and *Staphylococcus aureus* shall be absent. Test method for Bioburden is listed in Annex B.

NOTE—CFU stands for colony forming unit, used to measure the population of microbes in the given context.

8.2 Biocompatibility Evaluation– Cytotoxicity, Irritation and Skin Sensitization

The manufacturer shall ensure that raw materials used for manufacturing the final products are safe for the user based on its known toxicological characteristics at intended use. The biocompatibility of the material shall be detected by evaluating cytotoxicity, irritation and skin sensitization test as per IS/ISO 10993 Part 5 and IS/ISO 10993 Part 10 respectively.

For cytotoxicity, the material shall show reactivity as "None" when tested as per IS/ISO 10993 Part 5. Similarly, the material shall be "Non-irritant and Non-sensitizing" when tested as per IS/ISO 10993 Part 10. For preparation of samples for these tests, ISO 10993 Part 12 shall be referred.

8.3 Antibacterial treatment & activity Value (Optional)

If agreed between the buyer and seller, the raw material/fabric used for the apparel shall have an antibacterial treatment that is metal-free, proven non-toxic, non-leaching and an anti-bacterial activity value greater than or equal to 2 when tested by the absorption method prescribed in IS/ISO 20743.

8.4 Antifungal treatment & activity Value (Optional)

If agreed between the buyer and seller, the raw material/fabric used for the apparel shall have an antifungal treatment that is metal-free, proven non-toxic, non-leaching and an antifungal activity value greater than or equal to 2 when tested by IS 17333(Part 2)/ISO 13629-2.

8.5 Antiviral treatment & activity Value (Optional - relevant at time of viral outbreak)

If agreed between the buyer and seller, the raw material/fabric used for the apparel shall have an antiviral treatment that is metal-free, proven non-toxic, non-leaching and an antiviral activity value greater than or equal to 2 when tested by the absorption method prescribed in IS 17347/ISO 18184

8.6 Hydrophobic coating (Optional)

If agreed between the buyer and seller, the raw material/fabric used for the apparel shall have a PFAS-free hydrophobic coating when tested as per IS 390.

Table 2 Performance Requirements for Single use Scrub Suits

(Clause **8***)*

Sl No. (1)	**Characteristics** (2)	**Requirements** (3)	**Methods of Test, Ref to** (4)
i)	Impact penetration (g)	≤ 4.5	IS 17375/ISO 18695
ii)	Hydrostatic resistance (cmwc)	≥ 30	IS 391/ISO 811
iii)	Particle release [log10 (lint count)]	≤ 4	IS 15891-10
iv)	Tensile strength (dry and wet) (N)	≥ 20	IS 15891-3
v)	Bursting strength (dry and wet) (kPa)	≥ 40	IS 1966-1
vi)	Bacterial and Fungal Bioburden (CFU/gm)	≤ 10	IS/ISO 11737-1
vii)	Biocompatibility Evaluation		

	Cytotoxicity	None	IS/ISO 10993-5
	Irritation and Skin Sensitization	Non-irritant and Non-sensitizing	IS 17932 (Part 6)
viii)	Moisture vapour transmission rate (Breathability) (m^2Pa/W)	≤ 40	IS 17376 / ISO 11092
ix)	Antibacterial treatment & activity Value (Optional)	≥ 2	IS/ISO 20743
x)	Antifungal treatment & activity Value (Optional)	≥ 2	IS 17333(Part 2) ISO 13629-2

Table 3 Performance Requirements for Reusable Scrub Suits

(Clause **8***)*

Sl No. (1)	**Characteristics** (2)	**Requirements** (3)	**Methods of Test, Ref to** (4)
i)	Blood resistance	Pass	IS 16546/ ISO 16603
	Viral resistance	Pass	IS 16545/ ISO 16604
ii)	Breaking strength (N)		IS 1969-1
	Warp	≥ 420	
	Weft	≥ 350	
iii)	Tear strength (N)		IS 6489 (Part 1) ISO 13937-1
	Warp	≥ 20	
	Weft	≥ 10	
iv)	Pilling resistance (After 5 h of test)	≥ 4	IS 10971-1/ ISO 12945-1
v)	Biocompatibility Evaluation		
	Cytotoxicity	None	IS/ISO 10993-5

	Irritation and Skin Sensitization	Non-irritant and Non-sensitizing	IS 17932 (Part 6)

9 SAMPLING AND CRITERIA FOR CONFORMITY

9.1 Lot

All the products of the same material produced under similar conditions of manufacture shall constitute a lot.

9.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

9.1.2 The number of products to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, column 3 and column 5 of Table 4.

9.1.3 These products shall be selected at random from the lot. Guidance for the selection process shall be taken from IS 4905.

Table 4 Number of Scrub Suits to be selected

(*Clause* **9.1.2**)

SL. No.	**Lot Size**	**Non-Destructive Testing**		**Destructive Testing**	
		No. of apperals to be selected	**Acceptance Number**	**No. of apperals to be selected**	**Acceptance Number**
	N	*n*	*a*	*n*	*a*
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13	1	5	0
ii)	281 — 500	13	1	5	0
iii)	501 —1 200	20	1	5	0
iv)	1 201 —3 200	32	2	8	0
v)	3201—10 000	32	2	8	0
vi)	10001— 35000	50	3	8	0
vii)	35001 — 150 000	80	5	13	0
viii)	150001 — 500000	80	5	13	0
ix)	500001 and over	125	7	13	0

NOTE — for colourfastness and dimensional stability, hygiene testing, biocompatibility evaluation, antibacterial activity refer clauses **7** and **8**.

9.2 Number of Tests and Criteria for Conformity

9.2.1 All products to be selected as per column 3 of Table 4 shall be examined for workmanship and finish.

9.2.1.1 Any products failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 4 of Table 4. Otherwise, the lot shall be rejected.

9.2.2 Out of the sample already found satisfactory according to **9.2.1.1**, a sub-sample as per column 5 of Table 4 shall be taken. This sub-sample shall be further tested for the remaining requirements.

9.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective products found in the sample (*see* **9.2.2**) is less than or equal to the acceptance number as given in column 6 of Table 4.

9.2.4 The manufacturer shall perform the colour fastness and dimensional stability once for existing products and whenever there is a change in the raw material for manufacturing the product.

9.2.5 The manufacturer shall perform the hygiene testing for the final product every quarter for monitoring purposes and whenever there is a change in the raw material used, manufacturing premises, and the supplier of the raw material.

9.2.6 The biocompatibility evaluation shall be carried out once every 5 years for existing raw material and whenever there is a change in the raw material used for manufacturing of the product.

9.2.7 The anti-bacterial activity testing shall be carried out once every 2 years for existing products and whenever there is a change in the raw material used for manufacturing the product.

10 MARKING

10.1 Each package shall be legibly and indelibly marked with the manufacturer's name or trademark, number of products contained in it, and size designation in addition to the following:

a) Use and care instructions;
b) Storage instructions
c) Batch/Lot no. and date of manufacturing;
d) Country of origin, and
e) Additional features of antibacterial or strain repellent, and
f) Any other information required by law in force or agreed between the buyer and the seller.

10.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, *2016* and the Rules and Regulations framed there under, and the products may be marked with the Standard Mark.

11 PACKING

Scrub Suits and Patient Gowns shall be supplied in rigid or flexible packages made of suitable materials which are sealed so as to protect the product from moisture, soiling and contamination during storage and transportation. The package should be free of any torn or damaged areas.

ANNEX A

(*Clause* **2**)

IS No.	*Title*
IS 390: 1975	Method for determining the water repellency of fabrics by water spray test (*First Revision*)
IS 5887 -2 : 1976	Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of *staphylococcus aureus* and *faecal streptococci* (*First Revision*)
IS 16394:2015	Textiles — Woven shirting made of cotton, man-made fibres/filaments and their blend — Specification
IS 17932 (Part 6) : 2023	Biological Evaluation of Medical Devices Part 6 Tests for Skin Sensitization
IS 391 : 2020 ISO 811 : 2018	Textile Fabrics — Determination of Resistance to Water Penetration — Hydrostatic Pressure Test (Second Revision)
IS 1966 (Part 1) : 2022 ISO 13938-1 : 2019	Textiles — Bursting Properties of Fabrics Part 1 Hydraulic Method for Determination of Bursting Strength and Bursting Distension (*Third Revision*)
IS 1969 (Part 1) : 2018 ISO 13934-1 : 2013	Textiles — Tensile properties of fabrics—Determination of maximum force and elongation at maximum force using the strip method (*Fourth Revision*)
IS 4905 : 2015 ISO 24153 : 2009	Random sampling and randomization procedures (*First Revision*)
IS 6489 (Part 1) : 2011 ISO 13937-1 : 2000	Textiles — Tear Properties Of Fabrics Part 1 Determination Of Tear Force Using Ballistic Pendulum Method (Elmendorf) (*Second Revision*)

IS 10971 (Part 1) : 2022 ISO 12945-1 : 2020	Textiles — Determination of Fabric Propensity to Surface Pilling, Fuzzing or Matting Part 1 Pilling Box Method (Second Revision)
IS 15891(Part 3) : 2011 ISO 9073-3 : 1989	Textiles — Test methods for nonwovens—Determination of tensile strength and elongation
IS 15891 (Part 10) : 2017 ISO 9073-10 : 2003	Textiles — Test Methods for Nonwovens Part 10 Lint and Other Particle Generation in the Dry State
IS 16545 : 2016 ISO 16604 : 2004	Clothing for Protection Against Contact with Blood and Body Fluids — Determination of Resistance of Protective Clothing Materials to Penetration by Blood-borne Pathogens — Test Method Using Phi-X174 Bacteriophage
IS 16546 : 2016 ISO 16603 : 2004	Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood
IS 17333 (Part 2) : 2020 ISO 13629-2 : 2014	Textiles — Determination of antifungal activity of textile products - Part 2: Plate count method
IS 17347 : 2020 ISO 18184 : 2019	Textiles — Determination of Antiviral Activity of Textile Products
IS 17375 : 2020 ISO 18695 : 2007	Textiles — Determination of Resistance to Water Penetration — Impact Penetration Test
IS 17376 : 2020 ISO 11092 : 2014	Textiles — Determination of Physiological Effects — Measurement of Thermal and Water-Vapour Resistance under Steady-State Conditions (Sweating Guarded-Hot Plate Test)
IS/ISO 9001 : 2015	Quality Management Systems — Requirements (*Fourth Revision*)
IS/ISO 10993 -5 : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 10993-12 : 2012	Biological evaluation of medical devices Part 12 Sample preparation and reference materials

IS/ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
IS/ISO 13485 : 2016	Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes (*First Revision*)
IS/ISO 20743 : 2021	Textiles — Determination of Antibacterial Activity of Textile Products (*First Revision*)
IS/ISO 105-C06 : 2010	Textiles — Tests for Colour Fastness Part C06 Colour Fastness to Domestic and Commercial Laundering (*First Revision*)
IS/ISO 105-E04 : 2013	Textiles —Tests for Colour Fastness Part E04 Colour Fastness to Perspiration (*First Revision*)
IS/ISO 105-X12 : 2016	Textiles — Tests for Colour Fastness Part X12 Colour Fastness to Rubbing (*First Revision*)

ANNEX B

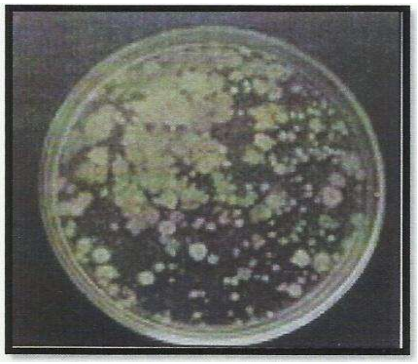
(*Clause* **8.1**)

8.1.1 *Bacterial and Fungal Bioburden*

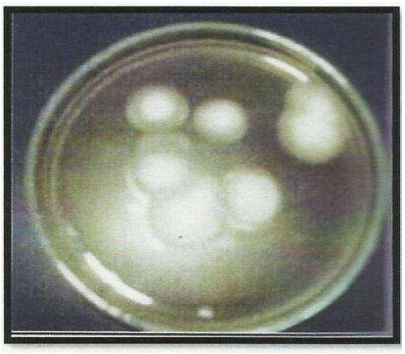
Medical apparel must be tested for bacterial and fungal bioburden using the method described below. For selecting sample item portion (SIP), appropriate eluent and methods of extraction; ISO 11737 -1) shall be referred.

8.1.1.1 *Test method*

A sample of 5 gm cut from the centre portion of the garment shall be checked for its absorbency in eluent such as 0.85 percent sodium chloride or equivalent medium till it reaches saturation limit. Add eluent either ten times the absorbent quantity of the garment or the quantity in which the garment completely immerse. The garment shall be shaken vigorously in the eluent and the liquid shall be extracted from it. Report the quantity of the eluent used for extraction, time and frequency of shaking in the test report. The extract shall be serially diluted and plated out on respective mediums, that is, plate count agar (PCA) for bacterial bioburden and sabouraud chloramphenicol agar (SCA) for fungal bioburden. Incubate PCA plates at 30 - 35^{0}C for 24 h and count colonies. Continue incubation upto 72 h, re-examine the plates after 48 h and 72 h, and report the results that have not resulted in overgrowth. Similarly incubate SCA plates at 20 - 25^{0}C for 3 days and count the fungi. Re-examine after incubation for 5 and 7 days. Report the results from incubation time that does not result in over growth. The typical colony characteristics are shown in Fig.1.



(A)



(B)

FIG 1 TYPICAL COLONY CHARACTERISTICS OF BACTERIAL BIOBURDEN (A) AND FUNGAL BIOBURDEN (B)

8.1.2 *Test for Common Skin Pathogen — Staphylococcus Aureus*

The apparel shall be tested for the presence of *Staphylococcus aureus* in accordance with the method given below. For the preparation of medium such as cooked salt medium, baird-parker medium and method for coagulase test; IS 5887 -2) shall be referred.

8.1.2.1 *Test method*

A sample of 5 gm cut from the centre portion of the garment shall be completely immersed in appropriate volume of enrichment medium like cooked salt medium or equivalent medium. Incubate for enrichment purpose at 37^0C for 24 h. Report the quantity of the medium used for enrichment in the test report. The incubated sample shall be shaken vigorously in the medium and the liquid shall be extracted from the garment. The extract shall be streaked onto a *Staphylococcal* isolation medium, such as Baird-Parker medium or equivalent and incubated at 37°C for 24-48 h and examine for growth. The result is considered positive if black colonies with a narrow white margin, surrounded by a zone of clearance are seen. Suspect colonies must show coagulase activity to confirm presence of *Staphylococcus aureus*. The typical colony characteristic is shown in Fig. 2.

FIG. 2 TYPICAL COLONY CHARACTERISTICS OF *STAPHYLOCOCCUS AUREUS*

ANNEX 8

(Item 4.*5*)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

Table 1 Performance requirements for sterilization wrap material made using nonwoven material

Sl.No	Characteristic	Requirement	Method of Test	
			Ref to	Annex
(1)	(2)	(3)	(4)	(5)
1.	Water resistance, mmwc, M*in* *(Rate of raising 60cmwc/min)*	400	IS 15891-16:2017 (Reviewed 2021)	
2.	Tensile strength, N/5cm, M*in*	Dry: 50 Wet: 50	IS 15891-18:2017 (Reaffirmed Year : 2021)	
3.	Bursting strength, kPa, *Min*	Dry: 130 Wet: 90	IS 1966 (Part 1):2022	
4.	Fluorescence	Complies with the test	-	B
5.	Water soluble substances, %, *Max*	0.5%	IS 14944 : 2020 Clause 6.12 Method I	
6.	pH	5-8	IS 1390:2022	
7.	EO residual (optional)	Complies with the test standard	IS/ISO 10993-7:2008	
8.	Linting, Log10, Max *(Measuring particle size: 3.0 to 25.0 micron)*	4.0	ISO 15891-10:2017 (Reaffirmed year:2021)	
9.	Microbial Barrier Testing of Packaging Materials for Medical Devices	Complies	-	C

Table 2 Performance requirements for sterilization wrap material made using woven material

Sl.No	Characteristic	Requirement	Method of Test	
			Ref to	Annex
(1)	(2)	(3)	(4)	(5)
1.	Tensile strength, N/5cm, M*in*	Dry: 300 Wet: 300	IS1969-1:2018	
2.	tear strength, gf, *Min*	Dry: 600 Wet: 600	IS 1966-1:2022	
3.	Fluorescence	Complies with the test		B
4.	Water soluble substances, %, *Max*	0.5%	IS 14944 : 2020 Clause 6.12 Method I	
5.	pH	5-8	IS 1390:2022	
6.	Microbial Barrier Testing of Packaging Materials for Medical Devices [Optional]	Complies		C
7.	Water resistance, mmwc, M*in* *(Rate of raising 60cmwc/min)* [Optional]	400	IS 15891-16:2017 (Reviewed 2021)	

ANNEX 10
(Item 4.5)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

MEDICAL TEXTILE — STERILIZATION WRAPS — SPECIFICATIONS

a) INPUTS FROM SHRI D. VEERASUBRAMANIAN, SITRA

Table 1 Performance requirements for sterilization wrap material made using nonwoven material

Sl.No	Characteristic	Requirement	Method of Test	
			Ref to	Annex
(1)	(2)	(3)	(4)	(5)
10.	Water resistance, mmwc, M*in* *(Rate of raising 60cmwc/min)*	400	IS 15891-16:2017 (Reviewed 2021)	
11.	Tensile strength, N/5cm, M*in*	Dry: 50 Wet: 50	IS 15891-18:2017 (Reaffirmed Year : 2021)	
12.	Bursting strength, kPa, *Min*	Dry: 130 Wet: 90	IS 1966 (Part 1):2022	
13.	Fluorescence	Complies with the test	-	B
14.	Water soluble substances, %, *Max*	0.5%	IS 14944 : 2020 Clause 6.12 Method I	
15.	pH	5-8	IS 1390:2022	
16.	EO residual (optional)	Complies with the test standard	IS/ISO 10993-7:2008	
17.	Linting, Log10, Max *(Measuring particle size: 3.0 to 25.0 micron)*	4.0	ISO 15891-10:2017 (Reaffirmed year:2021)	
18.	Microbial Barrier Testing of Packaging Materials for Medical Devices	Complies	-	C

Table 2 Performance requirements for sterilization wrap material made using woven material

Sl.No	Characteristic	Requirement	Method of Test	
			Ref to	Annex
(1)	(2)	(3)	(4)	(5)
8.	Tensile strength, N/5cm, M*in*	Dry: 300 Wet: 300	IS1969-1:2018	
9.	tear strength, gf, *Min*	Dry: 600 Wet: 600	IS 1966-1:2022	

10.	Fluorescence	Complies with the test		B
11.	Water soluble substances, %, *Max*	0.5%	IS 14944 : 2020 Clause 6.12 Method I	
12.	pH	5-8	IS 1390:2022	
13.	Microbial Barrier Testing of Packaging Materials for Medical Devices [Optional]	Complies		C
14.	Water resistance, mmwc, M*in (Rate of raising 60cmwc/min)* [Optional]	400	IS 15891-16:2017 (Reviewed 2021)	

ANNEX 11
(Item 4.5)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDRADS

Draft for comments only Doc No.: TXD 36(XXXXX)
XXXX 2024

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***भारतीय मानक* मसौदा**
वस्त्रादि — चिकित्सीय वस्त्रादि— स्टरलाइज़ेशन रैप — विशिष्टि

Draft *Indian Standard*
Textiles — Medical Textile — Sterilization Wraps — Specifications

ICS:

Technical Textiles for Medtech Applications Sectional Committee, TXD 36	last date for receipt of comments is XXXX 2024

FOREWORD

(Formal clause will be added later)

This standard addresses the performance of Sterilization Wraps which are used in the ever-advancing landscape of healthcare, the paramount importance of infection prevention and control cannot be overstated. Hence for ensuring the safety and well-being of the patients, maintaining the sterility of critical medical instruments and devices is required.

Sterilization wraps are specialized packaging materials designed to maintain the sterility of medical instruments and devices during storage, transportation, and until they are ready for use in medical procedures. These wraps form an integral part of the sterilization process, offering a reliable barrier against harmful microorganisms and mitigating the risk of healthcare-associated infections.

Maintaining the sterility of wrapped items is crucial until they are used for medical procedures. As long as the integrity of the sterilization wrap remains intact, it can preserve the sterility of the packaged items for an extended period. However, proper handling, storage, and adherence to manufacturer's guidelines are essential to ensure the effectiveness of these wraps and uphold patient safety.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*Second Revision*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1 SCOPE

1.1 This Standard specifies test methods and values for materials for Sterilization Wraps that are intended to maintain sterility of terminally sterilized medical devices to the point of use.

1.2 The general requirements and the test methods and values that are specific to Sterilization Wraps covered in this Standard.

2 REFERENCES

The standards listed in Annex A contain provisions which through reference in this text, constitute provision of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A.

3 TERMINOLOGIES

For the purpose of this standard the following definitions shall apply.

3.1 Sterilization Wraps — Sterilization wraps are specialized packaging materials used in healthcare facilities to maintain the sterility of medical instruments and devices. These wraps act as a barrier, preventing the entry of microorganisms and ensuring the contents remain sterile until they are ready for use in medical procedures.

3.2 Performance Level — Discrete standard defined to classify products according to the performance requirements of this standard.

3.3 Sterile Field — An area created by placing sterile surgical drapes around the patient's surgical site and on the stand that will hold sterile instruments and other items needed during surgery.

3.4 Burst Strength — The maximum pressure the sterilization wrap can withstand before rupturing.

3.5 Tensile Strength —The maximum force that the sterilization wrap can withstand before breaking or tearing during handling or use.

3.6 Manufacturer — Means processing of raw material or inputs in any manner that results in emergence of a new product having a distinct name, character and use. The term "manufacturer" shall be construed accordingly.

4 WORKMANSHIP AND FINISH

4.1 The workmanship of sterilization wraps shall meet stringent standards to ensure their integrity and effectiveness in maintaining the sterility of medical instruments and devices.

4.2 Sealing Integrity

The sealing process of sterilization wraps, whether heat sealing or adhesive sealing, shall be closely monitored to guarantee a consistent and hermetic seal. Any evidence of compromised sealing during routine monitoring shall be promptly investigated and addressed.

4.3 Perforation Prevention

Sterilization wraps shall be manufactured with meticulous attention to preventing unintended punctures or tears that could compromise the sterility of the contents. The materials used should be carefully selected to resist punctures, and the manufacturing process should incorporate quality control measures to detect and rectify any defects.

4.4 Material Strength

The strength and durability of sterilization wraps shall be thoroughly tested to ensure they can withstand the rigors of handling, transportation, and storage without tearing or degrading. The material's tensile strength and resistance to wear and tear shall be documented to maintain consistent quality**.**

4.5 Visual Inspection

Each sterilization wrap shall undergo a comprehensive visual inspection during the manufacturing process to identify and rectify any imperfections, such as uneven folds, uneven cuts, or inconsistencies in the material.

4.6 Folding and Packaging

Sterilization wraps shall be folded and packaged in a manner that ensures easy and efficient use in medical facilities. The packaging should facilitate the aseptic presentation of the wraps during the sterilization process and maintain the sterility of the contents until they are ready for use.

4.7 Traceability

Each batch of sterilization wraps shall be appropriately labeled and traceable to ensure accountability and facilitate tracking in case of any quality-related issues or recalls.

4.8 Packaging Disposal

Instructions for proper disposal of used sterilization wrap packages shall be clearly provided, adhering to relevant environmental regulations and waste management protocols.

4.9 User-Friendly Design

Sterilization wraps shall be designed with user convenience in mind, ensuring ease of handling, opening, and sealing to promote efficient sterilization processes in healthcare facilities.

4.10 Environmental Considerations

Manufacturers shall strive to use environmentally friendly materials and practices in the production of sterilization wraps, minimizing their environmental impact without compromising their effectiveness.

5 GENERAL REQUIREMENTS

5.1 Product Requirements for Sterilization Wraps

Sterilization wraps shall meet all the specified requirements in this standard throughout their designated useful life. If the manufacturer does not specify critical and non-critical areas of the product, the sterilization wraps shall meet at least the minimum performance requirements specified in Table 1.

5.2 Manufacturing and Processing Requirements and Documentation

The manufacturer of sterilization wraps shall establish and maintain a comprehensive quality management system that covers all aspects of product development, design, production, testing, packaging, labelling, distribution, and associated services. This quality management system shall comply with relevant medical device regulations and standards. A risk management procedure shall be implemented, considering inputs from risk assessments to ensure appropriate product realization and safety.

Microbiological monitoring (in accordance with ISO 14698-1), air monitoring of cleanroom environments (per ISO 14644-1), sterilization processes (in compliance with IS/ISO 11135), packaging (as per IS/ISO 11607 - Part 1 and Part 2), validation (per IS/ISO 11137 - Part 1 and Part 2, ISO 11138-7), and residual sterility (IS/ISO 10993-7) shall be consistently maintained by the manufacturer.

By adhering to these general requirements, manufacturers can produce sterilization wraps that consistently meet the necessary safety and performance standards. Such high-quality sterilization wraps will contribute to maintaining sterility, enhancing infection control, and ensuring the safe delivery of healthcare services.

6 PERFORMANCE REQUIREMENTS

6.1 Test specimens shall be taken from different sterilization wraps of the same lot. If multiple tests are to be performed (for example, the critical zone consists of more than one component, such as the base material, a seam, and a point of attachment), then test specimens for each component may be taken from the same wrap.

6.2 Sterilization shall conform to the requirements specified when tested according to the method given in Table 1. The test methods and standards listed in the table are applicable to evaluate the performance of Sterilization Wraps.

6.3 Compliance with these performance requirements ensures that sterilization wraps are effective, reliable, and safe for use in healthcare settings, contributing to the overall quality of sterilization processes and patient safety.

Table 1. Performance Requirements of Sterilization Wraps
(*Clause* **5.1** and **6.2**)

Sl No. (1)	**Characteristic** (2)	**Requirement** (3)	**Method of Test, Ref to** (4)
i)	Water resistance ,mmwc, *Min*	400	IS 391
ii)	Tearing resistance, ,mN, *Min*	3500	IS 6489 (Part 1)
iii)	Tensile Strength, N/5 cm, *Min*	20	IS 1969 (Part 1)
iv)	Wet Bursting strength, kPa, *Min*	80	IS 1966 (Part 1)
v)	Water soluble chlorides, percent, *Max*	0.05	IS 1060 (Part 4)
vi)	Determination of water soluble sulphates, percent *Max*	0.25%	IS 1060 (Part 4)
vii)	*p*H	5.0-8.0	IS 1060 (Part 4)
viii)	Wet Bacterial Penetration, CFU/ML, *Min*	750	IS 16549
ix)	Germ proofness	Pass the test	ISO 11607(Part 1)
x)	Bacterial Filtration Efficiency, percent, *Min*	99	IS 16288
xi)	Air Permeability, µm/Pa · s	>1.7	IS/ISO 5636-3 : 1992

7 SAMPLING AND CRITERIA FOR CONFORMITY

7.1 Lot

All the sterilization wraps of the same material and dimensions produced under similar conditions of manufacture and processing shall constitute a lot.

7.1.1 Each lot shall be tested separately to ascertain the conformity of the lot.

7.1.2 The number of sterilization wraps to be selected from the lot shall depend on the size of the lot as mentioned in Table 2.

7.1.3 These sterilization wraps shall be selected at random from the lot as per the procedure given in the relevant standard (e.g., IS 4905).

7.2 Number of Tests and Criteria for Conformity

7.2.1 All the sterilization wraps shall be examined for workmanship and finish (**4.1** to **4.3**).

7.2.1.1 Any sterilization wraps failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements if the total number of defectives found in the sample is less than or equal to the acceptance number. Otherwise, the lot shall be rejected**.**

7.2.2 Out of the sample already found satisfactory according to **7.2.1.1**, a sub-sample shall be taken. This sub-sample shall be further tested for the remaining requirements as given in Table 1.

7.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective sterilization wraps found in the sample (as per **7.2.2**) is less than or equal to the acceptance number.

By following these sampling and criteria for conformity guidelines, manufacturers can ensure that patient gowns consistently meet the required quality and performance standards, providing reliable and safe protective garments for patients and healthcare providers.

Table 2 Number of Sterilization Wrap Materials to be selected

(Clause **7.1.2***)*

Sl No.	**Lot size**	**Non-destructive testing**		**Destructive Testing**	
		No. of materials to be selected	Acceptance Number	No. of materials to be selected	Acceptance Number
(1)	(2)	(3)	(4)	(5)	(6)
i)	Upto 280	13*	1	8	0
ii)	281 to 500	20	2	8	0
iii)	501 to 1 200	32	3	13	0
iv)	1 201 to 3 200	50	5	13	0

v)	3 201 to 1 0000	80	7	20	1
*Or lot size when less than 13					

8 MARKING

8.1 Protective Packaging

The protective packaging shall be legibly and durably marked with the following information:

a) Reference, stock or catalogue number;

b) Quantity;

c) The manufacturers or supplier's name or trade name, and address;

d) Date of manufacture

e) Lot number;

f) Nominal sheet size or nominal width of rolls in millimeters and length in meters; and

g) The recommended storage conditions.

8.2 Inner Package

The inner package with sheets or inner label with reels shall be legibly and durably marked with the information a), b), c), e) and f) according to **8.1**.

8.3 Information to be supplied by the Manufacturer

a) Recommendations for particular applications of sterilization wrap (e.g. sterile barrier system, protective packaging, packaging system);

b) The nature and extent of any identified risks associated with the use of the packaging material and/or system.

8.4 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, *2016* and the Rules and Regulations framed there under, and the products may be marked with the Standard Mark.

8.5 Packaging

The sterilization wrap material shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. Packaging of the product should be such as to maintain the integrity of the product throughout its shelf life.

9 PACKAGING AND STERILIZATION

For packaging of the products, requirements as per IS/ ISO 11607-1 and 2 shall be followed.

For packaging and sterilization, the Medical Device Rule, 2017 shall be followed.

Validation of sterilization process shall be done as per IS/ISO 11135, IS/ISO 11137 -1 and 2, ISO 11138-7 and, IS/ISO 10993-7 standards.

ANNEX A

(*Clause* **2**)

LIST OF REFERRED STANDARDS

IS No.	*Title*
IS 4905 : 2015	Random sampling and randomization procedures (*first revision*)
IS 11056 : 2013	Textiles — Determination of the permeability of fabrics to air (*first revision*)
IS 16288:2014	Medical textiles — Method for evaluation of the bacterial filtration efficiency of surgical face masks
IS/ISO 11607-1 : 2019	Packaging for Terminally Sterilized Medical Devices Part 1 Requirements for Materials, Sterile Barrier Systems and Packaging Systems (First Revision)
IS 391 : 2020 ISO 811 : 2018	Textile Fabrics — Determination of Resistance to Water Penetration — Hydrostatic Pressure Test (Second Revision)
IS 1966 (Part 1) : 2022 /ISO 13938-1 : 2019	Textiles — Bursting Properties of Fabrics Part 1 Hydraulic Method for Determination of Bursting Strength and Bursting Distension (*Third Revision*)
IS 1969 (Part 1) : 2018 /ISO 13934-1 : 2013	Textiles — Tensile Properties Of Fabrics: Part 1 Determination Of Maximum Force And Elongation At Maximum Force Using The Strip Method (*Fourth Revision*)
IS 6489 (Part 1) : 2011 ISO 13937-1 : 2000	Textiles — Tear properties of fabrics Part 1 Determination of tear force using ballistic pendulum method (Elmendorf) (*second revision*)
IS 16549 : 2020 ISO 22610 : 2018	Surgical Drapes, Gowns and Clean Air Suits, Used as Medical Devices, for Patients, Clinical Staff and Equipment — Test Method to Determine the Resistance to Wet Bacterial Penetration (First Revision)
ISO 6588 (Part 2) : 2012	Paper, board and pulps — Determination of pH of aqueous extracts Part 2 Hot Extraction
ISO 9197 : 2016	Paper, board and pulps — Determination of water soluble chlorides
ISO 9198 : 2001	Paper, board and pulps — Determination of water soluble sulfates

ANNEX 12
(Item 5.*1*)

COMMENTS ON PUBLISHED STANDARDS

IS 17509 : 2021, Disposable Baby Diaper — Specification

A) BELLA PREMIER

We are writing on behalf of our Parent Company TZMO S.A located in torun Poland. We are in the process of obtaining BIS license for Baby diaper as per the 17509:2021 standard under the FMCS scheme .
While reading about the standard we have few queries with regards to rate of absorption :

1. In clause no 7.2 - Table 2 Requirement of Disposable Baby Diaper States Absorption rate per gush (s), Max is 60 for all sizes whereas under Annexure B Clause 5B-result states Test is passed if after applying a total of three gushes and 5 min waiting time after each gush all the applied saline solution got absorbed by the diaper core and there is no leakage out of the diaper. Please confirm the 60-second requirement should be individually considered per gush or the average of 3 gushes should meet the criteria?

2. The term size is only a recommendation as stated in the standard should we treat the same as reference or should we abide by the same value strictly for every dimension sir?

We request your Hon'ble office to kindly clarify our doubt with regards to the Baby diaper standard.

Dear Sir,

Further to the meeting held yesterday for inputs for amending the Standards on Sanitary Napkin and Bbau Diaper. Herewith PFB the recommendation from BellaPremier Happy HygieneCare Pvt.Ltd. (Member of TZMO S.A group) dealing in Bella and Bella Baby Happy brands .

Note to FIFA

Subject: Requisition to amend BIS IS 17509 : 2021-Baby Diaper

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Point No.1: Specification to include the requirements for Manufacturing and Testing Baby Diapers used for Premature Babies weighing between 500 grams to 2 kg.

Reasoning:
The clause no 7 of the standard refers to Performance Requirement, the sub clause 7.2 states to the Minimum Absorption Capacity for The baby diaper shall conform to the requirement for minimum absorption capacity without any leakage, rate of absorption and rewet under load as given in Table 2 when tested as per the method given in Annex B.

Table 2 Requirement of Disposable Baby Diaper

(*Clause* 7.2)

Minimum Absorption Capacity	Size	Number of Gushes	Requirement
	New Born	3	3 × 20 ml
	Small	3	3 × 35 ml
	Medium	3	3 × 50 ml
	Large	3	3 × 60 ml
	X Large	3	3 × 70 ml
Rate of absorption per gush (s), *Max*	All sizes	–	60
Rewet under load, (g), *Max*	All sizes	–	5

Table 2 mentioned in clause no 7.2 starts from size New Born weighing from 2 kilograms to 5 kilograms (>2kg to <5 kg) with requirement of Minimum Absorption Capacity for 3 Gushes as 3x20ml.

We request to add the Minimum Absorption Capacity for the Premature Babies whose weight is ranging from 500 grams to 700 grams (>500gm <700gm)) the minimum Absorption Capacity for 3 Gushes as 3x5ml.

We request to add the Minimum Absorption Capacity for the Premature Babies whose weight is ranging from 700 grams to 1200 grams (>700gm < 1200 gm) the minimum Absorption Capacity for 3 Gushes as 3x7ml.

We request to add the Minimum Absorption Capacity for the Premature Babies whose weight is ranging from 1200 grams to 2 kilograms (>1200gm <2000gm) the minimum Absorption Capacity for 3 Gushes as 3x10ml.

The testing requirement as provided in Annexure B sub clause B-4.4 states to Fill the measuring cylinder with the respective amount of saline solution from Table 2 (see 7.2). If we use the capacity of the New Born in the premature

baby diaper, the solution level is beyond the absorption capacity for a premature baby diaper. Hence we recommend the implementation of the Standard for the

-
-
- Newborn Premature Baby weigh from 500 grams to 700 grams (>500gm
- <700gm)
- the minimum Absorption Capacity for 3 Gushes as 3x5ml .
-
-
-
- Newborn Premature Baby weigh from 700 grams to 1200 grams (>700gm
- <
- 1200 gm) the
- minimum Absorption Capacity for 3 Gushes as 3x7ml.
-
-
-
- Newborn Premature Baby weigh 1200 grams to 2 kilograms (>1200gm <2000gm) the minimum
- Absorption Capacity for 3 Gushes as 3x10ml
-

Point No. 2 : Testing apparatus are not readily available in the market and need to be tailor made.

Reasoning: The equipment is very precise, the pressure transfer is not easy to apply to the product, and manufacturers are not interested in performing it.

Point No. 3 : The clause no B-2 APPARATUS AND REAGENTS;

In detail B-2.2 A Rigid Cover Plate, with weight, Total weight: 6300 g (plate 605.3 g, weight 5694.7 g) representing a pressure of 4.41 kPa (0.64 psi) for all sizes. The dimensions of the plate shall be around 200 mm × 70 mm and inner diameter of cylinder shall be around 40 mm (see Fig. 4).

Reasoning: The equipment is not adapted for premature babies' diapers. The pressure surface of the apparatus is much larger than the absorbent core. For the diapers in which the absorbing core is smaller than the surface of the apparatus , the assumed pressure of 0,64 psi is not met.

We request to adapt the document and apparatus to the size of diapers for premature babies.

Point No 4: The clause no 3.2 Absorbent Core

An absorbent core forming the middle layer(s) with filler materials such as cellulose pulp, tissue, wood pulp, other absorbent and super absorbent materials or
combination of these materials, etc.

Reasoning: Absorbent Core can be made using the air laid tape or SAP sheet technology, which also contains non-absorbent fibers.

We request to adapt the document to all current technological possibilities. Add non-absorbent fibers.

https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/surgical-devices.html

Bioburden of Surgical Devices
Print
Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)

In general, used medical devices are contaminated with a relatively low bioburden of organisms[179, 911, 912]. Nystrom evaluated medical instruments used in general surgical, gynecological, orthopedic, and ear-nose-throat operations and found that 62% of the instruments were contaminated with $<10^1$organisms after use, 82% with $<10^2$, and 91% with $<10^3$. After being washed in an instrument washer, more than 98% of the instruments had $<10^1$organisms, and none $>10^2$ organisms[911]. Other investigators have published similar findings[179, 912]. For example, after a standard cleaning procedure, 72% of 50 surgical instruments contained $<10^1$ organisms, 86% $<10^2$, and only 6% had $>3 \times 10^2$[912]. In another study of rigid-lumen medical devices, the bioburden on both the inner and outer surface of the lumen ranged from 10^1 to 10^4 organisms per device. After cleaning, 83% of the devices had a bioburden £10^2 organisms[179]. In all of these studies, the contaminating microflora consisted mainly of vegetative bacteria, usually of low pathogenicity (e.g., coagulase-negative **Staphylococcus**)[179, 911, 912].

An evaluation of the microbial load on used critical medical devices such as spinal anesthesia needles and angiographic catheters and sheaths demonstrated that mesophilic microorganisms were detected at levels of 10^1 to 10^2 in only two of five needles. The bioburden on used angiographic catheters and sheath introducers exceeded 10^3 CFUs on 14% (3 of 21) and 21% (6 of 28), respectively[907].

B) UNICHARM INDIA

Test Report Summary (Disposable Baby Diaper)

S.No	Lab	Test	Standard	Test			Standard
		pH		Rate of absorption			
1	TESTTEX	6.5	**5.5-8**	27 sec	44 sec	74 sec	**Max 60 sec**
		6.5		21 sec	48 sec	56 sec	
		6.5		19 sec	41 sec	42 sec	
		6.5		20 sec	46 sec	103 sec	
		6.5		8 sec	57 sec	71 sec	
2	SASMIRA	6.8	**5.5-8**	8 sec	10 sec	15 sec	**Max 60 sec**
		6.8		8 sec	12 sec	20 sec	
		6.8		11 sec	14 sec	23 sec	
		6.8		9 sec	13 sec	17 sec	
		6.8		8 sec	13 sec	18 sec	
3	SITRA	6.2	**5.5-8**	17 sec	46 sec	63 sec	**Max 60 sec**
		6.2		16 sec	47 sec	69 sec	
		6.2		19 sec	57 sec	80 sec	
		6.2		16 sec	60 Sec	82 Sec	
		6.2		17 sec	62 Sec	72 sec	

- The pH value of all the samples are within the requirements of BIS standard (5.5-8).
- The value of Rate of absorption is higher in some samples (highlighted in red color) than the standard requirement (Max 60 sec)

C) SOOTHE HEALTHCARE

SITRA Laboratory Report

Acquisition Rate & Rewet - Super Cutes Baby Diaper (XL)			
S.No	**Gush 1**	**Gush 2**	**Gush 3**

1)	44.70	123.80	154.17
2)	48.46	138.61	169.77
3)	34.71	34.71	178.62
Average	42.62	124.59	167.52

Rate of Absorption cl.7.2 was found failed.

OBSERVATION

Super Cutes does not complies the acquisition rate as per BIS IS: 17509:2021 in Gush 2 & 3 in SITRA lab report.

SIGMA Laboratory Report

TEST CERTIFICATE

Sample : Diaper	**Report No. : 21008831/B**
Sample Description : Super Cute's Premium Diaper Pants (Extra Large)	
Party's Ref No: Nil	Report Issue Date : 03/03/2023

TEST RESULTS

S.No.	Test Parameter	Test Result	Requirement as per IS : 17509-2021 Extra Large Size	Test Method	Conformity
2			There shall be elastic ban		
3	Manufacture Workmanship and Finish	Passes the test	The material shall be smooth, and safe for skin contact. It shall be free from defects or lumps. No loose stitching or visible defects on the material. It shall be free from odour, harmful dyes and all sorts of foreign matter. It shall be smooth the touch	IS : 17509-2021	Yes
4	Size, mm	-		IS : 17509-2021	-

	Length	477	520±20	--	No
	Width	327	310±05	--	No
	Absorbent Core Length	359	370±10	--	No
	Absorbent Core Width Back	115	110±10	--	Yes
	Absorbent Core Width Front	115	110±10	--	Yes
	Diaper Crotch	Not Present	215±10	--	No
	Core Crotch Width	Not Present	85±05	--	No
5	pH Value	7.41	5.5-8.0	IS: 1390-2019 (Cold Method)	Yes
6	Minimum Absorption Capacity, ml	3×70	3×70ml	IS:17509-2021 (Annex-B)	Yes
7	Rate of Absorption per gush, sec	8	60 Max.	IS:17509-2021 (Annex-B)	Yes
8	Rewet under load, g	0.0419	5 Max.	IS:17509-2021 (Annex-B)	Yes
Microbiological Parameter					
9	Bacterial and fungal Bioburden, cfu	<10	NMT-1000	IS: 17509-2021	Yes

OBSERVATION

Rate of Absorption cl.7.2 was found Okay and with in range.

As per the Sigma (a NABL accredited lab) report, when testing done as per BIS guidelines, the sample complies both the tests Acquisition rate(3x70ml) and Rewet under load, (<5g) as per BIS IS: 17509.

Soothe In-House Test Report

Acquisition Rate & Rewet - Super Cutes Baby Diaper (XL)					
			Sample 1	Sample 2	Sample 3
Acquisition Rate	G1	Sec	6	5	5
	G2		51	53	51
	G3		119	122	119
	Avg		58.67	60	58.33
Rewet		Gram	1.12	0.091	1.02

Soothe Observation

Rate of Absorption cl.7.2 was found Okay and with in range.

Both parameters Acquisition rate(3x70ml) and Rewet under load, (<5g) results are under the compliance in Soothe's internal. laboratory as per the BIS IS:17509.

As per product manual IS17509:2021 in Annexure B Clause B-5.2

B-5.2 Report the average tie taken by stop watch to completely absorb solution after each gush.

IS17509:2021 Dimension Reference

FIG. 1 SCHEMATIC SIZE OF BABY DIAPER (FOR REFERANCE ONLY)

TABLE 1 DIMENSION OF BABY DIAPER (mm) (For reference only)

(*Clause* 6.2)

Size	Diaper Length (A)	Diaper Width (B)	Diaper Crotch	Absorbent Core Length (C)	Absorbent Core Width Back (D)	Absorbent Core Width Front (E)	Core Crotch
New Born	350 ± 10	260 ± 05	195 ± 10	285 ± 10	110 ± 10	110 ± 10	85 ± 05
Small	390 ± 10	260 ± 05	195 ± 10	300 ± 10	110 ± 10	110 ± 10	85 ± 05
Medium	440 ± 10	310 ± 05	195 ± 10	340 ± 10	110 ± 10	110 ± 10	85 ± 05
Large	480 ± 10	310 ± 05	215 ± 10	370 ± 10	110 ± 10	110 ± 10	85 ± 05
X Large	520 ± 20	310 ± 05	215 ± 10	370 ± 10	110 ± 10	110 ± 10	85 ± 05

Core Crotch not matched as per Diaper Crotch as per Table 1.

Soothe Observation

No standard dimension mentioned in IS: 17509. The dimensions are given in Table- 1 is for reference only not mandate.

D) P & G INDIA COMMENTS

We are herewith submitting the proposal for rate of absorption to change it from 60 Seconds to 180 Seconds.
Title: Proposal for Speed of Acquisition criteria for disposable diapers Absorption method (IS 17509)

Summary: Per BIS IS 17509, current requirement for rate of absorption (RoA) per gush maximum is 60 seconds. This report summarizes the RoA data between P&G and BIS registered labs to propose for RoA to be changed from 60 seconds to 180 seconds.

Objective: To propose for RoA criteria to be 180 seconds based on data

Recommendation: Based on the above data, some pads are found to be above rate of absorption of 60 seconds. Hence, we would like to propose for the criteria to be amended to 180 seconds to allow for pad-to-pad variation.

	Sample 1			**Sample 2**			**Sample 3**			**Sample 4**		
	Gush 1	Gush 2	Gush 3	Gush 1	Gush 2	Gush 3	Gush 1	Gush 2	Gush 3	Gush 1	Gush 2	Gush 3
Internal R&D	26	70	103	29	80	122				60	93	140
Domestic Plant				29	89	118	48	121	164			
Choksi	22	23	23	25	26	26	26	27	28	16	17	18
Testtex	20	28	40	27	31	50	33	43	50	29	40	58
Sitra	3.6	12.2	22.4	22.1	42.5	47.3	39.2	45	58.5	49.4	80.2	110.4

Data from different lab

We have tested our product at BIS certified labs i.e Testtex and Sitra. In addition, we are undertaking that the above data generated at the P&G R&D center and P&G Plants in India have followed the BIS test method (IS 17509).

E) SITRA

Comparison between the adult and baby diaper testing

S. No	**Test parameter**	**Adult diaper**	**Baby diaper**	**Remarks**

1)	**Rate of absorption**			
	Test method	IS 17508 Annex B	IS 17509 Annex B	
	Test fluid used	Coloured 0.9 % Nacl solution	Coloured 0.9 % Nacl solution	---
	Quantity of test fluid used per test	150 ml	New born: 3 X 20 ml Small: 3 X 35 ml Medium: 3 X 50 ml Large: 3 X 60 ml X large: 3 X 70 ml	Baby diaper maximum quantity of test fluid is 210 ml (for X large)
	Applied load	No load	6300 g (plate 605.3 g, weight 5694.7 g)	Load is not applied for adult diaper testing. Uniform load has been given to all size of diaper irrespective of age/weight of the baby.
2)	**Rewet under load**			
	Test method	IS 17508 Annex B	IS 17509 Annex B	
	Applied load	2.5 Kg	2.5 Kg + 605.3 g (cover plate)	Additional load is applied for baby diaper testing.

S.No	Quantity of test fluid per gush in ml	Number of gush	Average rate of absorption in sec			Absorption Capacity	Rewet under load in g	Complies / Not Complies
			First	second	third			
1	50	3	17.64	46.42	63.35	Pass	0.0756	Not complies
2	50	3	16.41	47.49	69.66	Pass	0.0866	Not complies
3	50	3	19.51	57.16	80.21	Pass	0.0708	Not complies
4	50	3	16.6	60.38	82.48	Pass	0.1013	Not complies
5	50	3	17.39	62.23	72.88	Pass	0.0709	Not complies
6	20	3	7.37	15.89	31.31	Pass	1.0297	Complies
7	35	3	12.88	54.35	75.58	Pass	19.6206	Not complies

8	50	3	37.81	111.93	160.55	Pass	10.4539	Not complies
9	60	3	41.33	118.4	160.21	Pass	10.1786	Not complies
10	70	3	60.26	132.12	175.34	Pass	13.0436	Not complies
11	20	3	8.6	18.56	36.71	Pass	0.8264	Complies
12	35	3	24.34	111.7	163.21	Pass	5.2443	Not complies
13	50	3	30.62	108.06	147.56	Pass	10.4794	Not complies
14	60	3	57.21	185.55	282.45	Pass	6.7295	Not complies
15	70	3	76.41	122.05	175.6	Pass	22.5194	Not complies
16	50	3	22.09	42.47	47.32	Pass	0.237	Complies
17	60	3	49.39	80.19	110.43	Pass	1.7223	Not complies
18	20	3	3.59	12.18	22.4	Pass	0.1004	Complies
19	60	3	39.21	45	58.49	Pass	0.13	Complies
20	70	3	42.62	124.59	167.52	Pass	4.1367	Not complies
21	50	3	21.18	64.94	95.52	Pass	0.102	Not complies
22	50	3	35.87	157.42	201.91	Pass	6.1393	Not complies
23	50	3	18.7	28.97	30.84	Pass	0.154	Complies
24	50	3	19.29	33.57	37.3	Pass	0.1432	Complies
25	50	3	17.27	19.93	24.21	Pass	0.1118	Complies
26	50	3	18.41	97.9	154.15	Pass	3.3349	Not complies

ANNEX 13
(Item 5.*2*)

COMMENTS ON PUBLISHED STANDARDS

IS 18266 : 2023, Textiles — Medical Respirator — Specification

Comments of Shri N.K. Kansara

For IS 18266, I have the following comments:

1. Para 3 under Foreword mentions that the A medical respirator is a respiratory protective device designed to achieve a very close facial fit and covers at least the nose, mouth and may cover the chin. A respirator is worn by healthcare personnel (HCP) to reduce the wearer's risk of inhaling hazardous airborne particles such as dusts, fumes, vapors, infectious agents and aerosol/fluids (for example splashes, sprays) for use in healthcare settings.

2. Foreword mentions of what this product is not but does not elaborate on the difference vis-à-vis the Surgical Face Mask and Filtering Half Mask. It may also be mentioned when one would use this product instead of the other two.

3. The Definition given under Clause 3.9 of the standard is exactly the same as the 3rd para under Foreword, which doesn't seems to good editorially.

4. It would be appropriate to add some more information regarding the use of the product and the need to have a standard and the role of important stakeholders such as the regulatory bodies, the healthcare professionals who use it and the patients who are within the healthcare setting environment. Some information of their classification (IN95 & IN99) and their significance may also be mentioned.

5. Components of the Respirators also need to be described. This would also take care of the requirement of Head Harness which has been prescribed under Clause 4.3.

6. Illustrative sketch(es) of Medical Respirators and Do's & Don'ts for its use may be added as bulleted information rather than paragraphic detail as presently given under Annex C.

7. Clause C-8 a) tends to indicate that a medical respirator may have exhalation valves, vents, or other openings and if so than it is not be worn by the user. If it so, then this should be suitably reflected in the text of the standard, as requirement, i.e., Medical Respirator should not have exhalation valves, vents, or other openings.

8. Clause 6.1 e) - Instruction for use (it could be 'instructions' also) to be marked on each piece of medical respirator – whether it would be feasible to legibly mark.

9. Requirement for Biocompatibility Evaluation as given under Table 1 Sl. No. vii) is optional and doesn't have aspect related to flammability. However, the Note 2 under the Table makes two 'shall' statements and also requires to do test of flammability of the raw material. Therefore, it would be appropriate to prescribe requirements for the raw materials and cover it there to make a user friendly standard.
10. Classification of the Medical Respirators also need to be defined specifically and then related to the corresponding performance tests.

ANNEX 14
(Item 7.*1*)

LIST OF STANDARDS DUE FOR 5 YEARLY REVIEW

S.No.	IS Number	IS Title	Due Date
1	IS 10829 : 1993	X-Ray detectable gauze swabs and laparotomy sponges – Specification (first revision)	May, 2024
2	IS 14944 : 2020	Surgical Dressings — Methods of Test (First Revision)	March, 2025
3	IS 1681 : 1998	Textiles – Hospital blankets, woollen, dyed – Specification (third revision)	May, 2024
4	IS 4717 : 2020	Medical Textiles - Zinc Oxide Self-Adhesive Plaster - Specification (Second Revision)	March, 2025
5	IS 4738 : 2020	Medical Textiles - Bandage, Plaster of Paris - Specification (Third Revision)	March, 2025
6	IS/ISO 20645 : 2004	Textile fabrics – Determination of antibacterial activity - Agar diffusing plate test	May, 2024
7	IS 16288 : 2014	Medical textiles - Method for evaluation of the bacterial filtration efficiency of surgical face masks	May, 2024
8	IS 16289 : 2014	Medical textiles - Surgical face masks - Specification	May, 2024
9	IS 16290 : 2014	Medical textiles - Knitted viscose primary dressings - Specification	May, 2024
10	IS 16291 : 2014	Medical textiles - Paraffin gauze dressings - Specification	May, 2024
11	IS 16302 : 2020	Medical Textiles — Orthopedic Stockinet — Specification (First Revision)	March, 2025
12	IS 16303 : 2014	Medical textiles - Cast padding for orthopaedic plaster - Specification	May, 2024
13	IS 16466 : 2020	Medical Textiles - Povidone Iodine Ointment Based Knitted Dressing - Specification (First Revision)	March, 2025
14	IS 16549 : 2020/ISO 22610 : 2018	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment – Test method to determine the resistance to wet bacterial penetration (first revision)	March, 2025

15	IS 16671 : 2020	Medical Textiles — Belladonna Adhesive Plaster — Specification (First Revision)	March, 2025
16	IS 17349 : 2020	Medical textiles – Shoe covers – Specification	March, 2025
17	IS 17348 : 2020	Medical textiles – Adhesive incise drape – Specification	March, 2025
18	IS 17350 : 2020	Medical textiles – Abdominal binder – Specification	March, 2025
19	IS 17351 : 2020	Medical textiles – Dressing, shell compressed – Specification	March, 2025
20	IS 17352 : 2020	Medical textiles – Foam dressing – Specification	March, 2025
21	IS 17353 : 2020	Medical textiles – Pressure garment – Specification	March, 2025
22	IS 17354 : 2020	Medical textiles – Dental bib/Napkins – Specification	March, 2025
23	IS 17359 : 2020	Medical textiles – Anti-embolic stocking for Post op use upto thigh medium – Specification	March, 2025
24	IS 17333 (Part 1) : 2020ISO 13629-1:2012	Textiles – Determination of antifungal activity of textile products Part 1 Luminescence method	March, 2025
25	IS 17333 (Part 2) : 2020ISO 13629-2 : 2014	Textiles – Determination of antifungal activity of textile products Part 2 Plate count method	March, 2025
26	IS 17347 : 2020ISO 18184 : 2019	Textiles – Determination of antiviral activity of textile products	March, 2025
27	IS 17506 : 2020	Medical Textiles - Hydrocolloid Dressing - Specification	March, 2025
28	IS 17507 : 2020	Medical Textiles - Cellulose Wading - Specification	March, 2025
29	IS 17508 : 2020	Disposable Adult Incontinence Diaper - Specification	March, 2025
30	IS 4605 : 2020	Crepe Bandage - Specification (Second Revision)	March, 2025

ANNEX 15
(Item 7.*1*)

LIST OF PRE-2000 STANDARDS

Sl No.	IS Number	IS Title
1	IS 10829 : 1993	X-Ray detectable gauze swabs and laparotomy sponges – Specification (first revision)
2	IS 11046 : 1984	Specification for towel, operating
3	IS 12839 : 1989	Wool/polyamide blended flannel, hospital, grey - Specification
4	IS 14316 : 1995	Swabs, small, in bag of 50 - Specification
5	IS 1681 : 1998	Textiles – Hospital blankets, woollen, dyed – Specification (third revision)
6	IS 6237 : 1971	Specification for handloom cotton cloth for plaster of Paris bandages and cut bandages
7	IS 757 : 1971	Specification for handloom cotton lint, absorbent, bleached, non-sterilized (first revision)