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BUREAU OF INDIAN STANDARDS

AGENDA

Technical Textiles for Medtech Applications Sectional Committee, TXD 36 **29th Meeting**

Date	Time	Venue
23 December 2024 (Monday)	1400 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 28th meeting of the TXD 36 committee held on 13 September 2024 through CISCO webex videoconferencing was circulated vide our reference TXD 36/A 2.28 email dated 17 September 2024. No comments were received on the minutes.

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

Item 2 SCOPE AND COMPOSITION OF TXD 36

2.1 Smt. Tanya Mahajan vide email dated 19 December 2024 informed that her organisation affiliation has changed from The Pad Project, India to Zariya, New Delhi. Menstrual Health Action for Impact is the brand name and the registered organisation details are as follows:

Name: Zariya:

Type of org: Partnership firm

Registration number (GSTIN): 07AABFZ2842A1ZI

Registered Address: 3RD FLOOR, B-31, INDERPURI, Inderpuri, Central Delhi, Delhi, 110012

The Committee may **Consider.**

The updated scope and composition of the committee TXD 36 is given at **Annex 1 (Pages 9 to 11).**

2.1.1 The Committee may **REVIEW and DECIDE**.

2.2 Ms. Saloni Mayekar, Lagom Labs Pvt Ltd (Nua Woman), Mumbai vide email dated 15 November 2024 has requested for membership in TXD 36. She has 10+ years' experience working in the Healthcare sector in the UK, US and India. She has played multiple roles as a consultant,

researcher and a start-up founder in building, operationalizing, and marketing healthcare businesses. She wants to get involved in reviewing and helping develop guidelines for sanitary pads, tampons, reusable period underwear, disposable period panties etc. She has done graduation in Biochemistry with extensive lab experience at University College London, understanding of population health through Master in Public Health and product development work at Nua Woman.

2.2.1 The Committee may **DECIDE.**

2.3 Shri Piyush Sharma, Medical Technology Association of India (MTaI) vide email dated 28 October 2024 has requested for membership in TXD 36. MTaI - a leading association in the MedTech space in India and represents 54+ global medical device global companies in the country. In a short span of its existence, MTaI has become the premier industry body for Medical Technology in India & has been recognized as an important stakeholder by the Government of India. During this time, they have made several strategic and path-breaking efforts, for the growth and benefit of the Medical Device industry. The members representing MTaI in TXD36 will be as follows:-

a) Mr. Kulveen Singh Bali as Primary Member
b) Mr. Piyush Sharma as an Alternate Member

2.3.1 The Committee may **DECIDE.**

2.4 Shri Deepak , Quality Assurance, AMNONWOVENS, Madurai vide email dated 13 December 2024 has requested for membership in TXD 36. They have not shared the relevant details of education and expertise available.

2.4.1 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 28th meeting is given at **Annex 2 (Pages 12 to 13).**

3.1.1 The Committee may **NOTE**.

Item 4 DRAFT STANDARDS/AMENDMENT FOR FINALIZATION

4.1 As decided by the committee in last meeting, the following draft documents were issued under wide circulation vide our letter reference no. TXD 36/ 26617 dated 07 October 2024 for eliciting comments from stake holders for 30 days : -

i) Amendment No. 3 to IS 17509 : 2021 Disposable Baby Diaper — Specification, Doc: TXD 36 (26617)
ii) IS 5405 : 2024 Disposable Sanitary Napkin/ Pantyliner/ Maternity Pad/Period Panty — Specification (*third revision*) [Doc: TXD 36 (26679)]

The last date for comment was **07 November, 2024**.

The draft document as issued under wide circulation are given at **Annex 3 (Pages 14 to 26).**

Shri Kulveen Bali - Solventum India, Shri Arnab Das -DGQA and Shri R Krishnakumar, Cologenesis Healthcare Pvt. Ltd, Salem have sent comments in agreement for approval of amendment No. 3 to IS 17509 : 2021, TXD 36 (26617) through BIS portal.

The comments received from BIS FMCS Deptt, BIS Rajkot Branch Office, Shri M S Parmar, NITRA, Shri Harshad Kotian, Piramal Pharma Limited and Shri Nirmal Jain, Sekhani Industries Pvt. Ltd. on amendment No. 3 to IS 17509 : 2021, TXD 36 (26617) are given at **Annex 4 (Pages 27 to 32).**

Shri Kulveen Bali - Solventum India, Shri Arnab Das -DGQA and Dr. Prabha Hegde, 3 M India have sent comments in agreement for approval of IS 5405 : 2024 Disposable Sanitary Napkin/ Pantyliner/ Maternity Pad/Period Panty — Specification (*third revision*) [Doc: TXD 36 (26679)] through BIS portal.

The comments received from Kenvue, Kimberly Clark, P &G,TZMO Group, Shri R Krishnakumar, Cologenesis Healthcare Pvt. Ltd, Salem, Dr J.J. Jayalakshmi and FIHA on IS 5405 : 2024 Disposable Sanitary Napkin/ Pantyliner/ Maternity Pad/Period Panty — Specification (*third revision*) [Doc: TXD 36 (26679)] are given at **Annex 5 (Pages 33 to 40).**

4.1.1 The Committee may **DECIDE.**

4.2 As decided by the committee in last meeting, the following draft documents were issued under wide circulation vide our letter reference no. TXD 36/26697 dated 11 November 2024 for eliciting comments from stake holders for 30 days : -

i) Doc No.: TXD 36 (26680), Reusable Sanitary Pad/Sanitary Napkin/Period Panties — Specification (first revision of IS 17514)
ii) Doc No.: TXD 36 (26697), Textiles — Medical/Surgical Gowns and Medical/Surgical Drapes — Specification (First Revision of IS 17334)
iii) Doc No.: TXD 36 (26744), Medical Textiles — Nonwoven Gauze Swab— Specification
iv) Doc No.: TXD 36 (26729), Medical Textiles — Elastic Bandage — Specification (first revision of IS 16111)

The last date for comment was **11 December 2024**.

The draft document as issued under wide circulation are given at **Annex 6 (Pages 41 to 80).**

Shri Kulveen Bali - Solventum India, Shri Arnab Das -DGQA and Shri R Krishnakumar, Cologenesis Healthcare Pvt. Ltd, Salem and Dr. Prabha Hegde, 3 M India have sent comments in agreement for approval above documents through BIS portal.

Shri Asad Ullah Khan, Consumer Voice New Delhi informed that he has no comments on above documents.
The comments received from **Saukhyam Reusable Pads, Real Relief and Kenvue** on document TXD 36 (26680), Reusable Sanitary Pad/Sanitary Napkin/Period Panties — Specification (first revision of IS 17514) are given at **Annex 7 (Pages 81 to 86).**

The comments received from **O&M Halyard Health India Pvt. Ltd** on document TXD 36 (26697), Textiles — Medical/Surgical Gowns and Medical/Surgical Drapes — Specification (First Revision of IS 17334) is given at **Annex 8 (Pages 87 to 89).**

The comments received from **Ginni Filaments** on document TXD 36 (26744), Medical Textiles — Nonwoven Gauze Swab— Specification is given at **Annex 9 (Pages 90-91).**

The comments received from **KOB Medical Textiles** on document TXD 36 (26729), Medical Textiles — Elastic Bandage — Specification (first revision of IS 16111) is given at **Annex 10 (Pages 92 to 95).**

4.2.1 The Committee may **DECIDE.**

Item 5 DRAFT STANDARD/AMENDMENT FOR APPROVAL FOR WIDE CIRCULATION

5.1 Medical Textiles -Scrub Suit – Specification

In the 26th meeting of TXD 36, the committee decided the following :-

i) To exclude blood resistance and viral blood resistance test from the existing draft standard.
ii) Patient gown is to be excluded from existing draft standard of scrub suit.
iii) The minimum performance requirement of both single use and multiple use scrub suit shall be included in the draft standard. In case of multiple use, additional requirement of fabric may be specified.
iv) The requirement of bioburden (sterile and non-sterile gauze swab) shall be included as mandatory requirement. For sterile, 'No viable microorganism shall be present' and for non-sterile (CFU/100 cm^2) it shall be $\leq$ 300 CFU.
v) Assistance may be taken from International standard on the similar subject.
vi) In case of any additional clarification and technical information for preparation of preliminary draft, BIS may co-ordinate with

a) Ms. Shivani Swamy, Livinguard Mumbai
b) Dr. Sanjiiv Rehlan, FICCI, New Delhi
c) Mr. Apurva Ranka, Alpha Foam Ltd, Pune
d) Shri Khalil Khan, Surya Textech, Chandigarh

The technical inputs received from Ms. Shivani Swamy, Livinguard Mumbai has been given in **Annex 11 (Pages 96 to 104).**

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

The updated draft standard has been given in **Annex 12 (Pages 105 to 115).**

5.1.1 The Committee may **DECIDE.**

5.2 Medical Textile — Sterilization Wraps — Specifications

In the 26th meeting of TXD 36, the committee decided the following :-

i) The minimum performance requirement of sterilization wrap shall be included in the draft standard. In case of additional requirement applicable for sterilization wrap for a specific textile raw material, it may be specified separately.
ii) Assistance may be taken from International standard/International Practice on the similar subject.

iii) BIS shall prepare the preliminary draft after including scope, performance parameter, test method, sampling, packing, labelling and marking requirement. In case of any additional clarification and technical information for preparation of preliminary draft, BIS may co-ordinate with

a) Shri D. Veerasubramanian, SITRA
b) Shri Sumit Marwah, Dispoline India Pvt. Ltd., Bengaluru

iv) The committee also requested Shri Sumit Marwah to share the contact details of manufacturers of sterilization wrap for their technical inputs and comments.

The technical inputs received from Shri D. Veerasubramanian, SITRA has been given in **Annex 13 (Pages 116 to 117).**

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

The updated draft standard has been given in **Annex 14 (Pages 118 to 125).**

5.2.1 The Committee may **DECIDE.**

Item 6 NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD

6.1 Chitosan Haemostatic Dressings

Shri Saurav Rawat, Axio Bio-Solutions Private Limited vide email dated 31 July 2024 informed BIS that they do not wish to participate for formulation of standard on Chitosan Haemostatic Dressings. The extract of the email is reproduced as follows :-

'As per the latest communication with our management,we have concluded that we don't wish to participate in the standard generation for our product line at this time.

We don't see any benefit from this for our product. Mainly because our product line is unique, and no other manufacturers are currently manufacturing the same. Some competitors want to make similar devices, and putting our specifications and testing details to standard will benefit them.

We feel there is no immediate benefit for us from making a product standard, as overall, there is no awareness of the requirement. We will approach you once we have clarity in making the standard for sure.'

The committee may **WITHDRAW** the subject for the time being.

6.1.1 The Committee may **DECIDE.**

6.2 Tampon and IV Cannula Fixator Dressing

Smt. Roocha Khedkar, Kenvue and Dr. Prabha Hegde, 3 M India vide email dated 08 November 2024 and 02 December 2024 shared the technical inputs on Tampon and IV Cannula Fixator Dressing respectively.

The technical inputs received on new subjects - on Tampon and IV Cannula Fixator Dressing are given at **Annex 15 (Pages 126 to 152).**

6.2.1 The Committee may **DECIDE.**

Item 7 REVIEW OF R&D PROJECT - Project Number: TXD 0035 Study of safety, performance and constructional requirement for surgical sutures (absorbable and non-absorbable)

7.1 In the 25th meeting of TXD 36, the committee prepared and finalized the Terms of Reference (ToR) for the R&D project on 'Study of safety, performance and constructional requirement for surgical sutures (absorbable and non-absorbable).'

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The above-mentioned R&D project was then approved by the review committee after Head (TXD) and Member Secretary (TXD 36) apprised the review committee about the project and explained the rationale behind the proposed R&D project.

The approved ToR was then made available for public bidding. After receiving bids, the research evaluation committee decided to allocate the project to Johnson and Johnson, Mumbai under the leadership of Shri Hemant Sonawane.

The Term of reference and BIS R &D Guidelines are also given in **Annex 16 (153 to 185)**.

The mid-term progress report, Statement of Expenditure and Fund Utilization Report as submitted by Shri Hemant Sonawane, Johnson and Johnson, Mumbai are given in **Annex 17 (Pages 186-190)**.

7.1.1 The committee may **REVIEW**.

Item 8 INTERNATIONAL ACTIVITIES

8.1 The 5th plenary meeting of ISO/TC 338 'Menstrual Product' was held on 11 December 2024 through virtual mode. Since the subject matter being dealt by ISO/TC 338 are important from India's perspective, critical and sensitive in nature so a strong representation at the plenary meeting was proposed to represent India during the meeting.

The following delegation of experts participated in the 5th plenary meeting in virtual mode to represent India's point of view: -

1) Shri S. Sivakumar, (Head, Medical Textiles), SITRA, Coimbatore
2) Smt. Tanya Mahajan, MHAI/The Pad Project, New Delhi
3) Ms. Shivani Swamy, Livinguard Technologies Pvt. Ltd., Mumbai
4) Dr. E. Santhini, SITRA, Coimbatore
5) Shri Nirav Mehta, Dima Products, Mumbai
6) Ms. Roocha Khedkar, Kenvue, Mumbai
7) Shri J.K. Gupta, Scientist E & Head, Textiles (**Head of Delegation**)
8) Shri Dharmbeer, Scientist D, Textiles, Member Secretary TXD 36

The minutes of briefing meeting of experts to build India's point of view, the agenda of plenary meeting and resolution of ISO/TC 338 and report on outcomes of plenary meeting are given at **Annex 18 (Pages 191 to 202).**

As per Resolution 36 – 2024 of ISO TC 338

ISO/TC 338 agrees to start a ballot for creating a Task Group for Low- and middle-income countries (LMIC) coordination to improve the awareness, strengthen the perspective of LMIC, capacity building, implementation and adoption challenges of standard by SMEs. It was agreed to nominate Smt Tanya Mahajan from BIS India as a proposed Leader for task group and to launch a 4-week Committee Internal Ballot including call for experts.

The committee may CONSIDER and APPROVE nomination of Smt. Tanya Mahajan Zariya (Menstrual Health Action for Impact), New Delhi as a proposed leader for task group on co-ordination of Low- and Middle-Income Countries (LMIC) for disseminating the work of ISO/TC 338 to external stakeholders.

8.1.1 The Committee may **DECIDE.**

Item 9 COMMENTS ON PUBLISHED STANDARDS

9.1 IS 17787 : 2021, Medical Textiles — Nonwoven Wipes — Specification and IS 17788 : 2021 Medical Textiles — Nonwoven Fabric for Wipes — Specification

In 27th meeting of TXD 36, the committee decided the following :-

i) The following stakeholder will share the inhouse data and test report of NABL Approved lab for atleast 5 samples of non-woven wipes each for parameters like dimension, ph test, fiber composition, breaking strength:-

a) Shri Ayan Chakraborty, Ginni Filament, Haridwar
b) Smt. Roocha Khedkar, Kenvue Mumbai
c) Shri Basudev Basu, Welspun India Limited, Gujarat
d) Shri Rohit Srivatav, Unicharm Gurgaon

ii) Shri Ayan Chakraborty, Ginni Filament will share the inhouse data and test report of NABL approved lab of atleast 5 samples each for tensile strength and breaking strength as per IS 15891 (Part 3) : 2011 and IS 15891 (Part 18) : 2017.

iii) Shri Basudev Basu, Welspun India Limited, Gujarat will share the inhouse data and test report of NABL Approved Lab for atleast 5 samples each for **needle punched non-woven wipes** for all parameters as per IS 17787 : 2021 and IS 17788 : 2021.

The comments received during 27th meeting of TXD 36 from Ginni Filaments, Kenvue and Unicharm India on IS 17787 : 2021 and IS 17788 : 2021 are given at **Annex 19 (203 to 208).**

The test report and technical inputs received from Welspun India on for **needle punched non-woven wipes** and Ginni filament on spunlace nonwoven are attached

9.1.1 The Committee may **DECIDE.**

9.2 IS 17349:2020 Medical textiles — Shoe covers — Specification

The comments received from Ms Ankhi Chakraborty, BIS EROL Kolkata are given at **Annex 20 (Pages 209).**

9.2.1 The committee may **DECIDE.**

9.3 IS 17508: 2020, Disposable Adult Incontinence Diaper – Specification

The comments received from Shri Shubham, BIS Rajkot Branch Office are given at **Annex 21 (Page 210.**

9.3.1 The Committee may **DECIDE.**

Item 10 DATE AND PLACE OF NEXT MEETING

Item 11 ANY OTHER BUSINESS

ANNEX 1
(Item 2.1)
SCOPE AND COMPOSITION

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 (including medical devices made of textile material) such as healthcare and hygiene textile products, implantable and non-implantable and extra corporeal textile products.'

Meeting(s) held	**Date & Place**
27th Meeting	16th July, 2024 (Through VC)
28th Meeting	13th September, 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	Smt. Prabha Hegde (Smt. Kavitha Kulkarni)	2/2
3.	All Indian Institute of Medical Sciences, New Delhi	Dr. Vijaydeep Siddharth (Dr. Sidhartha Satpathy)	1/2
4.	Alpha Foam Ltd., Pune	Shri Rajiv Ranka (Shri Apurva Ranka)	2/2
5.	Association of Healthcare Providers, New Delhi	Capt. Baban Rai (Dr. Sunil Khetarpal)	2/2
6.	Association of Indian Medical Device Industry (AiMeD), New Delhi	Shri Amit Kumar (Smt. Rama Venugopal)	2/2
7.	Central Drugs Standard Control Organization, New Delhi	Mr. Aseem Sahu (Ms. Shyamni Sasidharan)	1/2
8.	Cologenesis Healthcare Pvt. Ltd, Salem	Shri R Krishana Kumar Shri K. Ramprasad	2/2
9.	DMSRDE, Kanpur (DRDO, (ASL), Hyderabad)	Dr. Mukesh Kumar Sinha	1/2

10.	Defence Research & Development Establishment (DRDE), Gwalior	Dr. Vikas B. Thakre (Shri Suraj Bharati)	1/2
11.	DGAFMS, Ministry of Defence, New Delhi	Surg Capt S.S Dalawayi (Surg Lt Cdr Kotian V. Gopal)	1/2
12.	DGQA (Ministry of Defence), New Delhi	Shri S.S Kashyap (Shri Arnab Das)	2/2
13.	Dima Products, Mumbai	Shri Nirav Mehta (Shri Raghavan Adiyodi)	2/2
14.	Director General of Health Services, New Delhi	Dr Atul Goel (Dr. Umesh Devappa Surangi)	2/2
15.	Dispoline India Private Limited, Bangalore	Shri Sumit Marwah	2/2
16.	Dr. Sabharwals Manufacturing Labs Pvt Ltd Panchkula	Shri Manish Sabharwal (Shri Dhruv Sabharwal)	2/2
17.	Federation of Indian Chambers of Commerce & Industry, New Delhi	Dr. Sanjiiv Rehlan (Ms Tulsi)	2/2
18.	Ginni Filaments Limited NOIDA	Shri Arun Nag (Shri Ayan Chakraborty)	2/2
19.	Indian Council of Medical Research, New Delhi	Dr. Sadhana Srivastav	2/2
20.	Indian Institute of Technology, New Delhi	Prof Ashwini Agarwal (Prof Bipin Kumar)	1/2
21.	Indian Technical Textile Association, Mumbai	Dr. Anup Rakshit (Shri Mahesh Kudav)	1/2
22.	JNTL Consumers Pvt Limited (Kenvue), Mumbai	Smt. Monika Sathe (Ms. Roocha Khedkar)	2/2
23.	KOB Medical Textiles Pvt Ltd, Palladam	Shri Arun Buchade (Shri T. Balaji)	2/2
24.	Livinguard Technologies Pvt. Ltd., Mumbai	Ms. Shivani Swamy (Shri Shashank Morje)	2/2
25.	Maulana Azad Medical College, New Delhi	Dr. Pawanindra Lal (Dr. KirtiNath Saxena) (Dr. Lalit Gupta)	2/2

26.	Medline Healthcare Industries Pvt. Ltd, Pune	Mr. Anothony D' Costa (Shri Dhaval Ghuge)	1/2
27.	Ministry of Textiles (NTTM), New Delhi	Shri Ajay Pandit	1/2
28.	National Accreditation Board for Hospitals and Healthcare Providers, New Delhi	Dr. Kashipa	1/2
29.	Nobel Hygiene, Mumbai	Shri Joy Devassy (Smt. Sneha Gupta)	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.	Surya Textech, Chandigarh	Shri Khalil Khan (Shri Yogesh Yadav)	1/2
33.	Textiles Committee Mumbai	Shri Kartikeyan Dhanda (Dr. P. Ravichandran)	2/2
34.	The South India Textile Research Association, Coimbatore — 641014	Shri S. Sivakumar (Dr. E. Santhini)	2/2
35.	The Synthetics & Art Silk Mills Research Association, Mumbai	Dr Manisha Mathur (Smt. Shradha Dongre)	1/2
36.	Tynor Orthotics Private Limited, Panjab	Shri Neeraj Mehra (Dr Chetan Mittal)	2/2
37.	Zariya (Menstrual Health Action Impact), New Delhi	Smt. Tanya Mahajan	2/2

ANNEX 2
(Item 3.1)

SUMMARY OF ACTIONS TAKEN ON THE MINUTES OF 28th 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	**DRAFT STANDARD FOR FINALIZATION** **Amendment No. 1 to IS 18266 :2023, Textiles — Medical Respirator — Specification** **[Doc: TXD 36 (25703)]** The committee decided that the above draft amendment as given in agenda is FINALIZED for publication as Amendment to Indian Standard.	The amendment has been published.
5.1	**DRAFT AMENDMENT FOR APPROVAL FOR WIDE CIRCULATION** **IS 5405 : 2019, Sanitary Napkins — Specification (Second Revision)** The committee decided that BIS shall prepare the draft revision of IS 5405 and send the same for wide circulation for 30 days for eliciting technical comments from stakeholders.	Coming up under discussion in agenda item **4.1.**
5.2	**DRAFT STANDARD/AMENDMENT FOR APPROVAL FOR WIDE CIRCULATION** **IS 17334: 2019, Medical Textiles — Surgical Gowns and Surgical Drapes — Specification** The committee decided that BIS shall prepare the draft revision of IS 17334 and send the same for wide circulation for 30 days for eliciting technical comments from stakeholders.	Coming up under discussion in agenda item **4.2.**
6.1	**COMMENTS ON PUBLISHED STANDARDS** **IS 17509: 2021 Disposable Baby Diaper — Specification** The committee decided that draft amendment no. 3 to IS 17509 shall be issued under wide circulation for 30 days for eliciting technical comments from stakeholders.	Coming up under discussion in agenda **item 4.1.**

6.2	**COMMENTS ON PUBLISHED STANDARDS** **IS 17514: 2021, Reusable Sanitary Pad/Sanitary Napkin/Period Panties — Specification** The committee decided that draft revision of IS 17514 shall be issued under wide circulation for 30 days for eliciting technical comments from stakeholders.	Coming up under discussion in agenda **item 4.2.**
6.3	**COMMENTS ON PUBLISHED STANDARDS** **IS 17630: 2021, Medical Textiles — Bedsheet and Pillow Cover — Specification** The committee decided to review the requirement of particle release test for woven fabric and requested SITRA to share the results of particle release testing for woven fabric of last six months. The committee also requested M/s Alok Industries to share the test report of NABL approved lab/inhouse technical data to decide the appropriate value of particle release test for woven fabric.	The technical inputs are yet to be received.

ANNEX 3
(Item 4.1)

DRAFT STANDARD/AMENDMENT FOR FINALIZATION

भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDRADS

Draft for comments only Doc No.: TXD 36 (26617)

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DRAFT AMENDMENT NO. 3 SEPTEMBER 2024

TO

IS 17509 : 2021 DISPOSABLE BABY DIAPER — SPECIFICATION

(*Page* 2, *clause* **6.2**, *Table* 1, *see* amendment 2 also) — Substitute the following for the existing note :

'NOTES —

1) The recommended dimension and tolerance (for reference) for premature baby and other variety not covered in Table 1 shall be declared by the manufacture.
2) The actual dimension of baby diaper may differ as per the product design of the manufacturer. If required, the manufacturer may also provide the figure/schematic diagram for measurement of dimension of baby diaper.'

(*Page* 7, *clause* **B 2.2,** *see* amendment 2 also) — Substitute the following for the existing:

'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 small, medium, large, X Large, XX Large and XXX Large sizes . The dimensions of the plate shall be around 200 mm x 70 mm and inner diameter of cylinder shall be 50 mm (*see* Fig. 4).

B 2.2.1 A rigid cover plate , with weight , total weight : 2500 g (plate 605.3 g, weight 1894.7 g) representing a pressure of 1.75 kPa (0.25 psi) for premature and new born sizes . The dimensions of the plate shall be around 200 mm x 70 mm and inner diameter of cylinder shall be 40 mm (*see* Fig. 4).'

(*Page* 7, *clause* **B 4.9**) — Substitute the following for the existing:

'B-4.9 Repeat step **4.4** to **4.8** another 2 times on same diaper without removing the weight.'

(*Page* 8, *clause* **B 6.4**, *first line*) — Substitute '2' for '5.'

भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDRADS

Draft for comments only Doc No.: TXD 36 (26679)

Draft Indian Standard

IS 5405 : 2024 Disposable Sanitary Napkin/ Pantyliner/ Maternity Pad/Period Panty — Specification (*third revision*)

FOREWORD

(Formal clause will be added later)

Sanitary napkin/panty liner/maternity pad/period panty is an absorbent hygiene material used to absorb fluid discharged during menstruation. As compared to cloth and other materials (husks, ashes, etc.) used during menstruation, it provides better hygiene and protection against leakage. Panty liners are a thinner, smaller version of a sanitary napkin. They are made of similar absorbent material for daily use to absorb light vaginal discharge, minor menstrual flow, or spotting. Maternity pads are generally thicker and can be longer version of a sanitary napkin used to absorb postpartum bleeding that happens for weeks after childbirth. Period panties are wearable form of sanitary napkin and made of absorbent material used to absorb fluid discharged during menstruation. Period panties are also referred as period underwear or period underpants. Sanitary napkins are also referred as sanitary pads or menstrual pads.

This standard was originally published in 1969; and subsequently revised in 1980 and 2019. The third revision has been made to incorporate the following major changes:-

a) All amendments have been incorporated.
b) Title and scope of the standard has been updated.
c) Material and sizes have been modified.
d) Requirement of pantyliner, maternity pad and period panty have been specified.
e) Manufacture, workmanship and finish have been modified.
f) The procedure and requirement of ability to withstand pressure after absorption have been modified.
g) pH and hygiene testing requirement have been updated.
h) The requirement of compostability has been updated.
i) Optional requirement of anti-bacterial activity test has been specified.
j) Sampling and criteria for conformity has been modified.
k) Marking clause has been modified.

l) References to Indian Standard have been updated.

This standard contains clause **5** which calls for an agreement between the purchaser and the supplier regarding dimensions. However, recommended dimensions have been specified.

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.

Draft Indian Standard

IS 5405 : 2024 DISPOSABLE SANITARY NAPKIN/ PANTYLINER/ MATERNITY PAD/PERIOD PANTY — SPECIFICATION

(*Third Revision*)

1 SCOPE

This standard covers the requirements for disposable (non-reusable) sanitary napkin/ pantyliner/maternity pad/period panty for external use.

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

All types of sanitary napkin/pantyliner/maternity pad/period panty basically consist of three major components:

a) cover or the top sheet;
b) absorbent core, and
c) the barrier or bottom sheet.

3.1 Cover/Top sheet

The cover/top sheet is the material which comes under contact with skin during use. The cover of sanitary napkin/pantyliner/maternity pad/period panty shall be of good quality cotton, rayon knitted sleeve or gauze, non-woven fabric or any other materials with sufficient porosity to permit the assembled product to meet the absorbency requirements. If cotton gauze is used, it shall conform to IS 758.

3.2 Absorbent Core

An absorbent core forming the middle layer(s) shall consist of filler materials, such as cellulose pulp, cellulose wadding, tissue, cotton, wood pulp, other absorbent and super absorbent materials or combination of these materials, etc. It shall be free from lumps (unintended), oil spots, dirt or foreign material (unintended foreign matter that can cause injury or discomfort) when examined visually.

3.3 Barrier or Bottom Sheet

The barrier shall be made of suitable leak proof material so that it meets the requirement specified in **7.2**.

'NOTE — The requirements given in **3.1** to **3.3** are for guidance of the manufacturer. The material and design may vary between different types and sizes of the sanitary napkin/pantyliner/maternity pad/period panty or as per the agreement between buyer and seller.'

4 TYPE AND SHAPES OF SANITARY NAPKIN/PANTYLINER/MATERNITY PAD/PERIOD PANTY

4.1 The sanitary napkin/pantyliner/maternity pad/period panty shall be of following types:

a) Sanitary napkin
b) Pantyliner
c) Maternity pad; and
d) Period panty

4.2 Sanitary napkin/pantyliner/maternity pad/period panty can be of various shapes and design such as wings/no wings, tab/tab-less etc. or as per purchaser's needs.

NOTES —

1) Sanitary napkin/pantyliner/maternity pad/period panty with wings provide better grip on the undergarments so that product remains in its position under dynamic conditions. Some products can also be folded to be carried in a small pouch.
2) The requirements given in **4.1** to **4.2** are for guidance of the manufacturer. The type and shape may vary between different design of the sanitary napkin/pantyliner/maternity pad/period panty or as per the agreement between buyer and seller or manufacturers product design.

5 SIZES

Size of sanitary napkin/pantyliner/maternity pad/period panty shall be as agreed to between the purchaser and the supplier. Sizes of sanitary napkin/pantyliner/maternity pad/period panty shall be variable depending on the absorbent capacity, purchaser's needs and wing features. The recommended sizes are classified as follows in table 1:

Table 1 Size of Sanitary Napkin/Pantyliner/Maternity Pad/Period Panty
(for reference and guidance only)

(*Clause* 5)

Sl No	**Name of product**	**Size class**	**Length (mm) (absorbent core only)**	**Width (mm) (absorbent core only)**
(1)	(2)	(3)	(4)	(5)

i)	Sanitary napkin	Regular	≤ 210	*Min* 55
		Large	211 to 240	
		Extra - large	241 to 280	
		XXL	≥ 281	
ii)	Pantyliner	Small	≤ 135	*Min* 30
		Regular	136 to 179	
		Large	≥ 180	
iii)	Maternity pad	-	≥ 281	*Min* 80
iv)	Period panty	-	> 230	*Min* 55

'NOTE —

1) The actual dimension of absorbent core may differ as per the product design of manufacturer. If required, the manufacturer may also provide the figure/schematic diagram for measurement of dimension of absorbent core length and width of the product.
2) The recommended dimension (for reference and guidance only) of absorbent core length and width for other size class/type of sanitary napkin/pantyliner/maternity pad/period panty not covered in Table 1 shall be declared by the manufacture.'

6 MANUFACTURE, WORKMANSHIP AND FINISH

6.1 The wood pulp or other absorbent filler shall be arranged and neatly cut to the required size and shape of the sanitary napkin/pantyliner/maternity pad/period panty without any wrinkles and distortion. The absorbent material is deposited on to a pre-glued or without glue cover in such a way that it does not cause lump formation with the effect of sudden pressure. The covering fabric should cover the filler completely and shall extend beyond the width of the filler or beyond the length of the filler to form tabs or loops at each end. The absorbent along with the cover is then fed to the embossing unit, if any pattern is required to be embossed. Finally, a pre-glued barrier is applied on to other side of absorbent filler, forming a complete sanitary napkin/pantyliner/maternity pad/period panty structure. A sanitary napkin/pantyliner/maternity pad/period panty is then sealed using heat and pressure or other methods along the periphery or alternatively, it can be stitched or glued, depending upon the type of material used. In case of tab-less sanitary napkin/pantyliner/maternity pad/period panty, an adhesive system or other suitable method may be introduced for holding the sanitary napkin/pantyliner/maternity pad/period panty securely in position. The barrier is applied with adhesives with release paper to fix the sanitary napkin/pantyliner/maternity pad/period panty to the undergarment, for the tab-less sanitary napkin/pantyliner/maternity pad/period panty.

'NOTE — The requirements given in **6.1** are for guidance of the manufacturer. The manufacture, workmanship and finish may vary between different design, types, and sizes of the sanitary napkin/pantyliner/maternity pad/period panty or as per the agreement between buyer and seller or as per manufacturers design. The manufacture should use elemental or total chlorine free bleached wood pulp in the absorbent core of the product.'

6.2 The sanitary napkin/pantyliner/maternity pad/period panty shall have a soft feel and when worn shall not chafe or give any uncomfortable feeling. They shall be free from all sorts of foreign matter (unintended foreign matter that can cause injury or discomfort).

7 REQUIREMENTS

7.1 *p*H Value

The *p*H of sanitary napkin/pantyliner/maternity pad/period panty (top and absorbent core) shall be from 3.5 to 7.5 when tested by the method given in IS 1390.

'NOTE — If the required weight of the test specimen in not sufficient in one sample, then more no. of samples of the same lot may be taken for testing of the product .

7.2 Ability to Withstand Pressure after Absorption

The sanitary napkin/pantyliner/maternity pad/period panty shall absorb coloured distilled water as given in table 2 and it shall not show leakage at the bottom or side edges of the product, when tested according to method given in Annex B.

Table 2 Ability to Withstand Pressure after Absorption for Sanitary Napkin/Pantyliner/Maternity Pad/Period Panty

(*Clause* 7.2, Annex B)

Sl No	Name of product	Liquid Absorption (ml), *Min*
(1)	(2)	(3)
i)	Sanitary napkin	30
ii)	Pantyliner	1
iii)	Maternity pad	50
iv)	Period panty	30

7.3 Hygiene Testing Requirement

Total viable count (total number of bacteria and fungi) shall not be more than 1 000 cfu/gm and *Staphylococcus aureus* shall be absent.

7.3.1 *Bacterial and Fungal Bioburden*

The sanitary napkin/pantyliner/maternity pad/period panty shall be tested for bacterial and fungal bioburden in accordance with method given in **7.3.1.1**. For selecting sample item portion (SIP), appropriate eluent and methods of extraction; IS/ISO 11737 (Part 1) shall be referred.

7.3.1.1 *Test method*

A sample of 5 gm cut from the centre portion of the sanitary napkin/pantyliner/maternity pad/period panty 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 sanitary napkin/pantyliner/maternity pad/period panty or the quantity in which the sanitary napkin/pantyliner/maternity pad/period panty completely immerse. The sanitary napkin/pantyliner/maternity pad/period panty 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°C for 24 h and count colonies.

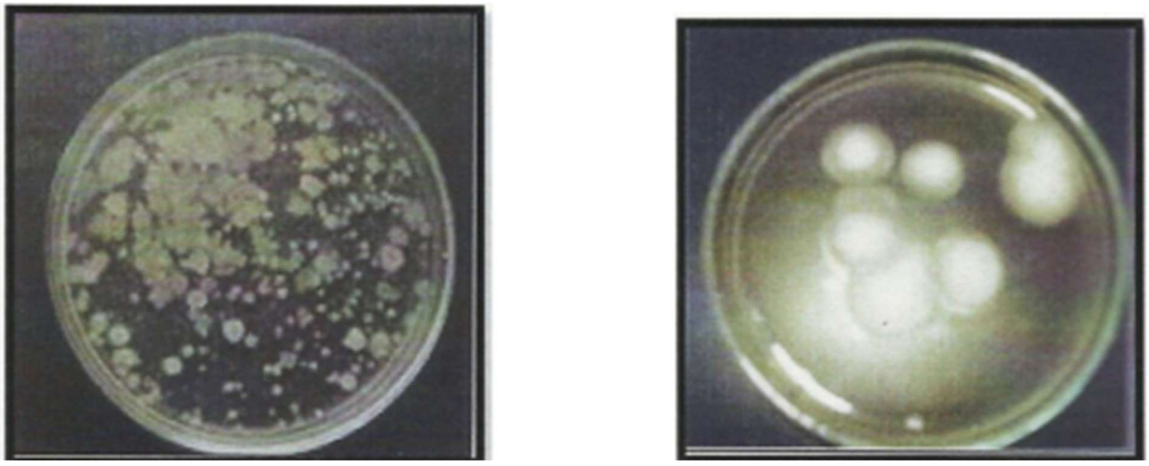
Continue incubation upto 72 h, re-examine the plates after 48 h and 72 h, and report the results that have not resulted in overgrowth. Similarly incubate SCA plates at 20-25°C for 3 days and count the fungi. Re-examine after incubation for 5 and 7 days. Report the results from incubation time that does not result in over growth. The typical colony characteristics are shown in Fig. 1.

7.3.2 *Test for Common Skin Pathogen — Staphylococcus Aureus*

The sanitary napkin/pantyliner/maternity pad/period panty shall be tested for the presence of Staphylococcus aureus in accordance with method given in **7.3.2.1.** For the preparation of medium such as cooked salt medium, baird-parker medium and method for coagulase test; IS 5887 (Part 2) shall be referred.

7.3.2.1 *Test method*

A sample of 5 gm cut from the centre portion of the sanitary napkin/pantyliner/maternity pad/period panty shall be completely immersed in appropriate volume of enrichment medium like cooked salt medium or equivalent medium. Incubate for enrichment purpose at 37°C 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 sanitary napkin/pantyliner/maternity pad/period panty. 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.



(A) **(B)**

Fig. 1 Typical Colony Characteristics of Bacterial Bioburden (A) and Fungal Bioburden (B)

Fig. 2 Typical Colony Characteristics of *Staphylococcus Aureus*

'NOTE — If the required weight of the test specimen under clause 7.3.1.1 and 7.3.2.1 is not sufficient in one sample, then more no. of samples of the same lot may be taken for preparation of test specimen.'

7.3.3 Good Manufacturing Practice Guideline for Hygiene Requirement

The sanitary napkin/pantyliner/maternity pad/period panty shall be manufactured under good hygienic conditions. The general guidelines for good manufacturing practice to maintain hygiene requirement at manufacturing facility are given in Annex C.

7.4 Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization (Optional)

If required by the buyer, the manufacturer shall ensure that raw material used for manufacturing the final product are safe for 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, IS 17932 (Part 7) and IS 17932 (Part 6) respectively.

For cytotoxicity, the material shall show reactivity as 'non-cytotoxic' when tested as per IS/ISO 10995 Part 5.

Similarly, the material shall be 'Non-irritant and Non-sensitizer' when tested as per IS 17932 (Part 7) and IS 17932 (Part 6) respectively. For preparation of samples for these tests, IS/ISO 10993 Part 12 shall be referred.

7.5 Phthalate Test

The amount of phthalate present in sanitary napkin/pantyliner/maternity pad/period panty shall be < 0.1 percent (individual or in combination) when tested as per the method given in IS 9873 (Part 6). The phthalate test shall be done at raw material stage once for existing raw material and whenever there is a change in the raw material for manufacturing the product. The manufacturer of final product shall also do the phthalate test once in a year.

7.6 Compostability (Optional)

The manufacturer who are claiming their product as compostable shall pass the test on the final product as per IS/ISO 17088.

7.7 Anti-Bacterial Activity Value (Optional)

If claimed by the manufacturer, the raw material used for the product or final product shall have antibacterial activity value greater than or equal to 2 when tested by the absorption method prescribed in IS/ISO 20743.

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 Lot

All the sanitary napkin/pantyliner/maternity pad/period panty of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot.

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

8.1.2 The number of sanitary napkin/pantyliner/maternity pad/period panty 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 3.

8.1.3 These sanitary napkin/pantyliner/maternity pad/period panty shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

Table 3 Number of Sanitary Napkin/Pantyliner/Maternity Pad/Period Panty to be Selected
(*Clause* 8.1.2)

Sl No.	**Lot Size**	**Non-Destructive Testing**		**Destructive Testing**	
		No. of Products to be Selected	Acceptance Number	No. of Products to be Selected	Acceptance Number
	N	*n*	*a*	n_1	a_1
(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)	3 201 - 10 000	32	2	8	0
vi)	10 001 - 35 000	50	3	8	0
vii)	35 001 - 150 000	80	5	13	0
viii)	150 001 - 500 000	80	5	13	0
ix)	500 001 and over	125	7	13	0

NOTES —

1) For hygiene testing, biocompatibility evaluation, compostability, anti-bacterial activity test refer clause **8.2.4**, **8.2.5, 8.2.6** and **8.2.7** respectively.
2) The sampling plan given in table 3 is for guidance of manufacturer/user. The other sampling plan may also be followed if agreed between buyer and seller or as per manufacturers quality assurance plans.

8.2 Number of Tests and Criteria for Conformity

8.2.1 All sanitary napkin/pantyliner/maternity pad/period panty to be selected as per column 3 of Table 3 shall be examined for workmanship and finish.

8.2.1.1 Any sanitary napkin/pantyliner/maternity pad/period panty 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 3. Otherwise, the lot shall be rejected.

8.2.2 Out of the sample already found satisfactory according to **8.2.1.1**, a sub-sample as per column 5 of Table 3 shall be taken. This sub-sample shall be further tested for the remaining requirements.

8.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective sanitary napkin/pantyliner/maternity pad/period panty found in the sample (*see* **8.2.2**) is less than or equal to the acceptance number as given in column 6 of Table 3.

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

8.2.5 The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material for manufacturing the product.

8.2.6 The testing for compostability shall be carried out once for existing products and whenever there is a change in the raw material for manufacturing the product.

8.2.7 The anti-bacterial activity testing shall be carried out once for existing raw material or final product and whenever there is a change in the raw material or source of supply of raw material for manufacturing the product.

9 MARKING

9.1 Each consumer pack shall be legibly and indelibly marked with the manufacturer's name or trade mark, size, type and number of sanitary napkin/pantyliner/maternity pad/period panty contained in the pack in addition to the following:

a) Directions of use;
b) Disposability instructions. The manufacturer shall provide the instruction to users for safe disposal of the product as per *Solid Waste Management Rules*, 2016 or any other rules and regulation published from time to time;
c) Batch/Lot no. and date of manufacturing;
d) The information whether the product is compostable (if applicable).
e) The information whether the material of the product is biocompatible that is, meets the requirement of the standard for biocompatibility evaluation – cytotoxicity, irritation and skin sensitization (if applicable);
f) Additional feature of antibacterial (if applicable) ; and

g) Any other information required by law in force or agreed between the buyer and the seller.

9.2 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.

10 PACKING

Sanitary napkin/pantyliner/maternity pad/period panty shall be packed in rigid or flexible packages that protect the product from contaminants during shipment and storage. This package could be constructed of materials, such as carton board, polyethylene, polypropylene, polyester or other safe materials that provide sufficient protection to the product. The package should be free of any torn or damaged areas.

ANNEX A
(*Clause* 2)
LIST OF REFERRED STANDRDS

IS No./Other Publication	*Title*
758 : 2023	Specification for cotton gauze, absorbent, non-sterilized (*fourth revision*)
1390 : 2022/ ISO 3071 : 2020	Textiles — Determination of *p*H of aqueous extract (*third revision*)
4905 : 2015	Random sampling and randomization procedures (*first revision*)
5887 (Part 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*)
9873 (Part 6) : 2021/ ISO 8124-6 : 2018	Safety of toys Part 6 Determination of certain phthalate esters in toys and children's products (*first revision*)
17932 (Part 6) : 2023	Biological evaluation of medical devices Part 6 Tests for skin sensitization
17932 (Part 7) : 2024	Biological evaluation of medical devices Part 7 Tests for irritation
IS/ISO 10993-5 : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity

IS/ISO 10993-12 : 2021	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 17088 : 2021	Compostable plastics — Specification (*second revision*)
IS/ISO 20743 : 2021	Textiles — Determination of antibacterial activity of textile products (*first revision*)

ANNEX B

(*Clause* 7.2)

METHOD FOR DETERMINATION OF ABILITY TO WITHSTAND PRESSURE AFTER ABSORPTION

B-1 TEST PROCEDURE

Lay the sanitary napkin/pantyliner/maternity pad/period panty on a flat level transparent surface, so that underside of sanitary napkin/pantyliner/maternity pad/period panty can be observed. Drip at the rate of 1 ml (pantyliner)/5 ml (other product) per min, coloured distilled water as given in table 2 maintained at temperature of 27°C ± 2°C on to the centre of the sanitary napkin/pantyliner/maternity pad/period panty from a height of 5-7 mm. After the sanitary napkin/pantyliner/maternity pad/period panty has absorbed full amount of coloured distilled water, keep a standard weight of 1 kg for 1 min on the portion where coloured distilled water was absorbed. Observe the bottom and side edges of sanitary napkin/pantyliner/maternity pad/period panty for any leak through. Test sample passes if liquid does not leak through and fails if liquid leak through.

'NOTES —

1) The dimension of 1 kg weight should have length and width of 150 mm x 50 mm with a tolerance of ± 1 mm.
2) For period panty, cut along the lateral seam on both the sides (left and right) and then lay the period panty flat for absorbency testing.'

B-2 Add 0.01 g colour of Bromocresol Purple (Grade – Chemical analytical grade or equivalent) in 1 000 ml of distilled water and stir evenly to get uniform coloured solution.

ANNEX C

(*Clause* 7.3.3)

GOOD MANUFACTURING PRACTICE FOR HYGIENE REQUIREMENT

Maintaining hygiene at production facility is essential for ensuring products are appropriate for consumers use. Following are recommended guidelines for ensuring hygiene at facilities:

a) Location should be free from objectionable odours, smoke, dust and other contaminants.

b) Separate areas shall be demarcated for storing raw materials, production and final product storage.
c) Separate area shall be demarcated for storing personal effects and personal protective equipment of unit workers to minimize risk of contamination.
d) Toilet and hand-washing station shall be positioned away from storage/production area.
e) Provision of 70 percent isopropyl alcohol (IPA) solution for hand sanitization inside the production facility.
f) Appropriate lighting and proper ventilation of the facility shall be ensured.
g) Flooring shall be either concrete, tiled or with chips to ensure ease of cleaning. Floors, walls, ceilings, doors and windows shall be easy to clean and without crevices or openings that shall not allow accumulation of dirt.
h) Regular pest control measures shall be put in place.
j) Adequate receptacles for disposing waste generated within the facility shall be made available and shall be frequently emptied and cleaned.
k) Poster/sign encouraging safety and hygiene practices like use of personal protective equipment, use of hand sanitizer etc. shall be displayed.
m) Pre-packaged finished product shall be checked thoroughly and ensured to be free from foreign particles, dirt, hair, and other visible contaminants.
n) Hand hygiene shall be practised during manufacturing.
p) A cleaning and maintenance schedule shall be drawn up for cleaning of the facility, toilets, washing areas, waste receptacles and for cleaning/disinfection of the equipment.

ANNEX 4
(Item 4.1)

DRAFT STANDARDS/AMENDMENT FOR FINALIZATION

Comments received on Amendment No. 3 to IS 17509 : 2021 Disposable Baby Diaper — Specification, Doc: TXD 36 (26617)

1) **BIS FMCS Deptt,**

This has reference to IS 17509:2021 pertaining to Product "Disposable Baby Diapers" and Draft Amendment 03 published for wide circulation. In this regard, the following comments are being offered for your kind consideration

1. Provision of providing Disposal Tape on the Diaper may be considered in Cl 4 of ISS.

Provision of providing Disposal Tape to ensure clean disposal of the used diaper so that the waste inside the diaper does not spill out in the Garbage Bin.

2. Types of Diapers as per Cl 6 of ISS (Pant Style Diapers and Tape Style Diapers)

There are two types of Diapers that are being manufactured in the Industry. One Type of Diaper is Pant Style Diaper and another type of Diaper is Tape Style Diaper. IS 17509:2021 mentions the types of Diapers based on the weight of the Infant or Toddler but there is no mention of the Types of Diapers whether it is Pant Style or Tape Style. It is proposed that Pant Style Diaper and Tape Style Diaper may be added in Cl 6 of ISS.

Also, during the preliminary inspection carried out by the undersigned, the foreign manufacturer conveyed that as per the European Regulations, Tape Style Diapers are considered to be best for use with premature and new born babies as they do not pose any health risks in limb growth of the baby.

3. Scope of the Standard (Clause-1 of ISS)

The scope of the Standard covers the requirements for disposable baby diapers for external use. It is proposed that an additional variety of swimming diapers may also be included in the scope of the standard as the constructional and functional requirements of the diaper are the same except for the Outer protective Barrier or Back Sheet which is waterproof in case of Swimming Diapers.

2) **BIS Rajkot Branch Office,**

Shri Shubham, BIS Rajkot Branch Office
IS 17509 : 2021, Disposable Baby Diaper - Specification

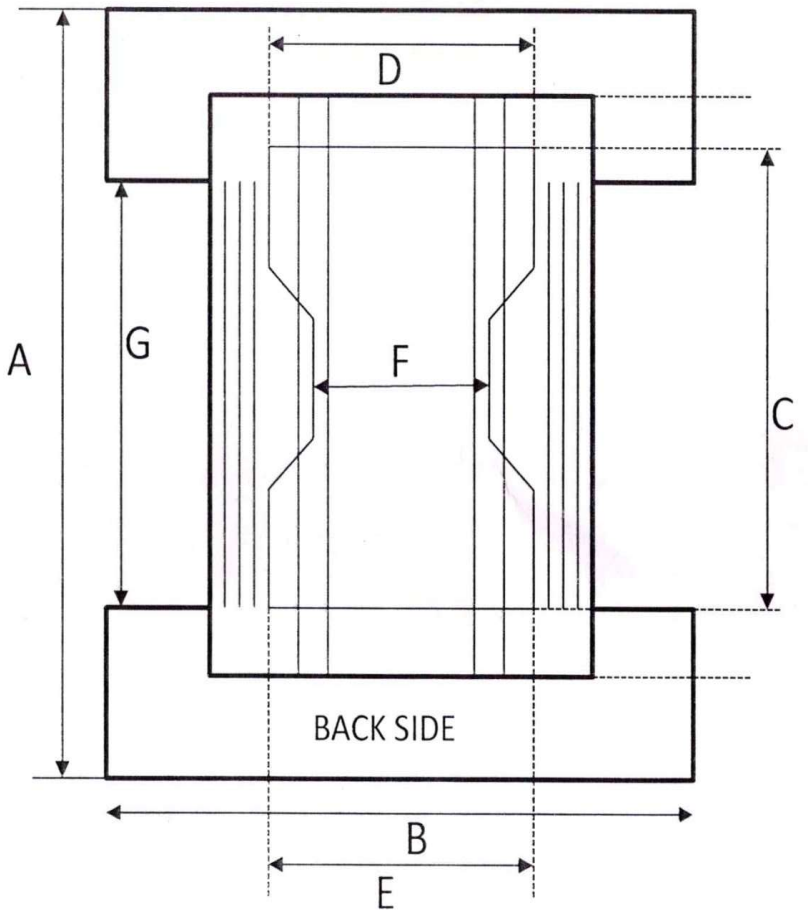
Figure 1 illustrates the dimensions of a baby diaper. While the figure effectively represents the overall size and key measurements using alphabetic labels, it lacks specific designations for the diaper crotch and core crotch.

It is recommended that the figure be revised to include clear labels for diaper crotch and core crotch, enhancing its clarity and comprehensiveness.
It seems there's a potential inconsistency between Clause B-6.3 and B-6.4 of IS 17509:2021. B-6.3 specifies placing the weight and cover plate for 2 minutes, while B-6.4 suggests removing them after 5 minutes.

To ensure clarity and adherence to the standard, I suggest the following interpretation and additional step:
Procedure:
i) Place the weight and cover plate on the filter paper stack for 2 minutes. This step aligns with Clause B-6.3. ii) Leave the weight and cover plate in place for an additional 3 minutes. This step is added to reconcile the 5-minute duration mentioned in Clause B-6.4. iii) Remove the weight and cover plate after a total of 5 minutes. This final step ensures compliance with both clauses.

DIAPER PARTS

A – DIAPER LENGTH
B – DIAPER WIDTH
C – ABSORBENT CORE LENGTH
D - ABSORBENT CORE WIDTH FRONT
E - ABSORBENT CORE WIDTH BACK
F - CORE CROTCH
G – DIAPER CROTCH



3) Shri M S Parmar, NITRA,

Following are not clearly formatted:

'B 2.2 — A rigid cover plate , with weight , total weight : 6300 g (plate 605.3 g, weight 5694.7 g)

A rigid cover plate , with weight , total weight : 2500 g (plate 605.3 g, weight 1894.7 g) representing a pressure of 1.75 kPa (0.25 psi)

4) Shri Harshad Kotian, Piramal Pharma Limited and

I am Harshad Kotian from Piramal Pharma Limited. We are a consumer product development unit and deal majorly with cosmetics(clean off and leave on) and personal care, which includes baby diapers. I am writing this mail with you as we need your support/suggestion to understand "Baby diaper classification by weight into category" in 17509:2021 Amendment 2(august 2024). In the above amendment in clause 6.1 we have following queries:

1) In point 6.1, Weight of the premature baby, infant and or toddler to be considered as standard or can the weight be varied basis our requirement

2) In point 6.1,

Sr. no.	Category	Weight of the Premature Baby, Infant and or Toddler
1	Medium	6kg to 11kg
2	Large	9kg to 11kg
3	X-Large	13kg to 15kg

Both have Medium and Large have same upper limit of 11kg.

There is no mention of **12kg** in any of weight categories. Which of the three sizes can be considered to for a **12kg** baby.

Request please help us to get clarity. Your guidance will be of great value to Industry. Looking forward for your support and cooperation.

5) Shri Nirmal Jain, Sekhani Industries Pvt. Ltd

DOCUMENT NO: Standard -IS 17509: 2021(Disposable Baby Diaper)				
Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Proposed Change in the existing clause	Technical References and justification on which (2), (3), (4) are based	Remarks
1	2	3	5	4

Annexure B Clause(7.2) (1) B-2.2A-Rigid Cover Plate (2) Rate of absorption per gush (s), Max (Second) First gush – 40 Second gush – 60 Third gush – 90	(1)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. (2) First gush – 40(second) Second gush – 60(second) Third gush – 90(second)	Our Proposal : When this high pressure is applied to the core, the low-density Pulp, which provides capillary action for liquid distribution, becomes compressed. This compression reduces capillary action, leading to localized absorption in the area of urine insult, thereby reducing the flow of urine to surrounding areas . We propose an optimal ratio of pulp and SAP, with even distribution of SAP throughout the core. The testing method should avoid applying 6,3 kg weight during the absorption test, allowing the liquid to flow freely across a larger surface area for accurate absorption measurement, supported by the cuffs that allow liquid within the core . Without applying pressure the Liquid get absorbed within	(1) Effects of Pressure on the Core: When this high pressure is applied to the core, the low-density Pulp, which provides capillary action for liquid distribution, becomes compressed. This compression reduces capillary action, leading to localized absorption in the area of urine insult, thereby reducing the flow of urine to surrounding areas . (2)Consideration of Baby Positions: SAP, in powder form, absorbs liquid quickly and transforms into gel. However, once the SAP reaches its absorption threshold, it slows down liquid absorption and attempts to transfer the liquid to	Challenges/ possible setback - with Increasing Absorption Rate under Pressure 1.Basis for Core Design :Increasing SAP content at the point of urine insult could improve absorption speed, but this risks making the diaper uncomfortable due to the swelling nature of SAP . 2. Core Absorption Mechanism: Increasing pulp weight could enhance absorption, but it would result in a heavier, less comfortable diaper for the baby . 3. Effects of Pressure on the Core: Introducing channeling or embossing to create air gaps, or creating grooves in the core might improve absorption but could lead to other issues, such as core breakage in wet conditions after multiple wettings , or a stiff & less softer diaper , less comfortable diaper. 4. Additionally, using acquisition layers (AL) can facilitate faster absorption, but these also add to the diaper's weight and cost, which may not be necessary if the core is designed optimally with the right SAP-pulp ratio with inbuilt designs. So based on above points we can remove pressure plate of 6.3 Kg from diaper during testing which will allow fluid to pass freely. 5 - Raw Material Sourcing and R&D Constraints: An additional point of concern is that, as an MSME in India, we source 100% of our SAP powder

		40, 60, 90 Seconds at same point of insult .(2).With such pressure(6.3 Kg Rigid plate) absorption rate need to increase 60,90 and 150 seconds per gush	nearby areas. Due to the pressure, this transfer happens at a slower rate, affecting the overall absorption speed .	and pulp from overseas suppliers. This limits our ability to conduct extensive R&D locally. Currently, we have access to only 3-4 major options for SAP and pulp grades, without the rights or flexibility to customize these materials for better performance . As the industry grows, we hope to see more local suppliers and R&D opportunities arise, enabling us to innovate further and create better diaper cores. Our goal is to continue producing high-quality, comfortable baby diapers, balancing all factors and using the available R&D resources and materials .

ANNEX 5
(Item 4.1)

FINALIZATION OF DRAFT STANDARD/AMENDMENT

Comments on IS 5405 : 2024 Disposable Sanitary Napkin/ Pantyliner/ Maternity Pad/Period Panty — Specification (*third revision*) [Doc: TXD 36 (26679)]

1) **Ms. Monika Sathe and Ms. Roocha Khedkar, R&D, Kenvue, JNTL Consumer Health (India) Pvt. Ltd.**

DOCUMENT NO: Proposed Draft Revision IS 5405: 2024 Disposable Pantyliner/Sanitary Napkins/Maternity Pad/Period Panty

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Specific Proposal (Draft clause to be add/amended)	Remarks	Technical References and justification on which (2), (3), (4) are based
(1)	(2)	(3)	(4)	(5)
FOREWORD …. This standard contains clause 5 which calls for an agreement between the purchaser and the supplier regarding dimensions. However, recommended dimensions have been specified.	To be deleted	Not required	Clarification	clause 5 has been revised and purchaser's need has been included.
6. MANUFACTURE, WORKMANSHIP AND FINISH 6.1…..In case of tab-less sanitary napkin/pantyliner/maternity pad/period panty, an adhesive system or other suitable method may be introduced for holding the sanitary napkin/pantyliner/maternity pad/period panty securely in position. The barrier is applied with adhesives with release paper to fix the sanitary napkin/pantyliner/maternity pad/period panty	Period panty to be deleted where mentioning of adhesive for holding the pad is made	**6. MANUFACTURE, WORKMANSHIP AND FINISH** 6.1…..In case of tab-less sanitary napkin/pantyliner /maternity pad, an adhesive system or other suitable method may be introduced for holding the sanitary napkin/pantyliner /maternity pad securely in	Simplification	Tab-less Sanitary napkin, Panty liners, Maternity pads have adhesive bands. Section 6.1 is relevant to these products. By design, period panty will not require adhesive system for holding it securely in position.

to the undergarment, for the tab-less sanitary napkin/pantyliner/maternity pad/period panty.		position. The barrier is applied with adhesives with release paper to fix the sanitary napkin/pantyliner /maternity pad to the undergarment, for the tab-less sanitary napkin/pantyliner /maternity pad.		
Annex C Numbering from 'j to p'	Numbering from 'j to p' should be corrected to 'i to m'	Correct numbering from 'i to m'	Typographical error correction	Error correction

2) Smt. Nor Hana Hamzah, Kimberly Clark,

NAME OF THE COMMENTATOR/ORGANIZATION: Kimberly Clark India Pvt Ltd

DOCUMENT NO: TXD 36 (26679)

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	**Comments**	**Specific Proposal (Draft clause to be add/amended)**	**Remarks**	**Technical References and justification on which (2), (3), (4) are based**
(1)	**(2)**	**(3)**	**(4)**	**(5)**
Page 2 This standard contains clause 5 which calls for an agreement between the purchaser and the supplier regarding dimensions. However, recommended dimensions have been specified.	The product sizes/dimensions may vary based on the product design and innovation which are at manufacturer's discretion to meet consumer	Proposal: **Either** i) remove the entire 2 sentences; or ii) amend to, "This standard contains clause 5 which specifies the recommended dimension, however manufacturers have the discretion to determine their		

	need and preference.	product dimensions in accordance to their design".		
Page 4 5 SIZES Size of sanitary napkin/pantyliner/maternity pad/period panty shall be as agreed to between the purchaser and the supplier.	The product sizes/dimensions may vary based on the product design and innovation which are at manufacturer's discretion to meet consumer need and preference.	Proposed statement: Size of sanitary napkin/pantyliner/maternity pad/period panty shall be as manufacturers' discretion.		

3) Shri Prashant Jadhav, P &G,

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	**Comments**	**Specific Proposal (Draft clause to be add/amended)**	**Remarks**	**Technical References and justification on which (2), (3), (4) are based**
(1)	**(2)**	**(3)**	**(4)**	**(5)**
5 Sizes, Table 1	-na-	Include XXXL size in the table 1	-na-	XXXL sized sanitary napkins are available in market and are required to be included in the standard sizes table.
6.2	Certain products may not necessarily have a soft feel because of texture and this may result in ambiguity in interpretation. Also a softness is subjective and vary from individual to individual	**Remove** the "soft feel" phrase. "The pantyliner/sanitary napkins/maternity pad/period panty when worn shall not chafe or give any uncomfortable feeling when observed visually. They shall be free	**N/A**	Same as in column 2

		from all sorts of foreign matter (unintended foreign matter that can cause injury or discomfort)"		
9. MARKING	"Type" was supposed to be removed from the statement in the Marking section (as agreed by the Panel)	Remove "Type" from the Marking Section	N/A	N/A

4) Shri/Smt Agnieszka Prabucka, TZMO Group,

Item Clause, Sub-Clause No. Commented Upon (Use Separate Box Afresh)	**Comments**	**Specific Proposal (Draft Clause To Be Add/Amended)**	**Remarks**	**Technical References And Justification On Which (2), (3), (4) Are Based**
(1)	**(2)**	**(3)**	**(4)**	**(5)**
7.1 pH Value	pH range	We suggest "from 3,5 to 8,0" instead of "from 3,5 to 7,5"		ph test results for sanitary napkins are around 7,0-7,5. It would be safe to extend the range to 8,0 - range consistent with that given in the standard for diapers
7.4 Biocompatibility Evaluation -	Wrong standard number	In the second paragraph it is written"(...)		ISO 10995 is a standard for the test method for the estimation of

Cytotoxicity, Irritation and Skin Sensitization (Optional)		when tested as per IS/ISO 10995 Part 5." Should it be IS/ISO 10993 Part 5?		the archival lifetime of optical media (e.g. DVD)
ANNEX B	Equipment Recommendation	Provide a recommendation for the equipment used to dose the liquid 1ml/5 ml per min		
5 Sizes Table 1 Size of Sanitary Napkin/Pantyliner/ Maternity Pad/Period Panty	Changing the size ranges for absorbent core/pantyliners	In accordance with the TZMO offer (for products manufactured by Bella sp. z o.o.) and the entries in the table, we recommend changing the ranges for pantyliners so that the classification regarding the length of the pad corresponds to the TZMO offer.		*proposal in the table below

Sl No.	**Name of Product**	**Size Class**	**Pad length (mm) (absorbent core only)**	**Pod with (mm) (absorbent core only)**
i)	Pantyliner	Small	134	Min 20
		Regular	135 to 157	
		Large	158	

Item Clause, Sub-Clause No. Commented Upon (Use Separate Box Afresh)	**Comments**	**Specific Proposal (Draft Clause To Be Add/Amended)**	**Remarks**	**Technical References And Justification On Which (2), (3), (4) Are Based**
(1)	(2)	(3)	(4)	(5)
Point 7.3.1 bacterial and fungal	-	The ISO 11737-1 : 2018 standard allows testing of	-	-

Bioburden		microbiological contamination using various research methods. Method 1: Dilution method using 0.85% sodium chloride solution. Method 2: Membrane filtration method with Ringer Solution. Is it permissible to use the method 2? The annex describes the dilution method using 0.85% sodium chloride solution.		
Point 7.3.2 test for Common skin Pathogen	-	What is the equivalent for ISO standard? Please share us with the IS 5887 standard. Is it possible to use a medium other than Baird-parker? (e.g. Chapman Agar).	-	-
Point 7.5 Phtalate test	Products need to be tested in external laboratory			

5) Shri R Krishnakumar, Cologenesis Healthcare Pvt. Ltd, Salem

I agree with the Draft
For Cytotoxicity the material show reactivity as non-cytotoxic when tested as per ISO 10995 part 5. Here ISO number should be ISO 10993 Part 5
Need to include the shelf life of the product.

6) Dr J.J. Jayalakshmi,

9.3.2 Test for Common Skin Pathogen — Staphylococcus Aureus
&

Fig. 2 Typical Colony Characteristics of Staphylococcus Aureus
Its a standard to describe genus in capital letter and species with small letter.
9.3.2 Test for Common Skin Pathogen — Staphylococcus aureus
& Fig. 2 Typical Colony Characteristics of Staphylococcus Aureus

7) **Shri Rakesh Shahni, FIHA**

On behalf of the Feminine and Infant Hygiene Association (FIHA), we would like to express our gratitude for the productive meeting held on 24th September 2024. We greatly appreciate the time and effort the Ministry of Textiles and BIS teams dedicated to addressing the industry's concerns, and we are encouraged by the collaborative dialogue. As the date of notification comes closer, FIHA would like to reiterate the following discussion points which require attention from the Ministry of Textiles and Bureau of Indian Standards(BIS).

Marking Fees for Sanitary Napkins
One of the key points discussed was the disparity in marking fees between sanitary napkins and baby diapers. As highlighted, both products are composed of similar materials and perform the same function—absorption—yet the current fee structure places an unequal financial burden on sanitary napkin manufacturers.

To reiterate, the current marking fees are as follows:
Baby Diapers:
1 unit = 100 pieces
Marking fee per unit: Rs 0.1
Marking fee per piece: Rs 0.001

Sanitary Napkins:
1 unit = 1000 pieces
Marking fee per unit: Rs 10
Marking fee per piece: Rs 0.01

We had respectfully requested BIS to consider aligning the marking fees for sanitary napkins with those of baby diapers. Given their material and functional similarities, we believe this would help create a more balanced and equitable regulatory environment for both products.

Additionally, as discussed during the meeting, FIHA has compiled data that, to the best of our knowledge, reflects the scale of the industry. For the past 12 months, the total production volume in India for baby diapers and sanitary napkins is approximately:

Production Volume 10,130,707,842 units

Based on the standard pack size of 6, the organized sector is estimated to be around 1.6 billion packages.

We hope that BIS will take this data into consideration as part of the decision-making process regarding the alignment of marking fees.

Approval of Foreign Manufacturers Certification Scheme (FCMS) Applications:
Many member companies have submitted **Foreign Manufacturers Certification Scheme (FMCS)** applications; however, delays in processing approvals are creating uncertainty and disrupting production planning.
This delay hampers manufacturers' ability to comply with QCO deadlines and risks supply chain disruptions for the special needs products.
Universal Packaging for Multi-Site Manufacturing:
The industry's request for approval of **universal packaging** for multi-site manufacturing remains unresolved.
Hygiene products, due to their bulkiness and widespread distribution, are often produced at multiple locations. Requiring separate packaging for each site leads to operational inefficiencies, increased plastic waste, and higher costs. Industry **request** Approval for **simplified packaging** listing all manufacturing locations and their respective BIS license numbers to ensure traceability without unnecessary burdens.
Notification on Legacy Stocks:
Despite earlier representations, no clarity has been provided on the management and utilization of **legacy stocks**, including inventory held by manufacturers, distributors, and retailers, as well as pre-printed packaging and promotional materials for the stocks produced before Dec.31st, 2024, in compliance with pre-QCO standards.
Without a notification specifying their allowable usage for the life cycle of the product , there is a risk of significant wastage, particularly for hygiene products that cannot be repackaged.
We urge the Ministry of Textiles and BIS to help FIHA by issuing a notification allowing the **sale, distribution, and exhibition of legacy stocks for their full lifecycle** to prevent market shortages and unnecessary environmental impact.
Conclusion and Prayer:
The industry is making significant efforts to align with QCO requirements, but the above challenges risk impeding seamless implementation. We respectfully request:

- **Notification on legacy stock utilization** to avoid wastage and market shortages.
- **Expedited approval of FMCS applications** to meet compliance timelines.
- **Revised marking fees for sanitary napkins** to ensure affordability.
- **Approval for universal packaging** to simplify operations and reduce waste.

FIHA humbly seek your intervention in addressing these issues to ensure a smooth transition and continued supply of essential hygiene products to consumers.

We sincerely appreciate the support and guidance that BIS and the Ministry of Textiles has provided throughout this process, which has enabled many companies to navigate regulatory requirements more effectively. We look forward to continued collaboration on these important matters and remain hopeful for a timely resolution of the issues discussed.

ANNEX 6
(Item 4.2)

FINALIZATION OF DRAFT STANDARD/AMENDMENT

भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDRADS

Draft for comments only Doc No.: TXD 36 (26680)

व्यापक परिचालन मसौदा

पुन: प्रयोज्य सेनेटरी पैड/सेनेटरी नैपकिन/पीरियड पैंटीज — विशिष्टि (पहला पुनरीक्षण)

(IS 17514 का *पहला पुनरीक्षण*)

Wide Circulation Draft

Reusable Sanitary Pad/Sanitary Napkin/Period Panties — Specification (*first revision of* IS 17514)

ICS 59.080

Technical Textiles for Medtech Applications Sectional Committee, TXD 36	last date for receipt of comments is 11 Dec 2024

FOREWORD

(Formal clause will be added later)
Reusable sanitary pad/sanitary napkin/period panties are hygiene products that are worn by menstruators (children and adults) to absorb blood and other fluids during menstrual periods.

This standard was originally published in 2021. The first revision has been made to incorporate the following major changes: -

m) All amendments have been incorporated.
n) Material and sizes have been updated.
o) The procedure and requirement of ability to withstand pressure after absorption have been modified.
p) pH and hygiene testing requirement have been updated.
q) Sampling and criteria for conformity has been modified.
r) Marking clause has been modified.
s) References to Indian Standard have been updated.

This standard contains clause **6** which calls for an agreement between the purchaser and the supplier regarding dimensions. However, recommended dimensions have been specified.

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.

Draft Indian Standard

IS 17514 : 2024 REUSABLE SANITARY PAD / SANITARY NAPKIN / PERIOD PANTIES — SPECIFICATION

1 SCOPE

This standard covers the requirements for reusable (multiple use) sanitary pad/sanitary napkin/period panties for external use.

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

The reusable sanitary pad/sanitary napkin/period panties generally consist of following major components:

a) cover or the top sheet;
b) absorbent core; and
c) bottom layer.

3.1 Cover/Top Sheet

The cover/top sheet is the material which comes under contact with skin during use. The material used for the top layer/cover shall be safe, soft to the touch and should not shed any fibers when rubbed dry or wet.

The cover of reusable sanitary pad/sanitary napkin/period panties shall be of good quality cotton, polyester, polyester/cotton blended fabric, viscose, polyester/viscose blended fabric, rayon knitted sleeve or gauze, non-woven fabric, or any other suitable materials as agreed mutually between the buyer and seller.

3.2 Absorbent Core

An absorbent core forming the middle layer(s) shall consist of filler materials, such as cotton, viscose, polyester, micro terry, viscose/polyester, cellulose pulp, cellulose wadding, tissue, nonwoven materials, a combination of these materials or any other suitable absorbent materials as agreed mutually between the buyer and seller. The absorbent materials must be free from lumps, oil spots, dirt or foreign material. The absorbent material shall not form lumps with the effect of sudden pressure.

3.3 Bottom Layer

The bottom layer of reusable sanitary pad/sanitary napkin/period panties shall be made of suitable material(s) that prevents the leakage when used.

'NOTE — The requirements given in **3.1** to **3.3** are for guidance of the manufacturer. The material and design may vary between different types and sizes of the reusable sanitary pad/sanitary napkin/period panties or as per the agreement between buyer and seller.'

4 MANUFACTURE, WORKMANSHIP AND FINISH

The material used for reusable sanitary pad/sanitary napkin/period panties shall be smooth, safe for skin contact, and shall not leach dyes or bleed colour. When visually examined, the reusable sanitary pad/sanitary napkin/period panties shall be free from defects or lumps. There shall be no loose stitching, or visible defects on the material. The materials shall be free from odour, smooth to the touch and when worn, shall not chafe or be uncomfortable for the user. They shall be free from all sorts of foreign matter.

5 FASTENING MECHANISM

If the style/design of the reusable sanitary pad/sanitary napkin/period panties requires a fastening mechanism, there shall be a suitable device for fastening the reusable sanitary pad/sanitary napkin/period panties for secure use for example, buttons, clasps, elastic, string, velcro or any other suitable material. The material used for the fastening mechanisms shall not cause harm to skin and shall not be abrasive when the product is used. The fastening mechanism shall be durable and free from rusting until the life cycle of the product as declared by the manufacturer.

6 SIZES

Size of reusable sanitary pad/sanitary napkin/period panties shall be as agreed to between the buyer and the seller. Sizes of reusable sanitary pad/sanitary napkin/period panties may be variable depending on the absorbent capacity or as per buyer requirement. The recommended sizes of reusable sanitary pad/sanitary napkin are classified as follows in table 1:

Table 1 Size of Reusable Sanitary Pad/Sanitary Napkin/Period Panties
(for reference and guidance only)

Sl No	Name of product	Size Class	Length (mm)	Width (mm)

(1)	(2)	(3)	**(Absorbent core only)** (4)	**(Absorbent core only)** (5)
i)	Sanitary Pad/Sanitary Napkin	Small	≤ 240	*Min* 60
		Medium	241 to 260	
		Large	261 to 280	
		Extra Large	≥ 281	
ii)	Period Panty	-	230-300	80-140

'NOTES —

1) The actual dimension of absorbent core may differ as per the product design of manufacturer. If required, the manufacturer may also provide the figure/schematic diagram for measurement of dimension of absorbent core length and width of the product.
2) The recommended dimension (for reference and guidance only) of absorbent core length and width for other size class/type of reusable sanitary pad/sanitary napkin/period panties not covered in Table 1 shall be declared by the manufacture.'

7 WASHING,DRYING AND HANDLING INSTRUCTION

The manufacturer shall provide the washing, drying, handling and storage instruction on every packet of reusable sanitary pad/sanitary napkin/period panties to ensure proper use and care by the consumer.

8 GENERAL REQUIREMENTS

The raw material/fabric used for manufacturing the product shall meet the following requirements (initially and after declared cycle washes) as specified in Table 2.

Table 2 Colourfastness and Dimensional Stability Requirement of Raw Material/Fabric
(*Clauses* 8 and 11.2.4)

Sl No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Colour fastness to rubbing		IS/ISO 105-X12
	a) Dry	4 or better	
	b) Wet	3 or better	
ii)	Colour fastness to perspiration (acidic and alkaline)		IS/ISO 105-E04
	a) Colour change	4 or better	
	b) Staining	4 or better	
iii)	Colour fastness to washing		IS/ISO 105-C06
	a) Colour change	4 or better	
	b) Staining	4 or better	
iv)	Dimensional stability to washing, percentage, *Max*		Annex C of IS 16394

	Length and width	± 5	

9 PERFORMANCE REQUIREMENTS

The reusable sanitary pad/sanitary napkin/period panties shall meet the requirements (initially and after declared cycle washes) as specified in **9.1** to **9.3**.

9.1 *p*H Value

The pH of reusable sanitary pad/sanitary napkin/period panties (top and absorbent core) shall be from 3.5 to 7.5 when tested by the method given in IS 1390.

'NOTE — If the required weight of the test specimen in not sufficient in one sample, then more no. of samples of the same lot may be taken for testing of the product.

9.2 Ability to Withstand Pressure after Absorption

The reusable sanitary pad/sanitary napkin/period panties shall absorb 10 ml (for small/medium size pad/napkin and period panties) and 30 ml (for large/extra-large size pad/napkin) of coloured distilled water and it shall not show leakage at the bottom or side edges of the reusable sanitary pad/sanitary napkin/period panties, when tested according to method given in Annex B.

9.3 Hygiene Testing Requirement

Total viable count (total number of bacteria and fungi) shall not be more than 1 000 cfu/gm and Staphylococcus aureus shall be absent.

9.3.1 *Bacterial and Fungal Bioburden*

The reusable sanitary pad/sanitary napkin/period panties shall be tested for bacterial and fungal bioburden in accordance with method given in **9.3.1.1**. For selecting sample item portion (SIP), appropriate eluent and methods of extraction; IS/ISO 11737 (Part 1) shall be referred.

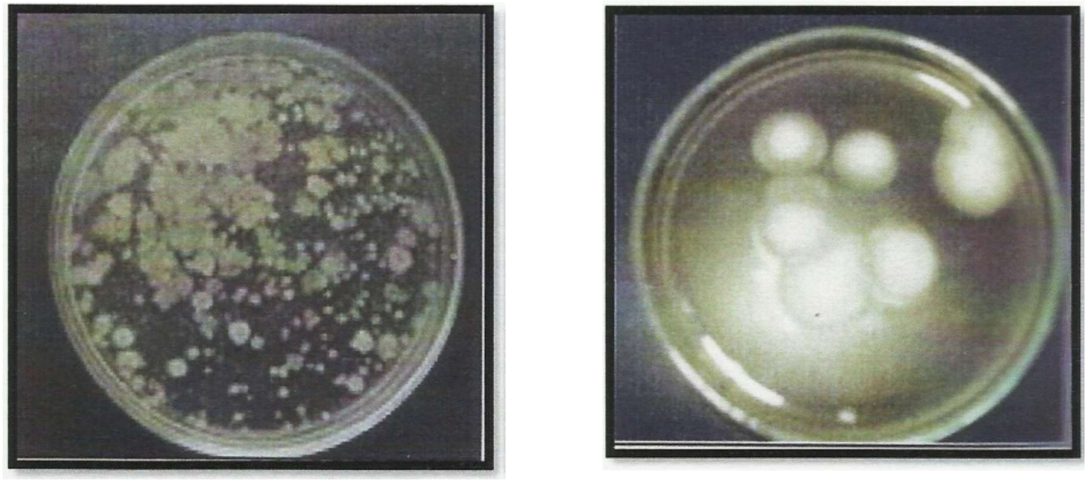
9.3.1.1 *Test method*

A sample of 5 gm cut from the centre portion of the reusable sanitary pad/sanitary napkin/period panties 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 pad/napkin/panty or the quantity in which the pad/napkin/panty completely immerse. The pad/napkin/panty 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 °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 °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.

9.3.2 *Test for Common Skin Pathogen — Staphylococcus Aureus*

The reusable sanitary pad/sanitary napkin/period panties shall be tested for the presence of Staphylococcus aureus in accordance with method given in **9.3.2.1**. For the preparation of medium, such as cooked salt medium, baird-parker medium and method for coagulase test; IS 5887 (Part 2) shall be referred.



(A) **(B)**

Fig 1 Typical Colony Characteristics of Bacterial Bioburden (A) and Fungal Bioburden (B)

9.3.2.1 *Test method*

A sample of 5 gm cut from the centre portion of the reusable sanitary pad/sanitary napkin/period panties shall be completely immersed in appropriate volume of enrichment medium like cooked salt medium or equivalent medium. Incubate for enrichment purpose at 37 °C 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 pad/napkin/panty. 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.

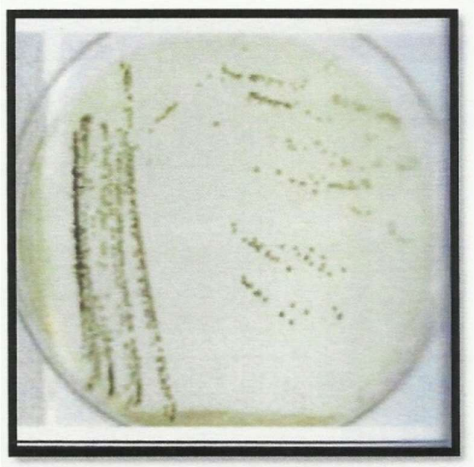


Fig. 2 Typical Colony Characteristics of Staphylococcus Aureus

'NOTE — If the required weight of the test specimen under clause 9.3.1.1 and 9.3.2.1 is not sufficient in one sample, then more no. of samples of the same lot may be taken for preparation of test specimen.'

9.3.3 *Good Manufacturing Practice Guideline for Hygiene Requirement*

The reusable sanitary pad/sanitary napkin/period panties shall be manufactured under good hygienic conditions. The general guidelines for good manufacturing practice to maintain hygiene requirement at manufacturing facility are given in Annex C.

9.4 Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization (Optional)

If required by the buyer, the manufacturer shall ensure that raw material used for manufacturing the final product are safe for 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, IS 17932 (Part 7) and IS 17932 (Part 6) respectively.

For cytotoxicity, the material shall show reactivity as "non-cytotoxic" when tested as per IS/ISO 10995 (Part 5). Similarly, the material shall be 'Non-irritant and Non-sensitizer' when tested as per IS 17932 (Part 7) and IS 17932 (Part 6) respectively. For preparation of samples for these tests, IS/ISO 10993 Part 12 shall be referred.

9.5 Phthalate Test

The amount of phthalate present in reusable sanitary pad/sanitary napkin/period panties shall be < 0.1 percent (individual or in combination) when tested as per the method given in IS 9873 (Part 6). The phthalate test shall be done at raw material stage once for existing raw material and whenever there is a change in the raw material for manufacturing the product. The manufacturer of final product shall also do the phthalate test once in a year.

10 ANTI-BACTERIAL ACTIVITY VALUE (OPTIONAL)

If agreed between the buyer and the seller, the raw material/fabric used for reusable sanitary pad/sanitary napkin/period panties shall have anti-bacterial activity value (initially and after declared cycle washes) greater than or equal to 2 when tested by the absorption method prescribed in IS/ISO 20743. The fabric shall be washed as per the procedure specified in **D-5.1** of IS 16394.

11 SAMPLING AND CRITERIA FOR CONFORMITY

11.1 Lot

All the reusable sanitary pad/sanitary napkin/period panties of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot.

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

11.1.2 The number of reusable sanitary pad/sanitary napkin/period panties 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 3.

11.1.3 These reusable sanitary pad/sanitary napkin/ period panties shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

Table 3 Number of Reusable Sanitary Pad/Sanitary Napkin/Period Panties to be Selected
(*Clauses* 11.1.2, 11.2.1, 11.2.1.1 11.2.2 and 11.2.3)

Sl No.	Lot size	Non-destructive Testing		Destructive Testing	
		No. of Pad/Napkin/Panty to be Selected n	Acceptance Number a	No. of Pad/Napkin/Panty to be Selected n_1	Acceptance Number a_1
(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)	3 201 – 10 000	32	2	8	0
vi)	10 001 – 35 000	50	3	8	0
vii)	35 001 – 150 000	80	5	13	0
viii)	150 001 – 500 000	80	5	13	0
ix)	500 001 and over	125	7	13	0

NOTES —
1) for colour fastness and dimensional stability, hygiene testing, biocompatibility evaluation, anti-bacterial activity refer clauses **11.2.4**, **11.2.5**, **11.2.6** and **11.2.7** respectively
2) The sampling plan given in table 3 is for guidance of manufacturer/user. The other sampling plan may also be followed if agreed between buyer and seller or as per manufacturers quality assurance plans.

11.2 Number of Tests and Criteria for Conformity

11.2.1 All reusable sanitary pad/sanitary napkin/period panties to be selected as per column 3 of Table 3 shall be examined for workmanship and finish.

11.2.1.1 Any reusable sanitary pad/sanitary napkin/ period panties 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 3. Otherwise, the lot shall be rejected.

11.2.2 Out of the sample already found satisfactory according to **11.2.1.1**, a sub-sample as per column 5 of Table 3 shall be taken. This sub-sample shall be further tested for the remaining requirements.

11.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective sanitary pad/sanitary napkin/period panties found in the sample (*see* **11.2.2**) is less than or equal to the acceptance number as given in column 6 of Table 3.

11.2.4 The conformance for colourfastness and dimensional stability as given in Table 2 may be accepted at fabric stage for a product if agreed between buyer and manufacturer. In such cases, the traceability certificate for conformance of the performance requirement of fabric shall be maintained by the product manufacturer for each lot.

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

11.2.6 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 of raw material for manufacturing the product.

11.2.7 The anti-bacterial activity testing shall be carried out once for existing products and whenever there is a change in the raw material or source of supply of raw material for manufacturing the product.

12 MARKING

12.1 Each consumer pack shall be legibly and indelibly marked with the manufacturer's name or trademark, number of reusable sanitary pad/sanitary napkin/period panties contained in it and total absorption capacity in addition to the following:

a) Use and care instructions;
b) Storage instructions;
c) Batch/Lot no. and date of manufacturing;
d) Declared life cycle/wash cycle or best before (years.);
e) Country of origin;

f) Size class and pad length for reusable sanitary pad/sanitary napkin or length for period panty.
g) Disposability instructions — The manufacturer shall provide the instruction to users for safe disposal of the product as per Solid Waste Management Rules, 2016 or any other rules and regulations published from time to time.
h) The information whether the material of the product is biocompatible that is meets the requirement of the standard for biocompatibility evaluation — cytotoxicity, irritation and skin sensitization (if applicable).
i) Additional features of antibacterial (if required); and
j) Any other information required by law in force or agreed between the buyer and the seller.

12.2 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.

13 PACKING

The reusable sanitary pad/sanitary napkin/period panties 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)
LIST OF REFERRED STANDARDS

IS No.	*Title*
IS 1390 : 2022/ISO 3071 : 2020	Textiles — Determination of *p*H of aqueous extract (*third revision*)
IS 4905 : 2015 ISO 24153 : 2009	Random sampling and randomization procedures (*first revision*)
IS 5887 (Part 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*)
9873 (Part 6) : 2021/ ISO 8124-6 : 2018	Safety of toys Part 6 Determination of certain phthalate esters in toys and children's products (*first revision*)
IS 16394 : 2015	Textiles — Woven shirting made of cotton, man-made fibres/ filaments and their blend — Specification
17932 (Part 6) : 2023	Biological evaluation of medical devices Part 6 Tests for skin sensitization
17932 (Part 7) : 2024	Biological evaluation of medical devices Part 7 Tests for irritation

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*)
IS/ISO 10993 (Part 5) : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 20743 : 2021	Textiles — Determination of antibacterial activity of textile products (*first revision*)
IS/ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
ISO 10993-12 : 2012	Biological evaluation of medical devices: Part 12 Sample preparation and reference materials

ANNEX B

(*Clause* 9.2)

METHOD FOR DETERMINATION OF ABILITY TO WITHSTAND PRESSURE AFTER ABSORPTION

B-1 TEST PROCEDURE

Thoroughly wash the reusable sanitary pad/sanitary napkin/period panty as per the wash care instruction with suitable detergent to ensure removal of any finishing treatment given to fabric for aesthetic purposes. Lay the reusable sanitary pad/sanitary napkin/period panties on a flat level transparent surface, so that underside of pad/ napkin/panty can be observed.

Drip at the rate of X ml (X = 50 percent of absorbency/min) with 1 min interval for total volume of 2 X ml of coloured distilled water maintained at temperature of 27 °C ± 2 °C on to the centre of the pad/napkin/panty from a height of 5 to 7 mm.

For example:

For small/medium size pad/napkin and period panties : 5 mL per min for total volume of 10 mL
For large/extra-large size pad/napkin: 15 mL per min for total volume of 30 mL

After the pad/napkin/panty has absorbed full amount of coloured distilled water, keep a standard weight of 1 kg for 1 min on the portion where coloured distilled water was absorbed.

Observe the bottom and side edge of pad/napkin/panty for any leak through. Test sample passes if liquid does not leak through and fails if liquid leak through.

'NOTES —
1) The dimension of 1 kg weight should have length and width of 150 mm x 50 mm with a tolerance of ± 1 mm.
2) For period panty, cut along the lateral seam on both the sides (left and right) and then lay the period panty flat for absorbency testing.'

B-2 Add 0.01 g colour of bromocresol purple (grade – chemical analytical grade or equivalent) in 1 000 ml of distilled water and stir evenly to get uniform coloured solution.

ANNEX C

(*Clause* 9.3.3)

GOOD MANUFACTURING PRACTICE FOR HYGIENE REQUIREMENT

Maintaining hygiene at production facility is essential for ensuring products are appropriate for consumers use. Following are recommended guidelines for ensuring hygiene at facilities:

a) Location should be free from objectionable odours, smoke, dust and other contaminants.
b) Separate areas shall be demarcated for storing raw materials, production and final product storage.
c) Separate area shall be demarcated for storing personal effects and personal protective equipment of unit workers to minimize risk of contamination.
d) Toilet and hand-washing station shall be positioned away from storage/production area.
e) Provision of 70 percent isopropyl alcohol (IPA) solution or equivalent or soap for hand sanitization inside the production facility.
f) Appropriate lighting and proper ventilation of the facility shall be ensured.
g) Flooring shall be either concrete, tiled or with chips to ensure ease of cleaning. Floors, walls, ceilings, doors and windows shall be easy to clean and without crevices or openings that shall not allow accumulation of dirt.
h) Regular pest control measures shall be put in place.
j) Adequate receptacles for disposing waste generated within the facility shall be made available and shall be frequently emptied and cleaned.
k) Poster/sign encouraging safety and hygiene practices like use of personal protective equipment,
use of hand sanitizer etc. shall be displayed.
m) Pre-packaged finished product shall be checked thoroughly and ensured to be free from foreign
particles, dirt, hair, and other visible contaminants.
n) Hand hygiene shall be practised during manufacturing.
p) A cleaning and maintenance schedule shall be drawn up for cleaning of the facility, toilets, washing areas, waste receptacles and for cleaning/ disinfection of the equipment.

व्यापक परिचालन मसौदा

वस्त्रादि — चिकित्सीय/सर्जिकल गाउन एवं चिकित्सीय सर्जिकल ड्रैप — विशिष्टि

(IS 17334 का *पहला पुनरीक्षण*)

Wide Circulation Draft

Textiles — Medical/Surgical Gowns and Medical/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 11 Dec 2024

FOREWORD

(Formal clauses will be added later)

Medical/surgical gowns and medical/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 medical/surgical gowns and medical/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.

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 updated.
iii) The levels given in the standard for surgical gown and surgical drape have been updated.
iv) The requirement of patient gown and isolation gown have been specified.
v) The requirement for blood resistance, particle release, cleanliness– microbial, biocompatibility evaluation (cytotoxicity) have been updated.
vi) The requirement for viral resistance test has been updated for level 4 gown.
vii) The requirement of impact penetration test has been specified for level 2 and level 3 gown and drapes.
viii) The requirement of resistance to dry and wet bacterial penetration test have been updated for level 2 and level 3 gown and drape.
ix) The requirement of breathability test (water vapour transmission rate) has been modified.
x) The general guidelines/recommendations to use different levels of medical/surgical gown and medical/surgical drape have been updated.

xi) References to Indian Standard have been updated.

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 medical/surgical gowns and medical/surgical drapes intended for medical use.

1.2 This standard is intended to be used primarily by manufacturers of medical/surgical gowns and medical/surgical drapes in qualifying, classifying, packaging, labelling, and sterilization of medical/surgical gowns and medical/surgical drapes, so that healthcare workers can make more informed decisions of selection of right medical/surgical gown and medical/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 medical/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 Medical/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 Medical/Surgical Drape — A covering for the patient for the prevention of transfer of infective agents, such as microorganisms, body fluids and particulate material. Medical/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 The size of medical/surgical gown and medical/surgical drape shall be as per agreement between the buyer and the seller. The size of gown shall be designated based on the measurement of height and chest. In case of elastic cuff/waist, it should have proper fit and should be adhered with glue to minimize risk of exposure.

5.1.1 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 "1" performance requirements as given in Table 1 and Table 2.

5.2 Manufacturing and Processing Requirements and Documentation

5.2.1 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 medical/surgical gown and medical/surgical drape. The quality management system shall include a risk management procedure where inputs for product realization shall include the outputs from risk management.

5.2.2 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 medical/surgical gowns and medical/surgical drapes.

5.2.3 Microbiological monitoring (as per ISO 14698-1), air monitoring of clean room (as per IS 18637 Part 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 medical/surgical gowns and

medical/surgical drapes can have one level less as compared to the standard earmarked for the medical/surgical gowns and medical/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 Medical/surgical gowns and medical/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 medical/surgical gown and medical/surgical drape for healthcare application and surgeries in hospitals have been given in Table 3.

Table 1 Performance Requirements for Medical/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	≤ 1.0	≤ 1.0	NA	IS 17375
ii)	Hydrostatic resistance (cmwc) the rate of rising at 60 cmWc/min	NA	≥ 20	≥ 50	NA	IS 391
iii)	Blood resistance, pressure cycle upto 14 kPa, procedure D	NA	NA	NA	Pass	IS 16546
iv)	Viral resistance, pressure cycle upto 14 kPa, procedure D	NA	NA	NA	Pass	IS 16545

v)	Particle release [log10 (lint count)] Particle size from 3.0 to 25.0 Microns	≤ 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) (for unsterile gown)	≤ 300	≤ 300	≤ 300	≤ 300	IS/ISO 11737-1
ix)	Resistance to microbial penetration — Dry (CFU) *(*see* Note)	NA	≤ 300 (for less critical zones)	≤ 300 (for less critical zones)	NA	IS 16548
x)	Resistance to microbial penetration — Wet (IB)	NA	≥ 2.8 (for critical zones)	≥ 2.8 (for critical zones))	NA	IS 16549
xi)	Biocompatibility Evaluation Test **(*see* Note)					
	a) Cytotoxicity	non-cytotoxic	non-cytotoxic	non-cytotoxic	non-cytotoxic	IS/ISO 10993 Part 5 IS/ISO 10993 Part 12
	b) Irritation	Non-irritant	Non-irritant	Non-irritant	Non-irritant	IS 17932 (Part 7)
	c) Skin sensitization	Non - sensitiz er	Non - sensitiz er	Non - sensitize r	Non - sensitiz er	IS 17932 (Part 6)
xii)	Breathability test (water vapour transmission rate), [g/m^2/day, *Max*]	NA	NA	NA	800	Annex F of IS 16390

NA- Not Applicable

NOTES –

1) Challenge concentration 108 CFU/g talcum and 30 min vibration time.
2) 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.
3) If agreed by the buyer and seller, the gown used for patient shall confirm level 1 of table 1. In Isolation gowns the critical area is the entire gown including the back and the joints.

4) In case of gown for level 4 when a sample fails in blood resistance test, viral tests shall not be carried out and the sample shall be reported as non- compliance/failure to the standard.

Table 2 Performance Requirements for Medical/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	≤ 1.0	≤ 1.0	NA	IS 17375
ii)	Hydrostatic resistance (cmwc), the rate of rising at 60 cmWc/min	NA	≥ 20	≥ 50	NA	IS 391
iii)	Blood resistance pressure cycle upto 14 kPa, procedure D	NA	NA	NA	Pass	IS 16546
iv)	Particle release [log10 (lint count)], Particle size from 3.0 to 25.0 Microns	≤ 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) (for unsterile drape)	≤ 300	≤ 300	≤ 300	≤ 300	IS/ISO 11737-1
viii)	Resistance to microbial penetration — Dry (CFU)	NA	≤ 300 (for less critical zones)	≤ 300 (for less critical zones)	NA	IS 16548
ix)	Resistance to microbial penetration — Wet (IB)	NA	NA	≥ 2.8 (for critical zones))	NA	IS 16549

x)	Biocompatibility evaluation * (*see* Note)					
	a) Cytotoxicity	non-cytotoxic	non-cytotoxic	non-cytotoxic	non-cytotoxic	IS/ISO 10993 Part 5 IS/ISO 10993 Part 12
	b) Irritation	Non-irritant	Non-irritant	Non-irritant	Non-irritant	IS 17932 (Part 7)
	c) Skin sensitization	Non - sensitizer	Non - sensitizer	Non - sensitizer	Non - sensitizer	IS 17932 (Part 6)

NA- Not Applicable

NOTES –

1) Challenge concentration 108 CFU/g talcum and 30 min vibration time.
2) 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 Recommendations for Use of Different Levels of Medical/Surgical Gowns and Medical/Surgical Drapes
(For guidance only)

(*Clause* **6.3**)

Sl No.	**Performance Level**	**Anticipated risk of exposure**	**Examples of Procedures with Anticipated Exposure Risks**
(1)	(2)	(3)	(4)
i)	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	Simple excisional biopsies Excision of "lumps and bumps" Ophthalmological procedures Simple ear, nose and throat (ENT) procedures

ii)	Level 2	Minimal to moderately invasive procedure Mild body fluid loss Mild risk to patient independent of anesthesia	Tonsillectomies adenoidectomies Endoscopic gastrointestinal procedures Simple orthopedic procedures with tourniquets Open hernia repair Minimally invasive surgery Interventional radiology or catheter lab procedures
iii)	Level 3	Moderate to significantly invasive procedure Moderate body fluid loss Moderate risk to patient independent of anesthesia	Mastectomies Arthroscopic orthopedic procedures Endoscopic urological procedures (for example, transurethral prostate resections) Open gastrointestinal and genito-urinary procedures
iv)	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	Any procedure in which the surgeon's hands and arms are in a body cavity Orthopedic procedures without a tourniquet Open cardiovascular or thoracic procedures Trauma procedures Caesarean sections

7 MARKING

7.1 Each pack of medical/surgical gown and medical/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 or as per Medical Device Rules 2017.

Each product or package, containing medical/surgical gowns, medical/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 medical/surgical gowns or medical/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 1, 2, 3 and 4 medical/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 1, 2, 3 and 4 medical/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 medical/surgical gowns or medical/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 medical/surgical gowns and medical/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 gowns/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 gowns/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 Gown/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

NOTE—The sampling plan given in table 4 is for guidance of manufacturer/user. The other sampling plan may also be followed if agreed between buyer and seller or as per manufacturers quality assurance plans.

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 gowns/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 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.'

9.1 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.

10 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 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 4905: 2015/ISO 24153: 2009	Random sampling and randomization procedures (*first revision*)
IS 15891 (Part 3) : 2024/ ISO 9073-3 : 2023	Nonwovens — Methods of test Part 3 Determination of tensile strength and elongation at break using the strip method (*first revision*)
IS 15891 (Part 10): 2017/ISO 9073-10: 2003	Textiles — Test methods for nonwovens: Part 10 Lint and other particles generation in dry state
IS 16390: 2015	Agro textiles — Nylon knitted seamless gloves for tobacco harvesters — Specification
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 17375: 2020/ISO 18695 :2007	Textiles — Determination of resistance to water penetration — Impact penetration test
IS 17932 (Part 6): 2023	Biological evaluation of medical devices Part 6 Tests for skin sensitization
17932 (Part 7): 2024	Biological evaluation of medical devices Part 7 Tests for irritation
IS 18637 (Part 1) : 2024	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
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/ISO 10993-5: 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 10993-12 : 2021	Biological evaluation of medical devices Part 12 Sample preparation and reference materials
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/ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
ISO 14698-1: 2003	Cleanrooms and associated controlled environments — Bio contamination control — Part 1: General principles and methods

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

B-1 PRINCIPLES OF THE CRITICAL ZONE

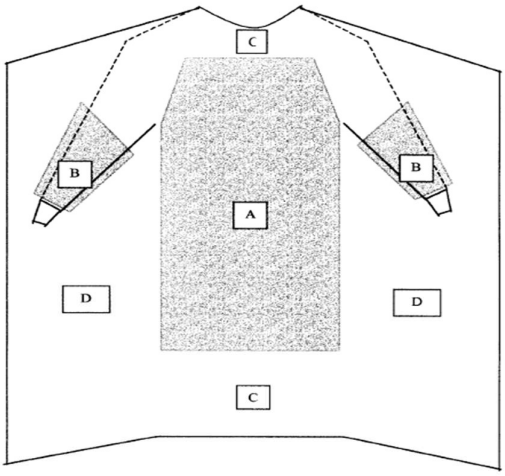
The critical zone can be described as an area approximately 12 inches around the fenestration of a drape where it is thought that reinforcement is needed to resist the penetration and strike through of fluids. Additionally, the critical zone (see Fig. 1) on medical/surgical gown encompasses the front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

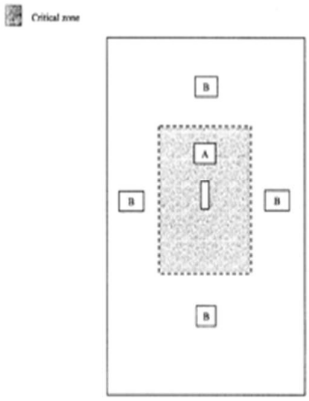
In this situation, it may be considered that the critical zone should be further expanded outside of the manufacturers region of reinforcement around the fenestration, thus further suggesting that the critical zone is a fluctuating zone that dependent on the procedure to be performed.

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 MEDICAL/SURGICAL GOWN



A - Critical zone
B - Less critical zone

FIG. 2 MEDICAL/SURGICAL DRAPE

भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDRADS

Draft for comments only Doc No.: TXD 36(26744)

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व्यापक परिचालन मसौदा

चिकित्सीय वस्त्रादि — बिना बुने हुए जालीदार फोहे — विशिष्टि

Wide Circulation Draft

Medical Textiles — Nonwoven Gauze Swab— Specification

ICS: 11.040.30; 59.080.01

Technical Textiles for Medtech Applications Sectional Committee, TXD 36

Last date for receipt of comments is 11 December 2024

FOREWORD

(*Formal clauses will be added later*)

Nonwoven gauze swabs are widely used in healthcare settings for wound care, surgical procedures, and general medical treatments. They are particularly effective in wound cleaning and dressing general healthcare and first aid for managing minor procedures, minor cuts, abrasions, burns, or small surgical incisions. Their high absorbency allows them to effectively soak up blood, exudate, and other fluids, keeping the wound dry and promoting healing.

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 performance requirement of nonwoven gauze swab (sterile and non — sterile) for single use intended for medical purpose. Non-woven gauze swab shall be used for general healthcare application and cleaning of outer surface of wound/skin during and post-surgery.

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 Manufacturer — Natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in the emergence of a new product having a distinct name, character and use.

3.2 Nonwoven Gauze Swab — It is of mesh structure made from viscose (rayon) and polyester staple fibers blended spun lace nonwoven fabric with minimum 20 percent viscose (rayon) content.

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

4 MATERIALS

The non-woven gauze swab (spunlace or spunbond or combination of both) shall be manufactured from cotton or viscose or blends of cotton, viscose, bamboo, polyester and polypropylene fibres. The product shall contain at least 20 percent of cotton or/and viscose fibre.

5 WORKMANSHIP AND FINISH

5.1 The nonwoven gauze swab shall be clean and free from substances liable to cause tendering during storage. The product shall be free from toxic or harmful substances.

5.2 The manufacture and preparation of the non-woven gauze swab shall be conducted under proper hygienic conditions.

6 REQUIREMENTS

The non-woven gauze swab shall conform to the requirements specified in Table 1.

Table 1 Performance Requirements for Nonwoven Gauze

(*Clause* 5)

Sl. No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Length and width, mm	As agreed to between the buyer and the seller with a tolerance of ± 1 mm	-
ii)	Fibre identification	At least 20 percent of cotton or/and viscose /absorbent fibres	IS 667/IS 3416
iii)	Weight per square metre, g/m^2, *Min*	30	IS 15891 (Part 1)
iv)	Absorbency (with distilled water) a) Liquid absorption time, s, *Max* b) Liquid absorptive capacity, percent, *Min*	 10 400	IS 15891 (Part 6)
v)	Tensile strength in machine direction (Dry) in N/5cm, *Min*	20	IS 15891 (Part 3)
vi)	Tensile strength in machine direction (Wet) in N/5cm, *Min*	20	IS 15891 (Part 3))
vii)	Cleanliness–Microbial/Bioburden Test (cfu/g), *Max* (in case of non-sterile)	100	IS/ISO 11737 Part 1
viii)	Cleanliness–Microbial/Bioburden Test (cfu/g), *Max* (sterile)	No viable microorganism shall be present’	IS/ISO 11737 Part 1
ix)	*p*H value of aqueous extract	5.5 to 8.0	IS 1390
x)	Water soluble substance, percentage, *Max*	1	IS 14944
xi)	Ether soluble substance percentage, *Max*	1	IS 14944
xii)	Particle release [log10 (lint count)]	≤ 4.0	IS 15891 (Part 10)
viii)	Freedom from optical whitener	No fluorescence or not more than occasional point of fluorescence visible’	Viewing under ultra-violet light

		when viewed under the ultra-violet (UV) light of wavelength 365 nm	
xiii)	Biocompatibility Evaluation Test **(*see* Note)		
	a) Cytotoxicity	Non- cytotoxic	IS/ISO 10993 Part 5 IS/ISO 10993 Part 12
	b) Irritation	Non- irritant	IS 17932 (Part 7)
	c) Skin sensitization	Non - sensitizer	IS 17932 (Part 6)

Note – Confirm the biocompatibility of raw material at designed stage. 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

7 MARKING

7.1 Each pack of the nonwoven gauze swab shall be legibly and indelibly marked with following information:

a) Name of the product;
b) Length and width of the product;
c) Number of gauze swab in a packet;
d) Manufacturer's name, initials or trademark, if any;
e) Month and year of manufacture,
f) Batch/lot number;
g) Country of origin;
h) Instruction for use, storage and safe disposal;
i) Information on sterilized or unsterilized: and
j) Any other requirement as per Medical Device Rules, 2017 or as required by the law in force or as agreed between the buyer and the seller.

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 product(s) may be marked with the Standard Mark

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 LOT

All the nonwoven gauze swab of the same material and dimensions produced under similar conditions of manufacture shall constitute a lot.

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

8.1.2 The number of packs of nonwoven gauze swab 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.

8.1.3 These nonwoven gauze swab shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

Table 2 Number of Nonwoven Gauze Swab to be selected
(*Clause* 8.1.2)

Sl No.	**Lot size**	**Non-destructive 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)	Up to 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					

8.2 Number of Tests and Criteria for Conformity

8.2.1 All nonwoven gauze swab selected as per column 3 of Table 2 shall be examined for manufacture, workmanship and finish.

8.2.1.1 Any nonwoven gauze swab 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 2. Otherwise, the lot shall be rejected.

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

8.2.3 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* **8.2.2**) is less than or equal to the acceptance number as given in col 6 of Table 2.

9 PACKING

The nonwoven gauze swab 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 STANDARDS

IS No.	*Title*
IS 667 : 1981	Methods for identification of textile fibres (*first revision*)
IS 1390 : 2022/ISO 3071 : 2020	Textiles — Determination of *p*H of aqueous extract (*third revision*)
IS 14944 : 2020	Surgical dressings — Methods of test (*first revision*)
IS 3416 : 2024/ISO 1833-11 : 2017	Textiles — Quantitative chemical analysis — Mixtures of certain cellulose fibres with certain other fibres (method using sulphuric acid) (*third revision*)
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 3) : 2024/ ISO 9073-3 : 2023	Nonwovens — Methods of test Part 3 Determination of tensile strength and elongation at break using the strip method (*first revision*)
IS 15891 (Part 6) : 2012/ ISO 9073-6 : 2000	Textiles — Test methods for nonwovens Part 6 Absorption
IS 15891 (Part 10): 2017/ISO 9073-10: 2003	Textiles — Test methods for nonwovens: Part 10 Lint and other particles generation in dry state
IS 4905 : 2015	Random sampling and randomization procedures (*first revision*)
IS/ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
IS 17932 (Part 6) : 2023	Biological evaluation of medical devices Part 6 Tests for skin sensitization
IS 17932 (Part 7) : 2024	Biological evaluation of medical devices Part 7 Tests for irritation
IS/ISO 10993 (Part 5) : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 10993-12 : 2021	Biological evaluation of medical devices: Part 12 Sample preparation and reference materials

चिकित्सीय वस्त्रादि — इलास्टिक पट्टी — विशिष्टि
(आई एस 16111 का *पहला पुनरीक्षण*)
Wide Circulation Draft
Medical Textiles — Elastic Bandage — Specification
(*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 11 Dec, 2024

FOREWORD

(*Formal clauses will be added later*)

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

a) Title of the standard has been updated.
b) All amendments have been incorporated.
c) Type of elastic bandage has been modified.
d) The requirement of manufacture, workmanship and finish has been updated.
e) The requirement of conditioning has been modified.
f) Sampling and criteria of conformity has been incorporated.
g) Packing and marking clause has been incorporated.
h) BIS certification marking clause has been updated.
i) References to Indian standards is updated.

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.

Draft *Indian Standard*
Medical Textiles — Elastic Bandage — Specification
(*First Revision* of IS 16111)

1 SCOPE

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*

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*)
6359 : 2023	Method for conditioning of textiles (*first revision*)
4905 : 2015	Random sampling and randomization procedures (*first 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) Type I — woven cellulosic yarn bandage
b) Type II — knitted cellulosic yarn bandage
c) Type III — woven non-cellulosic yarn bandage
d) Type IV — knitted non-cellulosic yarn bandage
e) Type V — combination of both cellulosic yarn/non-cellulosic yarns woven
f) Type VI — combination of both cellulosic yarn/non-cellulosic yarns knitted.

Based on functionality and end-use, elastic bandages can be classified as follows in table 1.

Table 1 General Guideline on Functionality of Elastic Bandage
(for reference only)
(*Clause* 4)

Sl No (1)	**Product category** (2)	**General Guideline on Functionality** (3)
(i)	Fixation	Retaining the primary wound dressing
(ii)	Support	Support for soft tissue, for post fracture treatment
(iii)	Compression	Compression therapy
(iv)	Elastic Crepe Bandage	Support and mild compression

5 DIMENSIONS AND TOLERANCES

The stretch length and width of the elastic bandage shall comply with the following requirements as given in Tables 2 :-

Table 2 Dimension of Elastic Bandage

(*Clause* 5)

Sl No. (1)	**Description** (2)	**Width** (cm) (3)	**Tolerance for width** (cm) (4)	**Stretched Length** (m) (5)	**Tolerance for Stretched Length** (cm) (6)
(i)	Elastic Bandages	2 - 4	± 0.2	1.5 - 4.0	± 20
				Above 4.0 - 10.0	± 40
				Above 10.0 - 20.0	± 60
		Above 4 - 12	± 0.5	1.5 - 4.0	± 20
				Above 4.0 - 10.0	± 40
				Above 10.0 - 20.0	± 60
		Above 12 - 20	± 0.7	1.5 - 4.0	± 20
				Above 4.0 - 10.0	± 40
				Above 10.0 - 20.0	± 60

6 MATERIAL

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

6.1.1 Elastic bandages shall have minimum 35 % of hydrophilic / cellulosic fibre content [*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 MANUFACTURE, WORKMANSHIP AND FINISH

7.1 The 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 with grey/white/coloured shade.

7.2 The elastic bandages shall be clean and free from substances liable to cause tendering during storage. The product shall be free from toxic or harmful substances. The manufacture and preparation of the elastic bandages should be conducted under proper hygienic conditions.

7.3 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.

8 CONDITIONING

8.1 Each roll of elastic bandage selected for test shall be conditioned for a minimum period of 24 h at 27 ± 2 °C and 65 ± 2 percent relative humidity (*see* IS 6359) prior to testing, and testing shall be in the same atmosphere. When the tests cannot be carried out in same atmosphere, the testing shall be commenced within 2 min of withdrawal of specimens from the conditioning atmosphere.

9 REQUIREMENTS

9.1 Test for Width

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

9.2 Test for Diameter

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

9.3 Weight

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

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

9.4 Stretched Length and Extensibility

The extensibility of elastic bandage shall be 55 to 270 percent. The requirement of stretched length and extensibility of elastic bandage shall be tested as per method given in Annex A.

9.5 Regain

The regain of the elastic bandage shall be not less than 70 percent when tested as per method given in Annex B.

10 SAMPLING AND CRITERIA FOR CONFORMITY

10.1 Lot

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

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

10.1.2 The number of bandages to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 1, 3 and 5 of Table 3.

Table 3 Number of Elastic Bandages to be Selected

(*Clauses* 10.1.2 *and* 10.2)

Sl No.	**Lot Size**	**Non-destructive Testing**		**Destructive Testing**	
		No. of Bandages to be Selected	Acceptance Number	No. of Bandages to be Selected	Acceptance Number
	N	N	a	n_1	a_1
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13*	1	8	0
ii)	281 to 500	20	2	8	0
iii)	501 to 1200	32	3	13	0
iv)	1201 to 3200	50	5	13	0
v)	3201 to 10000 and above	80	7	20	1

* or lot size when less than 13

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

10.2 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

10.2.1 All the bandages selected as per column 3 of Table 1 shall be examined for workmanship and finish (**7**).

10.2.1.1 Any bandage 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 3 of Table 3. Otherwise, the lot shall be rejected.

10.2.2 Out of the sample already found satisfactory according to **10.2.1.1**, a sub-sample as per column 5 of Table 3 shall be taken. This sub-sample shall be further tested for the remaining requirements.

10.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective bandages found in the sample (as per **10.2.2**) is less than or equal to the acceptance number as given in column 6 of Table 3.

11 MARKING

11.1 Each package of elastic bandage shall be legibly and indelibly marked with the following information:-

a) Name and trade-mark of the manufacturer;
b) Colour, if any;
c) Width and stretched length; and
d) Batch/lot number.

e) Month and year of manufacture; and
f) Any other requirement as per Medical Device Rule 2017 or as agreed between buyer and seller.

11.2 BIS Certification Marking

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

12 PACKING

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

ANNEX A
(*Clause* **9.4**)

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 L_1 immediately. Mark 5 cm on both ends and fix clamp A and clamp B on the bandage at both ends X_1 and X_2 (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 60 s. Measure the distance between two marks and record the stretched length L_2 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 L_2 and derive the final stretched length $L_3 = L_2 + CF$.

A-3.1.1 For bandage of stretched length above 5 m, measure the unstretched length L_1, 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.

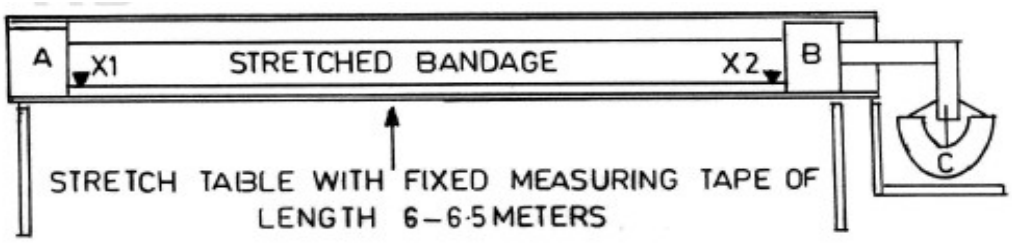

FIG. 1 APPARATUS FOR MEASURING OF STRETCHED LENGTH EXTENSIBILITY OF ELASTIC BANDAGE

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

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 = Stretched length (for 100 cm unstretched length) – Unstreched length (100 cm) × 100

Unstreched length (100 cm)

ANNEX B
(*Clause* **9.5**)

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:

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

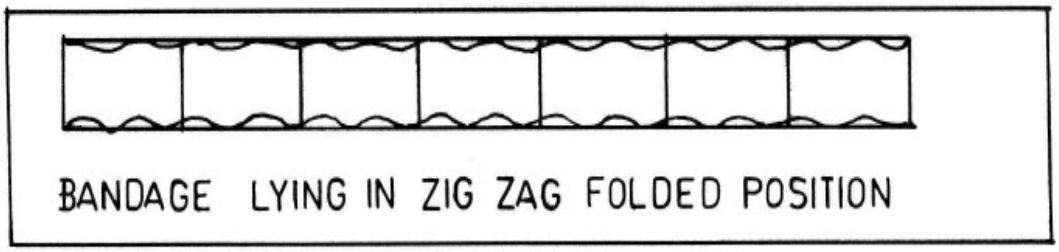

FIG. 2 APPARATUS FOR MEASURING OF REGAIN OF ELASTIC BANDAGE

ANNEX 7
(Item 4.2)

FINALIZATION OF DRAFT STANDARD/AMENDMENT

Comments received on Doc No.: TXD 36 (26680), Reusable Sanitary Pad/Sanitary Napkin/Period Panties — Specification (first revision of IS 17514)

1) **Smt. Anju Bisht, Saukhyam Reusable Pads**

We have begun our testing process for ISO certification.

We are working with Dr Santhini at SITRA for the product testing. There is one parameter for which we are requesting language change in the standard, upon discussion with other stakeholders, including Tanya ji of MHAI.

Unipads and Safepad also have faced the same issue, in our understanding.

The issue is with leakage at the seams, during the pressure test, where the PU has been stitched onto the cloth.

In real life usage scenarios, blood would not go upto the seam and would not leak from there.

Requesting your guidance Sir and an early resolution as we are trying to meet the Jan 1 deadline of the QCO. After the product testing, the on-site inspection will also take about 1 month, is our understanding.

Just to provide an introduction about Saukhyam. We are about 7 years old. We are an NGO. Our activity report for the past 3 years can be accessed at this url.
https://tinyurl.com/SaukhyamActivityReport

2) **Shri Karthik Thangavel, Real Relief**

Good day, hope you are doing well.
On behalf of all reusable pad manufacturers in India currently facing significant challenges in obtaining the BIS certification due to failing the *Absorption Under Pressure* test (Clause 9.2), I am attaching our consolidated comments following extensive discussions with various stakeholders in the sector.

By making slight modifications to the standards, we can enable more manufacturers to obtain certification, ensuring a wider availability of certified products across India.
Please feel free to reach out if you require additional details. We are also available for a call to discuss this further.

Thank you and I wish you a nice day.
Regards

Karthik Thangavel

NAME OF THE COMMENTATOR/ORGANIZATION: Karthik Thangavel, Real Relief

DOCUMENT NO:

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	**Comments**	**Proposed Change in the existing clause**	**Remarks**	**Technical References and justification on which (2), (3), (4) are based**
(1)	**(2)**	**(3)**	**(4)**	**(5)**
ANNEX B (Clause 9.2) METHOD FOR DETERMINATION OF ABILITY TO WITHSTAND PRESSURE AFTER ABSORPTION	**Reduction of Absorbency level**	**Panty Liner- 2ml Light / Small – 4ml Regular / medium -8ml Heavy / Large – 16ml**	**Since the level stated in the standards are same as disposable pads where it will convert as gel after absorbency; but reusable pads use only cloth, so we need to reduce the capacity accordingly.**	Discussions among reusable pad manufactures viz. Livinguard, Real Relief, Unipads and Saukhyam With Ms. Tanya Mahajan and Dr. Santhini **Uganda Standards – 1782:2017**

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	**Comments**	**Proposed Change in the existing clause**	**Remarks**	**Technical References and justification on which (2), (3), (4) are based**
(1)	**(2)**	**(3)**	**(4)**	**(5)**
ANNEX B (Clause 9.2) METHOD FOR DETERMINATION OF ABILITY TO WITHSTAND PRESSURE AFTER ABSORPTION	**Use of Artificial blood with similar viscosity of natural blood**	Drip at the rate of X ml (X = 50 percent of absorbency/min) with 1 min interval for total volume of 2 X ml of Artificial blood solution* maintained at		Discussions among reusable pad manufactures viz. Livinguard, Real Relief, Unipads and Saukhyam With Ms. Tanya

		temperature of 27° C ± 2° C on to the centre of the pad/napkin/panty from a height of 5 to 7 mm. *Water-glycerol-urea solutions: These solutions match the density and viscosity of blood i.e. 3.5 to 5.5cP and are less expensive. After the pad/napkin/panty has fully absorbed the artificial blood, place a standard weight of 1 kg on the area where the Artificial blood was absorbed and leave it for 1 minute. Carefully observe the bottom of the pad/napkin/panty for any signs of leakage. **Pass Criteria**: The test sample passes if no liquid leaks through the bottom layer in the area where absorbency testing was conducted. **Fail Criteria**: The test sample fails if liquid leaks through the bottom layer in the tested area.		Mahajan and Dr. Santhini

		Note: Any liquid that travels through the sides from the top fabric or stitching holes to the bottom layer should not be considered a failure.		

3) Ms. Monika Sathe and Ms. Roocha Khedkar, R&D, JNTL Consumer Health (India) Pvt. Ltd.

DOCUMENT NO: IS 17514: 2021 Reusable Sanitary Pad / Sanitary Napkin / Period Panties — Specification

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	**Comments**	**Specific Proposal (Draft clause to be add/amended)**	**Remarks**	**Technical References and justification on which (2), (3), (4) are based**
(1)	(2)	(3)	(4)	(5)
9.3 Hygiene Testing Requirement Total viable count (total number of bacteria and fungi) shall not be more than 1 000 cfu/gm and Staphylococcus aureus shall be absent.	N/A	Hygiene testing to be made optional for manufacturing who recommend washing the product before first use.	N/A	https://www.thinx.com/products/period-all-night-ultra-soft-sleep shorts?variant=40174028750920
3.2 The absorbent materials must be free from lumps, oil spots, dirt or foreign material	Lump formation is irrelevant to reusable product made of textile material. Rather lump should no be formed post washing the product.	The absorbent materials must be free from, oil spots, dirt or foreign material	N/A	N/A
4.0 When visually examined, the reusable sanitary pad/sanitary napkin/period panties shall be free from defects or lumps.	Lump formation is irrelevant to reusable product made of textile material. Rather lump should not be formed post washing the product.	When visually examined, the reusable sanitary pad/sanitary napkin/period panties shall be free from defects	N/A	N/A

3.1 "The cover/top sheet is the material which comes under contact with skin during use. The material used for the top layer/cover shall be safe, soft to the touch and should not shed any fibers when rubbed dry or wet.	Will there be a Recommended TM for rubbing/fiber shedding?	N/A	N/A	N/A
4 The material used for reusable sanitary pad/sanitary napkin/ period panties shall be smooth, safe for skin contact, and shall not leach dyes or bleed colour.	N/A	Will there be a recommended TM to assess skin contact safety and dyes durability? For the dyes it could be good to add "under recommended cleaning and usage conditions".	N/A	N/A
7 The manufacturer shall provide the washing, drying, handling and storage instruction on every packet of reusable sanitary pad/sanitary napkin/period panties to ensure proper use and care by the consumer.	Are there any existing ISO norms for textiles that should be followed for labelling and assessment of washability (e.g., in Europe, GINETEX care symbols are used)?	N/A	N/A	N/A
8 The raw material/ fabric used for manufacturing the product shall meet the Following requirement (initially and after declared cycle washes) as specified in Table 1. Table 1 Colorfastness' and dimensional Stability Requirement of Raw Material/ Fabric	Can the assessment be performed on finished product instead of each RM?	8 The raw material/fabric used for manufacturing the product shall meet the following requirements (initially and after declared cycle washes) as specified in Table 1. Table 1 Colourfastness and dimensional Stability Requirement of Raw Material/Fabric or finished product.	N/A	N/A
9 The reusable sanitary pad/sanitary napkin/ period panties shall meet the requirements (initially and after declared cycle washes)	Is this a requirement for standard underwear today? Why is it relevant on a textile. If needed, it should not be	N/A	N/A	N/A

as specified in 9.1 to 9.3.	post-washing as it will be influenced by detergent used.			
9.2 The reusable sanitary pad/sanitary napkin/period panties shall absorb 10 ml (for small/medium size pad/napkin and period panties) and 30 ml (for large/extralarge size pad/napkin) of coloured distilled water and it shall not show leakage at the bottom or sides of the reusable sanitary pad/sanitarynapkin/period panties, when tested according to method given in Annex B.	Should the absorbent capacity not be linked to the flow level? Capacity can be kept same for all sizes	N/A	N/A	N/A
12.1 Each package of reusable sanitary pad/sanitary napkin/period panties shall be legibly and indelibly marked with instructions; b) Storage instructions; c) Batch/Lot no. and date of manufacturing	Why are storage Instructions needed? Is this a textile requirement today? Is the batch code on the box sufficient or needed on the panty itself?	N/A	N/A	N/A

ANNEX 8
(Item 4.2)

FINALIZATION OF DRAFT STANDARD/AMENDMENT

Comments received on Doc No.: TXD 36 (26697), Textiles — Medical/Surgical Gowns and Medical/Surgical Drapes — Specification (First Revision of IS 17334)

NAME OF THE COMMENTATOR/ORGANIZATION: **Ms Reena George, O&M Halyard Health India Pvt. Ltd.**

DOCUMENT NO: 1

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	**Comments**	**Proposed Change in the existing clause**	**Remarks**	**Technical References and justification on which (2), (3), (4) are based**
(1)	**(2)**	**(3)**	**(4)**	**(5)**
5.3 Non-critical areas of the medical/surgical gowns and medical/surgical drapes can have one level less as compared to the standard earmarked for the medical/surgical gowns and medical/surgical drapes.	Change Non-critical area to less critical area	Change Non-critical area to less critical area		Noncritical area is not explained on section 3.0 TERMS AND DEFINITIONS
Table 1 and Table 2	Based on section 5.3 non-critical areas of the medical/surgical gowns and medical/surgical drapes can have one level less as compared to the standard earmarked for the medical/surgical gowns and medical/surgical drapes. if a gown is differentiated	Cleary specify which area (critical or less critical or both) the each of individual test requirement on Table 1 and Table 2 are applicable to.		

	with critical area and less critical area, for instance level 4 gown is claimed, what is the minimum requirement for less critical area? Must it be level 3? or level 1 and level 2 are acceptable			
Section 5.1 In case of elastic cuff/waist, it should have proper fit and should be adhered with glue to minimize risk of exposure.	Not sure the implication of the waist, Is it referring to front tie attachment or reinforced material attachment on front check?			
Table 4 NOTE—The sampling plan given in table 4 is for guidance of manufacturer/user. The other sampling plan may also be followed if agreed between buyer and seller or as per manufacturers quality assurance plans.	Should sampling plan on table 4 be used as test plan for design verification test against performance requirement on Table 1 or Table 2?			
<u>Clause 1.3 Universal Pack</u> On the Universal procedure Pack/customized procedure pack, the clause 1.3 needs clarification. **1.3** This standard does not include universal proce packs designed for specific procedures, how contents of customized procedure packs shal manufactured in accordance with this standard.	Please clarify what is Universal procedure pack and what is customized procedure pack. Does the Universal Pack have surgical gowns and surgical drapes in it, will the surgical gowns and surgical	Define Universal procedure pack and customized procedure pack		

	drapes in the Universal Pack need to meet IS 17334?			
Query on Equipment covers like :Back Table Cover and Mayo Stand Cover	Do Back Table Cover and Mayo Stand Cover which are used to maintain sterility of environmental surfaces need to meet IS 17334?			

ANNEX 9
(Item 4.2)

FINALIZATION OF DRAFT STANDARD/AMENDMENT

Comments received on Doc No.: TXD 36(26744), Medical Textiles — Nonwoven Gauze Swab— Specification

Shri Arun Nag, Ginni Filaments

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Proposed Change in the existing clause	Remarks	Technical References and justification on which (2), (3), (4) are based
(1)	(2)	(3)	(4)	(5)
Table 1(ii) / 3.2	Minimum 20% Viscose to be used	A tolerance range of (± 2 %)	Tolerance Limit is always considered in the test results because of variation of test results from Lab to Lab. Documented proof for 20% input can be provided.	Based on daily process monitoring & analysis
Table 1 Performance Requirements for Non woven Gauze Sr. no. 1(xii)	Particle release Log10(Lint Count) ≤ 4.0	Should have tolerance range of ≤ 5.0	IS 15891 Part 10 or ISO 9073-10:2003 Part 10	a) Woven Gauze fabric has value of Log10(Lint count) as >5.0 b) There is no reference for values for Lint count in ISO for

				Gauze Swabs **c) Moreover, the product is not to be used in "Operation Theatre" and we can do away with the clause ,altogether**

ANNEX 10
(Item 4.2)

FINALIZATION OF DRAFT STANDARD/AMENDMENT

Comments received on Doc No.: TXD 36 (26729), Medical Textiles — Elastic Bandage — Specification (first revision of IS 16111)

Shri T Balaji, KOB Medical Textiles Pvt. Ltd.,

DOCUMENT NO: TXD 36 (26729)

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Proposed Change in the existing clause	Remarks	Technical References and justification on which (2), (3), (4) are based
(1)	(2)	(3)	(4)	(5)
4. Types: In Type V – Combination of both cellulosic yarn / non - cellulosic yarns woven knitted.	Knitted to be removed	Since Combination of both cellulosic yarn / non - cellulosic yarns woven.	Type VI separately given for knitted.	Woven and knitted are different manufacturing technology. Type V is meant for Woven and Type VI is meant for Knitted.
5. Dimensions and tolerances – Stretched length 2.0 to 4.0 m	1.5 m variant can be included.	2.0 to 4.0 m +/- 20 cm length category can be revised as 1.5 m to 4.0 m +/- 20 cm.	Length category scope is widened.	1.5 m length variant enable to use Elastic Bandage on smaller parts of human body (like fingers).
6. Material Part 6.1.1 Hydrophilic/cellulosic fibre content, minimum 35 percent [see IS 1889 (part 1)]	Sounds as each material shall be 35 % of hydrophilic content.	Elastic bandages shall have minimum 35 % of hydrophilic / Cellulosic fibre content. [See IS 1889 (part 1)]	'Elastic bandages' text to be added to make clarity as 35 % hydrophilic content in bandage form and not in material (yarn form)	Elastic bandages shall be made from cellulosic / non cellulosic yarn.

7 Manufacture, workmanship and finish 7.1 The elastic bandages shall be in woven/knitted bandages containing cellulosic, noncellulosic yarns or a combination of both with non-fraying closed selvedges /edges and or grey/while/coloured shade.	Text 'or' wrongly mentioned. Typo error in text 'while'.	Text 'or' to be replaced with text 'with'. Typo error in text 'while' to be correctly mentioned as ' 'white'.	To have actual/ correct meaning of the sentence.	NA
8 Conditioning 8.1 Each roll of elastic bandage selected for test shall be conditioned for a minimum period of 24 h at 27 ± 2 °C and 65 ± 2 percent relative humidity (see IS 6359) prior to testing, and testing shall be in the same atmosphere	Relative humidity tolerance (65 ± 2) is too narrow.	Relative humidity tolerance to be revised as 65 ± 5 percent.	As per IS 4605 for Crepe bandage relative humidity with tolerance is 65 +/- 5	Relative humidity to be mentioned as per IS 4605 standard requirement.
8 Conditioning 8.2 The outer three layers of each roll shall be discarded before taking the specimen for test	This requirement is not relevant to Elastic bandages	Section 8.2 to be removed.	Elastic bandages shall be tested as whole for length requirement	Ref Annex A of this draft document
9.3 Weight 9.1.1 The weight of elastic bandage determined by weighing the whole bandage divided by the stretched surface area gives the weight per unit area.	Clause wrongly mentioned as 9.1.1.	Clause 9.1.1 is to be changed as 9.3.1	To get correct sequence of numbers.	For correct documentation.

10.2 Number of tests and criteria for conformity 10.2.1 All the bandages selected as per column 3 of Table 3 shall be examined for workmanship and finish (7).	For 'Workmanship' check, bandage needs to be opened. The 'Finish' test regarding Optical Brightener presence is carried out at Raw material inspection stage	10.2.1 All the bandages selected as per column 5 of Table 3 shall be examined for workmanship (7) and other requirement tests (9).	Workmanship check (to ensure the cleanliness) should be carried out through destructive test method (by unroll the bandage) only.	Non destructive test method shall not be applicable in testing of elastic bandages.
10.2.1.1, 10.2.2 & 10.2.3 10.2.1.1 Any bandage 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 3 of Table 3. Otherwise, the lot shall be rejected. 10.2.2 Out of the sample already found satisfactory according to 10.2.1.1, a sub-sample as per column 5 of Table 3 shall be taken. This sub-sample shall be further tested for the remaining requirements. 10.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective bandages found in the sample (as per 10.2.2) is less than or equal to the acceptance number as	Clause 10.2.1.1 & 10.2.2 can be removed and 10.2.3 can be considered as 10.2.2	10.2.2 The lot shall be considered as conforming to the requirements of the specification if the total number of defective bandages found in the sample (as per 10.2.1) is less than or equal to the acceptance number as given in column 6 of Table 3.	All tests requirements (clause 7 & 9) for Elastic bandages are involved with destructive tests and addressed in proposed clause of 10.2.1 ***(Pl. refer previous comment)***	Non destructive test method shall not be applicable in testing of elastic bandages.

given in column 6 of Table 3.				
Annex A Method for measuring of stretched length and extensibility of elastic bandage	Extended time of load on bandage is mentioned as 30 Sec.	Extended time on load for bandage shall be as 60 Sec.	According to DIN 61632 bandages subject to keep extended condition for 1 minute.	Bandage extended condition time shall be in align with DIN 61632 standard.

ANNEX 11
(Item 5.1)

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 12
(Item 5.1)

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. (1)	**Characteristic** (2)	**Requirement** (3)	**Method of test Ref to** (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	± 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	
(1)	*N* (2)	**No. of apperals to be selected** *n* (3)	**Acceptance Number** *a* (4)	**No. of apperals to be selected** *n* (5)	**Acceptance Number** *a* (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 - 35^0C 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

- 25^0C 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.

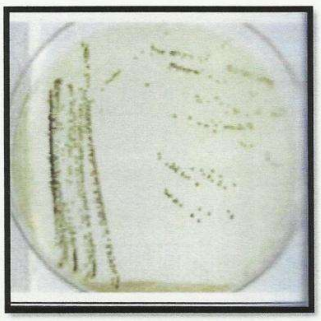

FIG. 2 TYPICAL COLONY CHARACTERISTICS OF *STAPHYLOCOCCUS AUREUS*

ANNEX 13
(Item 5.2)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

Technical inputs received 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)
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 14
(Item 5.2)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDRADS

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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 15

(Item 6.2)

NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD

TAMPON AND IV CANNULA FIXATOR DRESSING

Working draft on Tampon Specification

1. SCOPE

This standard specifies the requirements for disposable menstrual tampons for internal use.

2. REFERENCES

2.1 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 indicated in Annex- A.

3. MATERIALS

A tampon is a feminine hygiene product designed to absorb the menstrual fluid by insertion into the vagina during menstruation. Tampons are absorbents like sanitary napkins & liners but are compressed to a small size so that they can be inserted into vagina. As a result, Tampons expand as they absorb the menstrual fluid.

As compared to sanitary napkins, it provides a discrete way to manage the menstruation or periods. Tampons basically consist of three major components: cover, absorbent fibers and the withdrawal cord or string. Some tampons in the market are manufactured without using cover as well.

3.1 Cover

Cover is an outer material which holds absorbent fibers together in a tampon. The cover of tampon should be of good quality, smooth, clean & hygienic. A cover can be made of fiber web, non-woven fabrics (natural or synthetic fibers) or aperture plastic film or any other materials with sufficient porosity to permit the assembled tampon to meet the absorbency requirements. The cover shall be securely attached to the surface of the tampon.

3.2 Absorbent Fibers

Absorbent fibers absorb and retain the fluid, forming main body of a tampon. Absorbent fibers may contain cellulosic polymers such as cotton, viscose rayon, wood pulp fibers or synthetic fibers or other suitable absorbent fibers, provided that no demonstrable hazard exist for such polymers. Fibers can be used either singly or in combination as fibers in absorbent core may impart structural stability to the tampons. The fibers must be clean & free from dirt or foreign material.

Note: Use of Polyester foam, Carboxymethylcellulose (CMC) and acrylate modified rayon have been restricted due to consumer safety concerns.

3.3 Withdrawal cord / String

A string or withdrawal cord in a tampon is made of Polyethylene Terephthalate (PET) fibers or other suitable fibers having good tensile strength. The string shall be firmly attached on the tampon. The string allows safe withdrawal of tampon form the body after use.

3.4 Applicator

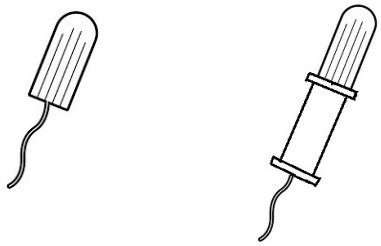
Tampons may also come with applicator to assist in insertion of the tampons in the vagina. An applicator is a cardboard or plastic insertion aid use to insert the tampon inside vagina.

4. TYPES OF TAMPONS

There are mainly two types of tampons: namely digital & applicator tampons. Digital tampons can be inserted without use of an external aid. Tampons can be of various constructions depending upon type of tampon, embossing / groove patterns, cover materials and any attachments of the cover to form wing like shapes, etc. and as per purchaser's needs. Some examples are shown in Fig 1.

Tampons can exist in two forms or designs namely, either compressed radially wound pledget or compressed Rectangular/square pad. In radially wound pledget, the fibrous fleece is rolled up and then compressed to produce a tampon that expands primarily in the width-wise/ radial direction.

In Rectangular/square pad form, fibrous fleece is in the rectangular or square pad form, which is compressed in both the longitudinal and radial directions. This tampon therefore expands in both the longitudinal and width ways directions but predominantly in the longitudinal direction.



(a) **(b)**

Fig 1 Schematic diagrams of tampons – (a) digital and (b) applicator (for reference only)

5. SIZES

Size of tampon is linked with its fluid absorption capacity, which is indicated by number of droplets. It shall be as agreed between the purchaser and the supplier. The recommended absorbency ratings are as per EDANA and the sizes are as follows:

Droplets	Absorbency (g)	Length (mm)	Diameter (mm)
		Tampons shall be designed to provide comfort to fit inside the vagina. Below are the recommendations for length and diameter.	
	<6	35-55	10-20
	6-9		
	9-12		
	12-15		
	15-18		
	18-21		

6. MANUFACTURE, WORKMANSHIP AND FINISH

6.1 The tampons are generally manufactured as per the following process:

A fiber web/fleece in rolled form which may be bonded with a suitable bonding mechanism, is cut to a specific length. A piece of cover is cut, attached to the fiber web and sealed. A withdrawal cord is placed around the fleece and knotted at the ends. The fiber web is then asymmetrically folded, rolled and compressed to a cylindrical shape with dome at the tip. Grooves with different pattern like straight, helical, wavy, converging are formed by compressing operation. The tampon is then covered with a desired primary packaging i.e., wrapper, and sealed from tip to the base. This forms a digital or coiled tampon, which expands radially.

Second type (typically used for applicator tampons) starts from a rectangular fiber fleece. A withdrawal cord is sewn across the length of the tampon fiber pad which is then compressed to a cylindrical shape. Alternatively, the withdrawal cord can be attached after the compression by pierce and loop attachment of the cord at the bottom section of the tampon. This tampon expands both radially and longitudinally.

The manufacturing process may be differ based on innovations that aim to improve efficiency, productivity, and product quality.

7. REQUIREMENTS

A Tampon should provide a smooth insertion and withdrawal from vagina and should not give any uncomfortable feeling. They shall be free from all sorts of foreign matter. (un-intended foreign matter that can cause injury or discomfort).

7.1 Length of withdrawal cord

The length of withdrawal cord hanging free from the tampon shall not be less than 80 mm for easy and hassle-free withdrawal of tampon.

7.2 Absorptive capacity

Absorption capacity value of tampons must fall in the absorbency range specified / claimed for respective tampon size as mentioned in Section 5, when tested as per method given in Annex-C.

7.3 Pull strength of withdrawal cord

When tested as per method described in Annex- D, mean pull force to break or detach the withdrawal cord from its attachment point should not be less than 28 N.

7.4 Hygiene Testing

When tested in accordance with procedure in Annex- E, the total aerobic microbial count (TMAC), in each tampon (and applicator where provided) shall not exceed 100 CFU/g and 10 CFU/g for TYMC

7.4.1 Frequency of Hygiene Testing and Good Manufacturing Practice Guideline for Hygiene Requirement

A manufacturer shall perform the hygiene testing for final products when the product is first launch in the market. Depending on the manufacturing controls in place it can be decided on how frequently the checks are performed. The hygiene testing shall be performed whenever there is a change in raw material, manufacturing premises, and supplier of the raw materials used in a product.

A tampon shall be manufactured under good hygienic conditions. The general guidelines for good manufacturing practice to maintain hygiene requirement at manufacturing facility are given in Annex-B.

7.5 Biocompatibility Evaluation

The manufacture shall ensure that all ingredients used in a product are safe for human use based on its known toxicological characteristics for intended use. Manufacturers shall complete the evaluation of final products as per IS/ISO 10993-1 guidance based on product chemical composition and addressing relevant safety endpoints.

ISO:10993 part 1 is a broad guidance for medical device safety which considers various safety endpoints including chemical characterization for the product. The Chemical characterization of the product can be primarily performed based on product composition and its clinical exposure to the consumers. When this information is available there is no requirement to perform extractable and leachable studies. Manufacturer shall ensure that adequate information is available for risk assessment of the product.

7.6 Biodegradability or Compostability (Optional)

The manufacturer who are claiming their product as biodegradable or compostable shall perform the above testing for the final product. The product shall be biodegradable or compostable when tested as per IS/ISO 17088. The information whether the product is biodegradable, compostable or oxy-degradable shall be marked on every pack.

This testing shall be carried whenever there is a change in a raw material for manufacturing the product and the supplier of the raw material.

8. SAMPLING AND CRITERIA FOR CONFORMITY

8.1 LOT

All tampons using with same raw material, shape, dimensions and produced under similar conditions of manufacture shall constitute as one lot. Manufacturer can also define a lot basis their internal controls and standard operating procedure.

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

8.1.2 The required number of tampons shall be selected at random from the lot according to IS 2500-1. Reference may be made to IS 4905 for guidance on random sampling.

Other sampling plan may also be followed if agreed between buyer and seller or as per manufacturers quality assurance plans

8.2 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

8.2.1 All tampons selected for testing shall be examined for workmanship and finish against parameters such as length, weight, visual appearance / defects. The diameter of the tampons without wrapper and length of the cord can be checked as in process checks defined by the manufacturer during its manufacturing process.

8.2.2 Out of the samples already found satisfactory according to **8.2.1**, a sub-sample shall be further tested for the remaining requirements.

8.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective tampons found in the sampling are less than or equal to the acceptance number as per IS 2500-1.

9. Marking

Each product packet shall be legibly and indelibly marked with the manufacturer's name or trademark, Batch / Lot number, number of tampons contained and number of droplets indicating absorbency range. A warning statement with the word 'WARNING' in capital must be included on pack regarding Toxic Shock Syndrome (TSS), such as:

WARNING: Toxic Shock Syndrome (TSS) is a rare but serious disease. The enclosed leaflet contains valuable information about TSS and it's corresponding symptoms. Please read and save it for your health and hygiene.

Following instructions & information shall be included in leaflet of every packet of tampons:

i) Directions of use including the need for hygiene and care in insertion

ii) Information about TSS with symptoms
iii) Any other information required by law in force or agreed between buyer and seller

10. BIS Certification Marking

The consumer pack may also be marked with the Standard Mark.

10.1 The use of the Standard Mark is governed by the provisions of the Bureau of Indian Standards Act, 2016 and the rules and regulations made thereunder. The details of conditions under which the license for the use of Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

11. PACKING

Individual tampons shall be wrapped in Polyethylene, Polypropylene or other suitable packaging materials to protect the product from contamination. Specified number of individually wrapped tampons shall be contained in a rigid or flexible package that protect the product from contaminants during shipment and storage. This package could be constructed of materials such as carton board, Polyethylene, Polypropylene, Polyester or other safe materials that provide sufficient protection to the product and maintaining product quality until opened by the consumer. The package should be free of any torn or damaged areas.

ANNEX -A

(*Clause 2.1*)
IS / ISO No. *Title*

IS 4905: 2015 Random sampling and randomization procedures (*first revision*)

IS 2500-1 Sampling procedure for inspection by attributes

10993-1: 2009, Biological evaluation of medical devices Part 1 Evaluation and Testing within a risk management process

17088: 2012 Specifications for compostable plastics (*first revision*)

ISO 11737-1: 2018, Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products

ANNEX-B

(*Clause* 7.3.3)

GOOD MANUFACTURING PRACTICE FOR HYGIENE REQUIREMENT

Maintaining hygiene at production facility is essential for ensuring products are appropriate for consumer use. Following are recommended guidelines for ensuring hygiene at facilities:

i) Location should be free from objectionable odours, smoke, dust and other contaminants.

ii) Separate areas should be demarcated for storing raw materials, production and final product storage.
iii) Separate area should be demarcated for storing personal effects and personal protective equipment of unit workers to minimize risk of contamination.
iv) Toilet and hand-washing station should be provisioned away from storage/production area.
v) Provision of 70% isopropyl alcohol (IPA) solution for use inside the production facility.
vi) Appropriate lighting and proper ventilation of the facility should be ensured.
vii) Flooring should be either concrete, tiled or with chips to ensure ease of cleaning. Floors, walls, ceilings, doors and windows should be easy to clean and without crevices or openings that should not allow accumulation of dirt.
viii) Regular pest control measures should be put in place.
ix) Adequate receptacles for disposing waste generated within the facility should be made available and should be frequently emptied and cleaned.
x) Poster/sign encouraging safety and hygiene practices like use of personal protective equipment, use of hand sanitizer etc. should be displayed.
xi) Pre-packaged finished product should be checked thoroughly and ensured to be free from foreign particles, dirt, hair, and other visible contaminants.
xii) A cleaning and maintenance schedule should be drawn up for cleaning of the facility, toilets, washing areas, waste receptacles and for cleaning/disinfection of the equipment.

ANNEX C

C1. Scope

This Annexure describes a method for measuring the absorptive capacity of a tampon under counter pressure.

C2. Principle

The principle is to simulate the vaginal environment in the laboratory by applying standard pressure to a tampon inside a flexible membrane (a certain type of condom) and then introducing defined amounts of fluid until the tampon leaks. The tampon weight is taken before and after the test to calculate the weight of fluid absorbed.

C3. Material and Reagents

a) Distilled or de-ionized water.
b) Sodium chloride (analytical reagent grade).
c) Color agent: acid fuchsin, Fisher F97 Certified Biological Stain, Color Index N° 42685; Fisher Scientific Company or Fruchterot dye, E 144 or Ponceau Cochenillerot E 124 or FD&C Red #40.
d) Sodium chloride solution: Dissolve 10g sodium chloride in 1 liter distilled or de-ionized water.
e) Syngina fluid: Dissolve 0.5g color agent in 1 litre sodium chloride solution.
f) Syngina fluid should be regularly replaced to avoid microbiological contamination.
g) Syngina fluid should be stored and used at room temperature.

C4. Apparatus

a) Standard laboratory equipment

b) Syngina apparatus
The syngina apparatus set-up is illustrated in Figure C1. This is designed to provide constant hydrostatic pressure of 180 ± 10 mm.
i) Syngina chamber, details of which are provided in Figure 2.
ii) Infusion pump - set up to deliver 50 ± 2 ml/hour.
iii) Thermostatic bath, with external circuit, set up to 27 ± 1°C.

c) Straight unlubricated condoms
Having a tensile strength between 17 MPa and 30 MPa measured in accordance with ISO 4074:2002 Annex I.

Condom Installation and Replacement

1. Open and unravel a condom.

2. Mark the condom at 20 mm and 160 mm length from the open end (see Figure C3).

3. Insert the condom through the chamber with the aid of a rod so that the 160 mm mark rests on the edge of the smaller opening of the chamber (see Figure C2).

4. Cut the tip of the condom and secure with a rubber band, such that the 160 mm mark remains on the edge of the small opening of the chamber.

5. Draw the condom through the large chamber opening so that the 20 mm mark rests on the opening's edge (see Figure C3) and secure with a rubber band.

6. Replace condoms (a) if they leak, (b) after every tenth test or (c) daily – whichever applies first.

C5. Preparation of test specimens

The test specimen (tampon) shall be removed from its wrapping and applicator, if applicable. Tampon shall be unwrapped immediately before testing.

C6. Procedure

1. Weigh the specimen (tampon) to be tested (including withdrawal cord) to the nearest 0.01 gram and record the weight.

2. With the syngina chamber empty place the tampon within the condom so that the center of the tampon is at the center of the chamber and the withdrawal cord is positioned toward the bottom of the chamber (see Figure C2).

3. Insert the infusion needle (cannula) through the optional septum cap so that it contacts the top end of the tampon.

4. Fill the outer part of the chamber with water and adjust the flow such that water trickles over the head and back to the water bath. The liquid must not rise into the atmospheric vent.

5. Examine the position of the tampon and, if necessary, drain, re-center and repeat steps 3 and 4.

6. Pump the syngina fluid into the chamber

7. The “end point” is defined by the first drop of liquid that exits the apparatus. Terminate the test by stopping the fluid flow.

   NOTE: The test shall be discarded if fluid is detected in the folds of the condom before the tampon is saturated.

8 Drain the water from the chamber remove the tampon and weigh it immediately to the nearest 0.01 g and record the wet weight.

9 After the tampon has been weighed carefully remove any residual fluid (using a non-fiber shedding absorbent laboratory wipe) from the inside of each condom in preparation for the next test.

   NOTE: If the test stand comprises more than one chamber, use tampons with the same absorbency, for parallel testing.

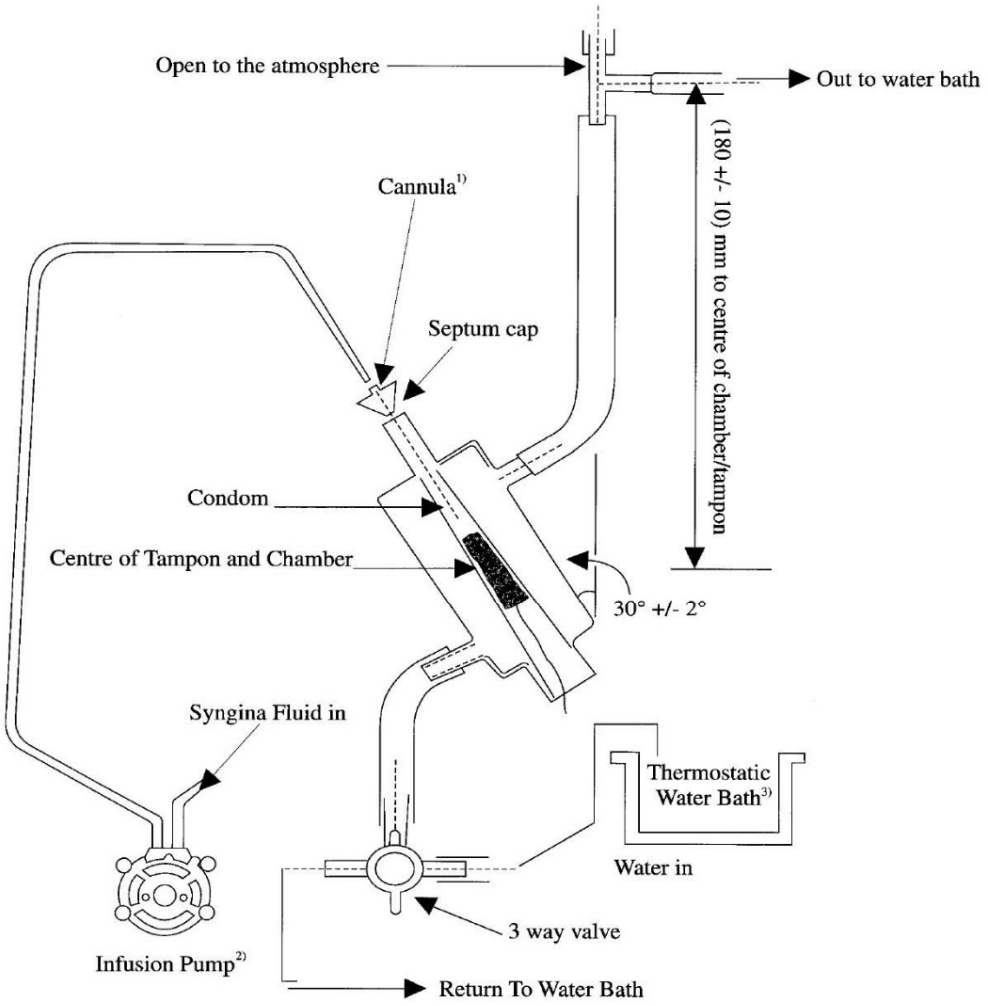
C7. Calculation and Expression of Results

Calculate the absorbency of each specimen tampon as follows and express the results to the first decimal:

$A=B-C$ where: A = Absorbency of tampon in grams

B = Weight in grams of saturated tampon

C = Weight of dry tampon in gram



[1)] min 100 mm long; (1,5 +/- 0,15) mm I.D.

[2)] see 5.2.2

[3)] see 5.2.3

Figure C1. Syngina Apparatus

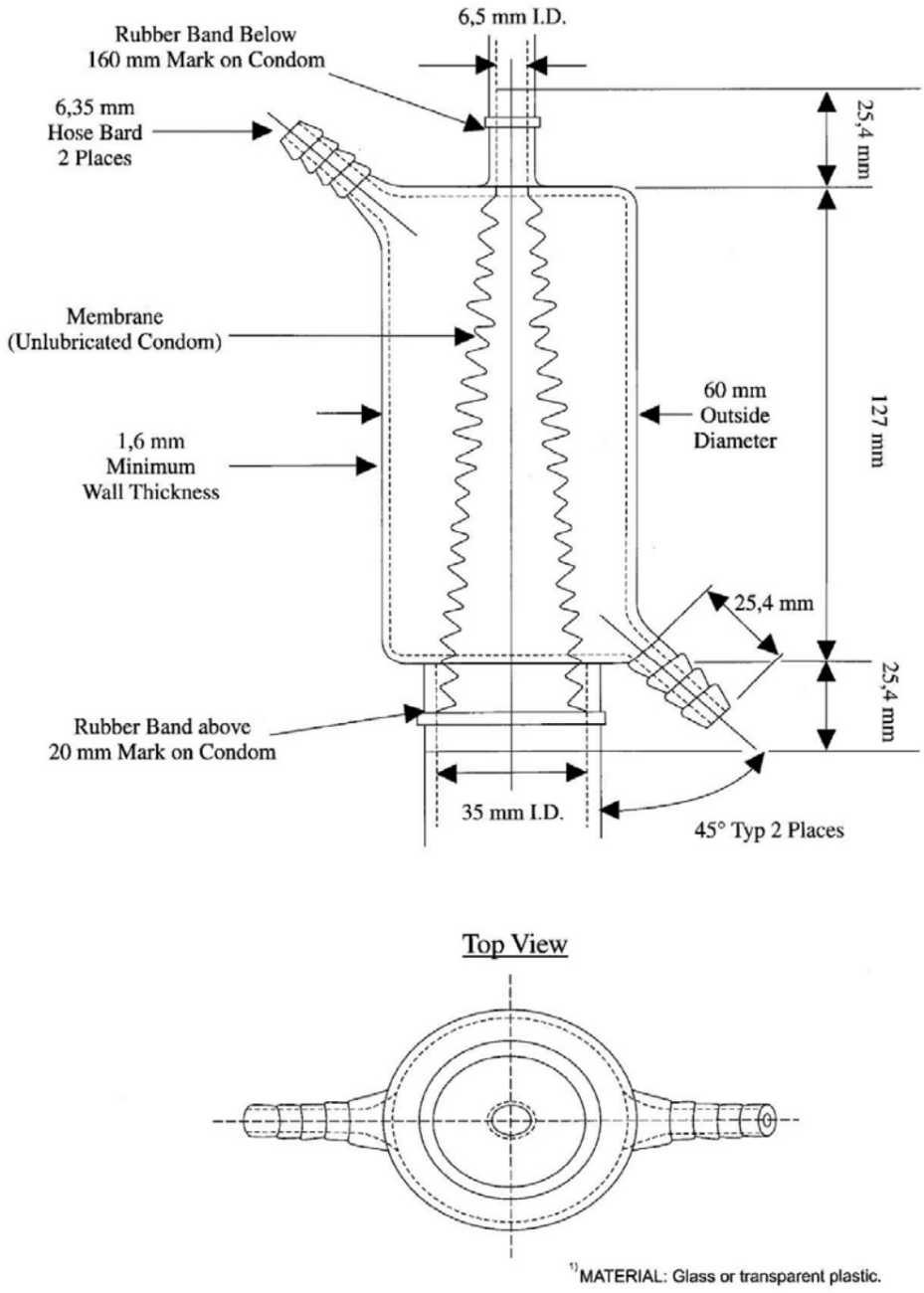


Figure C2. Syngina chamber

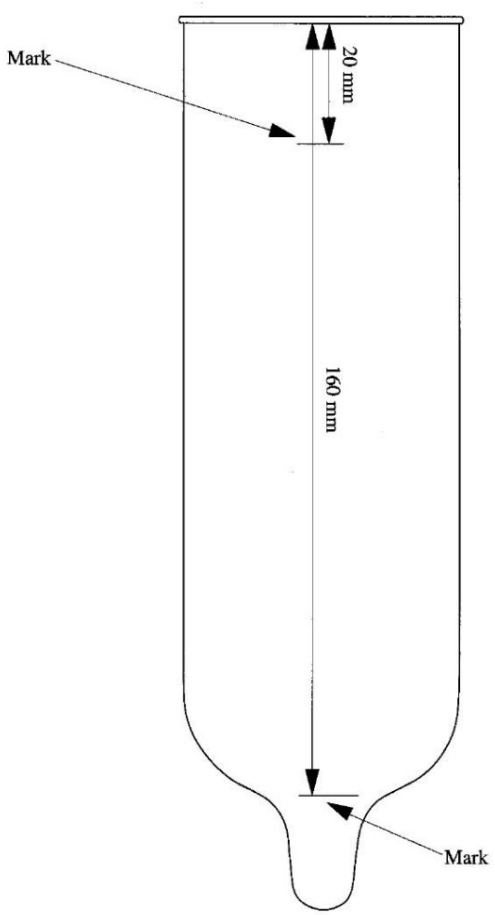


Figure C3. Condom marking

ANNEX -D

D1. Scope

This Annex describes method for testing the strength of the withdrawal cord from its attachment point in wet and dry conditions.

D2. Principle

The tampon is supported in a holder leaving the withdrawal cord free. The holder containing the tampon is rigidly supported while an increasing force is applied to the withdrawal cord until either the cord breaks or it is detached from the body of the tampon. Figure D1 gives a diagrammatic sketch of the arrangement.

D3. Apparatus

The following apparatus is required:

(a) Tensile testing machine complying with the following:

(i) The error in measurement of length shall not exceed 1.0 mm.

(ii) The machine shall provide means for indicating the force applied to the test specimen clearly and continuously on a dial scale or chart. It shall also provide means for indicating the force required to break or detach the cord.

(iii) The capacity of the machine or the range selected shall be such that the force required to break the test specimen shall be not less than 10% of the machine capacity.

(iv) The machine shall be capable of extending the specimen at a constant rate of 200 ±25 mm/min.

(v) The force measuring mechanism of the machine shall allow little or no movement of the fixed jaws in the direction of the applied force.

(vi) The fixed and moving jaws of the machine shall be in the same plane, parallel to one another and at right angles to the direction of application of the force.

(vii) The jaws of the machine shall be constructed so that they do not damage the test specimen.

NOTE: Suitable packing materials or embedding techniques may be used whenever necessary to prevent test specimens slipping in the jaws.

(b) Two holders (see Figure D2) having internal diameters of 26 ± 1 mm and 29 ± 1 mm, respectively.

NOTE: The example of a holder shown in Figure D2 will introduce a small error as the applied force will be slightly offset. This error is typically < l%. The flat pl ate of that holder has been offset to allow easy insertion of the tampon.

(c) A wire 200 mm long with the end bent to form a hook as shown in Figure D3. If optional slotted holders are used, wire is not required.

(d) Timer, capable of measuring 5 min accurately.

(e) Beaker of 1 L capacity

(f) Pair of tongs.

(g) Distilled or deionized water.

D4. TEST SPECIMENS

Select 20 unopened tampons at random from one batch. Should a test be invalid in accordance with Paragraph D6, the necessary additional test specimens shall be drawn to complete 20 valid tests. Of the 20 tampons, 10 shall be used for testing in the dry state and 10 for testing in the wet state.

D5. PROCEDURE

D5.1 Dry state

The procedure shall be as follows:

(a) Condition the wrapped tampons for not less than 12 h at 20 ± 2°C and 65 ± 5% relative humidity.

(b) Unwrap a tampon, remove the applicator where provided, and extend the withdrawal cord away from the body of the tampon.

(c) Using the hook, which is inserted through the hole in the base of the holder, pull the withdrawal cord through the hole so that the tampon is held within the 26 mm internal diameter holder with cord free (see Figures D2 and D3). Alternatively, if the slotted holder is used, the tampon can be threaded into the holder without using the wire hook.

(d) Place the flange on the holder in to the upper jaw of the tensile testing machine. The base of the holder should be at least 60 mm above the top of the lower jaw.

(e) Extend the cord so that there are no kinks in it and clamp the lower end in the lower jaw (see Figure D1).

(f) Set the machine to give a constant rate of extension of 200 ± 25 mm/ min.

(g) Set the machine in motion and record the force required to either break the cord or detach it from the body of the tampon.

(h) Repeat Steps (b) to (g) a further nine times.

(i) Calculate the mean force.

D5.2 Wet state

The procedure shall be as follows:

(a) Unwrap a tampon, remove the applicator, where provided, and place the tampon in the 1000 mL beaker in an excess of the water.

(b) Leave the tampon in the water for at least 5 min.

(c) Remove the tampon with the tongs and gently squeeze it to remove excess water.

(d) Place the tampon in the 29 mm internal diameter holder, inserting the withdrawal cord through the hole in the base.

(e) Follow Steps (d) to (i) specified in Paragraph D5.1.

D6. INVALID TEST

A test shall be considered invalid if the cord breaks at the point where it enters the lower grips.

A new tampon shall be inserted into the holder in each such case and the procedure is repeated.

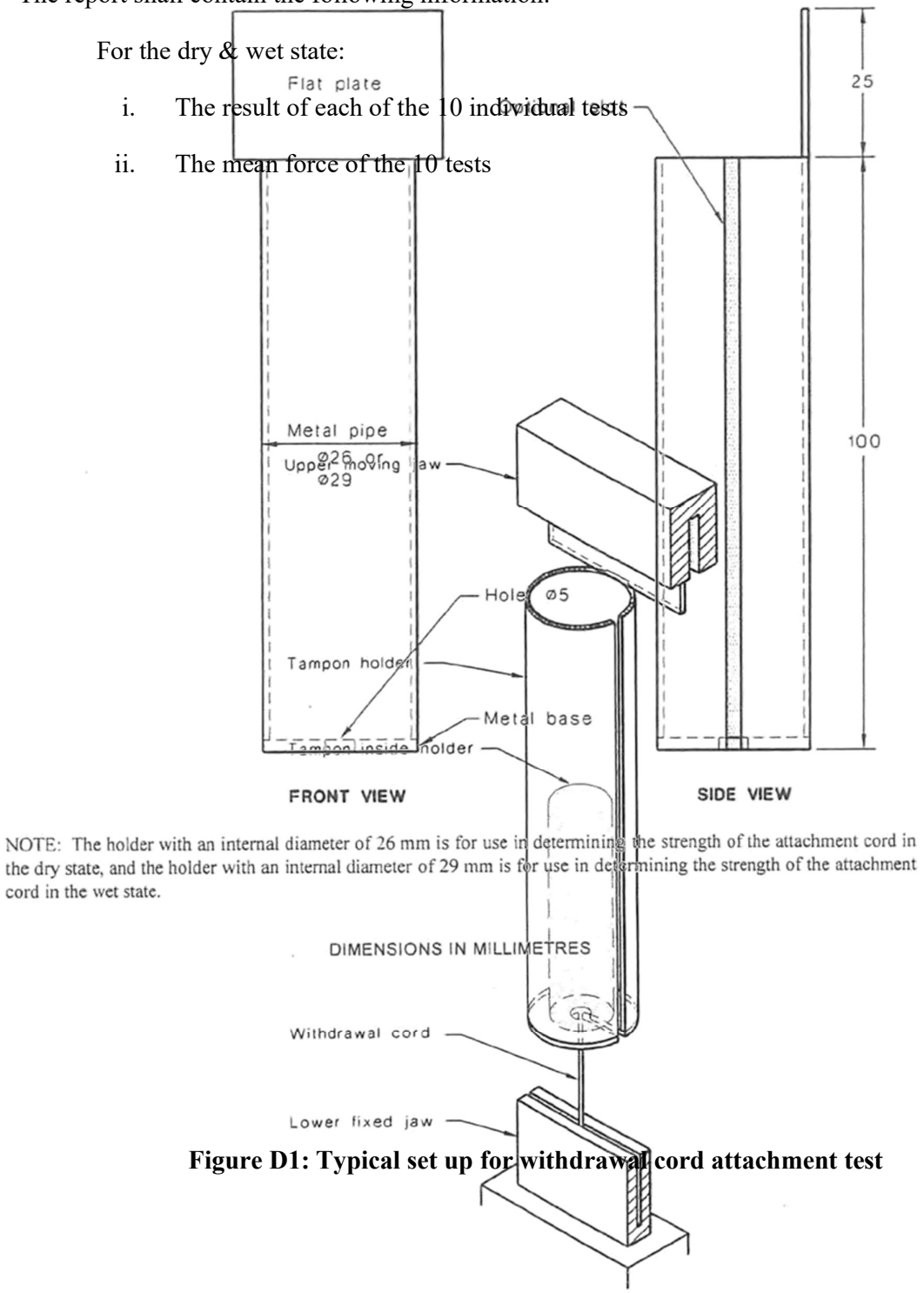
D7. TEST REPORT

The report shall contain the following information:

For the dry & wet state:

i. The result of each of the 10 individual tests

ii. The mean force of the 10 tests



NOTE: The holder with an internal diameter of 26 mm is for use in determining the strength of the attachment cord in the dry state, and the holder with an internal diameter of 29 mm is for use in determining the strength of the attachment cord in the wet state.

Figure D1: Typical set up for withdrawal cord attachment test

Figure D2: Front and side views of typical tampon holder

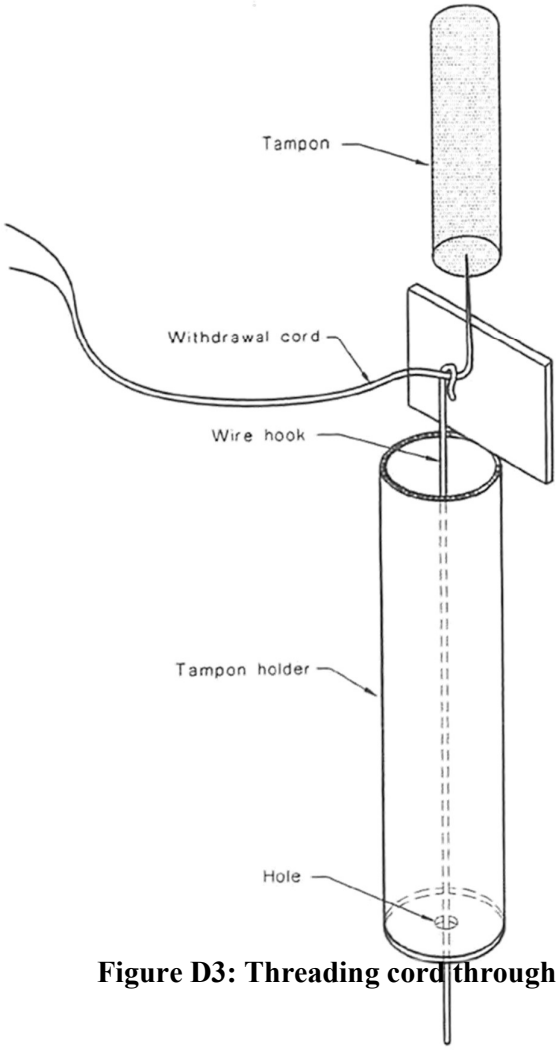


Figure D3: Threading cord through tampon holder

ANNEX -E

METHOD FOR DETERMINING TOTAL AEROBIC MICROBIAL COUNT

E1. SCOPE

This Annex sets out a method for determining the total aerobic microbial count in tampons and in their applicators, where these are provided.

E2. PRINCIPLE

Samples of tampon and applicator, where provided, are cultured for aerobic bacteria and fungi on appropriate nutrient media and incubated under optimal conditions. The total microbial count per gram is determined separately for the tampon and the applicator.

E3. APPARATUS

The following apparatus is required:

(a) Incubators capable of maintaining a temperature at 32 ± 2°C and 20°C - 25°C

(b) Laboratory blender.

NOTE: A 400 mL capacity stomacher type has been found to be appropriate.

(c) 80 sterile Petri dishes for tampons; 80 sterile Petri dishes for applicators, where provided.

NOTE: Nominally 90 mm Petri dishes are suitable.

(d) Colony counter.
(e) 10 sterile pipettes for tampons 10 sterile pipettes for applicators, where provided.
(f) Sterile stomacher bags.
(g) Top pan balance, accurate to 0.l g.
(h) Disinfectant.
(i) Scissors.
(j) Forceps.
(k) Scalpel blades.
(l) Tray or sterile Petri dishes.
NOTE: The scissors, forceps, scalpel blades and tray are to be provided sterile for each use or are to be dipped in ethanol (see Paragraph F5(d)) and flamed between uses.
(m) Laminar flow cabinet complying with relevant standard.

E4. CULTURE MEDIA AND REAGENTS

The following culture media and reagents are required:

(a) Plate count agar (PCA).

(b) Sabouraud dextrose agar (SDA), with or without 0.01% oxytetracycline (w/v).

(c) Sterile solution of 0.1% peptone water with 0.01% Tween 80.
(d) Ethanol, 70% (w/w) or greater concentration, for flaming forceps, scissors, blades and tray.

E5. LABORATORY CONDITIONS

Before commencing the test, carry out the following proced ures:

(a) Switch on laminar flow, disinfect all working surfaces and leave for 15 min .
(b) Conduct environment control monitoring of the test area to detect background contamination.

(c) Monitor media for microbial contamination by use of appropriate control plates.

NOTE: One plate from each flask of agar is considered adequate.

E6. TEST SPECIMEN

Select 10 primary packs at random from one homogeneous batch. From each of these packs remove a single unit pack with forceps. Place samples on a sterile surface, e.g. tray *or* Petri dish. These 10

tampons and their applicators, where provided, make up the test sample and are individually tested .

E7. PROCEDURE

In the laminar flow cabinet, the procedure shall be as follows:

(a) Tare a sterile stomacher bag.

(b) Aseptically remove a tampon and the applicator, where provided, from the wrapper.

(c) Dip forceps in ethanol and flame between each transfer.
NOTE: The methodology to be used will depend on the type of wrapping on the tampons.

(d) Aseptically transfer the tampon to the stomacher bag and weigh it. Repeat for the applicator.

(e) Add 100 mL of sterile peptone solution (see F4(c)) to sterile stomacher bag containing the tampon or applicator and process for 1 min.

(f) Transfer 5.0 mL aliquots of the extract to each of eight Petri dishes, taking care to avoid fibers in the extract. Repeat for the applicator, where provided .
NOTE: The testing of four x 5.0 mL aliquots for each of the bacterial and fungal counts is equivalent to testing duplicace 10.0 mL samples.

(g) Add PCA (approximately 15 mL) into each of the first set of four plates and SDA with or without oxytetracycline (approximately 15 mL) into each of the second set of four plates.

(h) Mix contents by swirling and allow to set.
NOTE: Because of the extra volume in the plates, care must be taken during swirling so that the contents are not spilt.

(i) Incubate all PCA plates at 32 ±2°C for 48 h for aerobic bacteria.

(j) Incubate all SDA plates at 20°C to 25°C for 5 days for fungi.

(k) Repeat steps (a) to (U) for the remaining 9 tampons (and the 10 applicators if provided).

E8. DETERMINATION OF AEROBIC COUNT

Determine counts for tampons and applicators separately as follows:

(a) Using colony counter, examine all plates and count colonies observed. Do not count fungal colonies that appear on the PCA plates or bacterial colonies that appear on the SDA plates.

(b) Calculate the bacterial count using the following equation:

Total aerobic bacterial count per gram of tampon or applicator =

$$\left[\frac{\frac{(C1 + C2) + (C3 + C4)}{2}}{T} X\ D\right]$$

Where

C1 : count on PCA plate 1,
C2 : count on PCA plate 2,
C3 : count on PCA plate 3,
C4 : count on PCA plate 4,
D : dilution factor of the plates being counted = 10
T : weight of the tampon or applicator, in grams

(c) Calculate the fungal count using the following equation :

Total aerobic fungal count per gram of tampon or applicator =

$$\left[\frac{\frac{(C5 + C6) + (C7 + C8)}{2}}{T} X\ D\right]$$

Where

C5 : count on SDA plate 5,
C6 : count on SDA plate 6,
C7 : count on SDA plate 7,
C8 : count on SDA plate 8,
D : dilution factor of the plates being counted = 10
T : weight of the tampon or applicator, in grams

(d) Calculate the total aerobic microbial count using the following equation:

Total aerobic microbial count per gram of tampon or applicator = total aerobic bacterial count + total aerobic fungal count

(e) Calculate the count per gram of tampon and applicator separately.

E9. TEST REPORT

The report shall contain the following information:

(a) The total aerobic microbial count per gram of each tampon .
(b) The total aerobic microbial count per gram of each applicator (if they are provided).

Proposed draft Indian Standard

Medical Textiles — Dressing, Wound Care IV Cannula Fixator Dressing — Specification

FOREWORD

(Formal clauses to be added later)

IV Cannula Fixator Dressing is I.V. dressing designed for optimal catheter securement. It ensures secure placement by preventing edge lift, adapting to patient movement, and managing moisture effectively. The product should deliver securement and comfort, offering extended wear time and gentle removal for enhanced patient care. It is indicated for use with short peripheral and midline venous catheters, central venous catheters (including subclavian, jugular, femoral, and PICCs), arterial catheters, tunneled central vascular devices, enteral feeding tubes, dialysis catheters, adult and pediatric venous catheters, and pulmonary artery catheters.

1 SCOPE

This standard specifies requirements for IV Cannula Fixator Dressing with or without antimicrobial, intended for medical use.

2 REFERENCES

The product will comply to the requirements of applicable regulatory requirements prevalent at the time, such as but not limited to the Medical Device Rules, 2017 under the Drugs & Cosmetics Act, 1940 and Rules thereunder. In case the product is being manufactured for exports, the applicable importing country regulations will be applicable.

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 TERMS AND DEFINITIONS

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

3.1 IV Cannula Fixator Dressing – A sterile flexible dressing made of an adhesive material with a water-resistant film to secure and protect I.V. catheters or cannulas in place and prevent the catheter from dislodging or moving, reducing the risk of infiltration or infection

3.2 Barrier properties - The waterproof film serves as a barrier against liquids, bacteria, and viruses, helping prevent surgical site infections while providing secure, comfortable wear with extended duration and gentle removal.

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

3.3 Moisture vapor transmission: The rate at which a barrier permits moisture to penetrate or escape. In pharmaceutical packag ing the moisture vapor transmission rate is one element that determines the shelf life and expi ration of a medication.

3.4 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 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.

5 GENERAL REQUIREMENTS

5.1 Product (s) shall meet all the requirements specified in this standard throughout their useful life. Raw materials and packaging materials used should not contain natural rubber latex, animal derived materials or DEHP (di(2-ethylhexyl) phthalate).

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 IV Cannula Fixator Dressing. The quality management system shall include a risk management procedure where inputs for product realization shall include the outputs from risk management.

The requirements specified in this standard shall be met and documented that the fitness for the intended purpose has been established for IV Cannula Fixator Dressing.

Microbiological monitoring (as per ISO 14698-1), air monitoring of clean room (as per ISO 14644-1), sterilization (as per /ISO 11137), packaging (as per ISO 11607 Part 1 & Part 2) and validation (as per ISO 11137 Part 1 & 2) shall be maintained by the manufacture.

6 REQUIREMENTS

6.1 IV Cannula Fixator Dressing shall conform to the requirements specified in Table 1.

Table 1 Performance Requirements for IV Cannula Fixator Dressing

(Clause 5.1)

Sl. No.	**Characteristics**	**Requirement**	**Method of Test, Ref to**
(1)	(2)	(3)	(4)
i)	Waterproofness*	Complies with test	IS 14944 Fluid-

ii)	Length (± 5% cm)	Complies	Physical Measurement
iii)	Width (± 5% cm)	Complies	Physical Measurement
iv)	MVTR*	NLT 1 g/10 cm^2/24 hours	IS14944
v)	Bacterial and viral barrier *	Complies	Annexure B
vi)	Cytotoxicity *	Complies	ISO 10993
vii)	Primary Skin Irritation *	Complies	ISO 10993
viii)	Skin Sensitization test *	Complies	ISO 10993
ix)	Border Available	Complies	Physical Measurement
x)	Hypo-allergenic *	Complies	Reference ??
xi)	latex-free dressing*	Complies	Reference??
xii)	Sterility Testing	Complies	IP Pharmacopoeia
xiii)	Package integrity testing	Complies	ISO11607

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* These tests need to performed during the design finalization of the product, any change in the critical raw materials or process changes calls for reevaluation and testing if required.

7. MARKING

7.1 Each piece of the IV Cannula Fixator Dressing shall be legibly marked with the following information:

a) Name of the product

b) Manufacturer's name, initials or trade-mark, if any;

c) Month and year of manufacture;

d) Size; and

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

7.2 BIS Certification Marking

The product may also be marked with the Standard Mark.

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

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 Lot

All the IV Cannula Fixator Dressing of the same material and dimensions produced under similar conditions of manufacture within a single Sterilization Batch shall constitute a lot.

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

8.1.2 The number of IV Cannula Fixator Dressing to be selected from the lot shall depend on the size of the lot and shall be in accordance with col 1, 2 and 4 of Table 2.

Table 2 Number of IV Cannula Fixator Dressing to be selected

(*Clause* 7.1.2)

Lot Size	**Non-destructive Testing**		**Destructive Testing**	
	No. of dressings	Acceptance	No. of dressings	Acceptance
to be selected	Number	to be selected	Number	
N	n	a	n_1	a_1
(1)	(2)	(3)	(4)	(5)
Upto 280	13*	1	8	0
281 to 500	20	2	8	0
501 to 1 200	32	3	13	0
1 201 to 3 200	50	5	13	0
3 201 to 1 0000	80	7	20	1

* or lot size when less than 13

8.1.3 These IV Cannula Fixator Dressing shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

8.2 Number of Tests and Criteria for Conformity

8.2.1 All the selected IV Cannula Fixator Dressing as per col 2 of Table 2 shall be examined for workmanship and finish (see **4.1**).

8.2.1.1 Any IV Cannula Fixator Dressings 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 3 of Table 2. Otherwise, the lot shall be rejected.

8.2.2 Out of the sample already found satisfactory according to 7.2.1.1, a sub-sample as per col 4 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

8.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective tapes found in the sample (as per **8.2.2**) is less than or equal to the acceptance number as given in col 5 of Table 2.

9.PACKING

The IV Cannula Fixator Dressing shall be packed securely to allow normal handling and transport without tearing and exposing the contents and sterility to be maintained till the pack is opened. 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.

10 Labelling

Labelling should include the name of the product, batch number, manufacturing date, license number and address as per the labelling and marking requirements of Medical Device Rules 2017.'

ANNEX 16

(Item 7.1)

REVIEW OF R&D PROJECT - Project Number: TXD 0035 Study of safety, performance and constructional requirement for surgical sutures (absorbable and non-absorbable)

Doc no. SCMD/R&D Guidelines/20240522

GUIDELINES FOR RESEARCH & DEVELOPMENT PROJECTS FOR FORMULATION AND REVIEW OF STANDARDS (*First Revision*)

1 INTRODUCTION

Bureau of Indian Standards (BIS), as the National Standards Body of India is responsible for formulating Indian Standards for products, processes and services. In the pursuit of this endeavour, it has so far developed more than 22000 Indian Standards. Action Research and Research & Development Projects have always been part of the standardization process. However, there has been a growing realisation in the context of the increasing diversification, innovation and complexities in the manufacturing sector and evolution of services and also due to the fast pace of changes in the manufacturing and services landscapes, research & development projects have to be made an integral part of the standardization process. The idea is that in principle no standard should be developed without intensive and insightful research work, which is not confined only to the review of the existing literature and focus group discussions on the subject chosen for standardization, but also covers the detailed field level study of the existing processes and practices in product manufacturing and service delivery. This requires a large network of domain area experts to carry out the research & development work. The existing network encompasses only a small segment of experts, who are either associated with technical committees as members or belong to some R&D organizations. The Memorandum of Understanding with the premier educational institutions imparting technical and professional education opens the window to the opportunities to expand this network substantially by utilizing the intellectual capital that resides with the faculty and the research scholars in these institutions. This association is conceived not only as a way to promote research & development work necessary for standards formulation but also to enrich the research ecosystem in these educational institutions.

2 OBJECTIVES

Objectives of this Scheme are to:

2.1 support and commission research & development projects to generate knowledge, empirical data and insights that would help in formulating new standards and updating & upgrading the existing Indian standards;

2.2 expand the network of domain area experts to carryout research & development projects in the areas related to standardization and conformity assessment; and

2.3 enrich the research ecosystem in the educational institutions imparting technical and professional education.

3 RESEARCH & DEVELOPMENT PROJECTS

3.1 Research & development projects under these guidelines are described as follows:

A project aimed at comprehensive, in depth and incisive study of a product, process or service or all taken together in respect of a subject under standardization, encompassing literature review, analysis of the data from secondary sources, collection and analysis of data from primary sources and stakeholder consultations.

3.2 The duration of a project shall not exceed six months counted from the date of release of the first instalment of the funds to acceptance of the final report by the Sectional Committee concerned, provided that the Sectional Committee must not take more than one month to give its decision on the final report. Further provided that the time taken by the Sectional Committee for giving its decision shall not be counted. The Sectional Committee may extend the duration but for not more than 2 months in special circumstances, the reasons for which shall be recorded in the minutes of meeting of the Sectional Committee.

3.3 The upper limit for expenditure for a project shall be Rs 10 lakhs (including taxes) only.

3.4 BIS will publish a list of research & development projects along with Terms of Reference (ToR) on Standardization portal or any other suitable digital platform.

3.5 If any organization or an expert on behalf of an institute wants to propose a research & development project on any new and emerging area in which they have expertise, they can do so through the same platform for the consideration of the Sectional Committee.

4 TERMS OF REFERENCE (ToR)

4.1 The ToR of Research& development project shall be prepared by the Sectional Committee concerned, and shall contain:

a) Title, background and objectives of the study;
b) Expected research methodology (brief information, for example, survey, testing, industry visits, etc.);
c) Scope of study;
d) Outline of the tasks and final deliverables expected from the Proposers;
e) Methods of review, schedule for submitting the 1st draft report and project completion report;
f) Any support or inputs to be provided to the Proposer; and
g) Maximum duration of project and timelines for submission of proposal.

4.2 While preparing the Terms of Reference (ToR) the sectional committee may consider the following points as a research & development project may include one or mix of the following:

a) Secondary research based on internet or published information including authentic data sources;
b) Survey based research (including industry visits) to ascertain prevailing market conditions and practices, standards in use, industry and consumer preferences, availability of infrastructure, technical capabilities, comparative trends, economic trends;
c) Ascertaining compliance to existing and proposed standards through testing, review of past test reports, other validation and verification checks; and
d) Basic and innovative research to establish normative criteria. Criteria may include performance, health, safety, environmental impact.

5 APPROVAL OF COMISSIONING OF THE RESEARCH AND DEVELOPMENT PROJECTS

5.1 There shall be a Review Committee for approving the projects recommended by the Sectional Committee. The composition of Review Committee shall be as follows:

DDG (SCMD)	: Chairperson
DDG (Standardization) concerned	: Member
DDG (Certification)	: Member
DDG (Labs)	: Member
Officer in-charge for research works in SCMD	: Member Secretary

5.2 The Head of Technical Department concerned and Member Secretary of the Sectional Committee shall apprise the review committee about the project and explain the rationale behind the proposed research & development project.

6 ELIGIBILITY CRITERIA

6.1 The following shall be eligible for carrying out research & development projects under the Scheme:

a) Academic institutions & universities having MoU with BIS and faculties and research scholars thereof;
b) Member(s) of Technical Committees of BIS.
c) Government research laboratories of repute like CSIR, DRDO, ICAR etc.

6.2 Faculties and research scholars shall submit proposals through their institute. Members

of technical committees belonging to any association/organization shall submit the proposals through their association/organization. Members of technical committees in personal capacity can submit their proposals directly to BIS, however if carrying out a research & development

project requires collaboration with any institution/organization, concurrence of the same shall also be submitted.

7 PROCEDURE FOR APPLICATION

7.1 Submission of Proposal

7.1.1 Applications for undertaking research & development projects shall be submitted in the manner prescribed by the Bureau and within the prescribed timelines,

7.1.2 Proposer(s) shall submit their proposal in a "single stage - two envelope bid system" consisting of separately sealed "Technical and Financial proposals". The Technical Proposal shall be submitted as per format prescribed in **Annex A** and the Financial Proposal shall be submitted in the format prescribed as per **Annex B**, clearly specifying expected expenditure against each element such as manpower, equipment (shall not include standalone desktops/laptops/printers etc), travelling, testing, consumables, stationery, overheads, etc.

7.2 The proposals shall inter-alia consist of the following:

7.2.1 In respect of the research & development projects put up by the Bureau:

a) Details of the Project team along with the organization/institution associated with;
b) The CV of the Project leader and expert/expert(s) to be associated with the project and a letter from organization authorizing Project Leader and expert/expert(s) to undertake the research as proposed.
c) A write up on the understanding of the scope and objectives of the project.
d) Methodology (sampling size, if applicable) to be adopted for the proposed study with a clear road map and time plan for completion of the project;
e) Stage wise timelines for completion of the project.

7.2.2 In respect of research & development projects proposed by any expert/organization:

a) Details of the Project team along with the organization/institution associated with;
b) The CV of the Project leader and expert/expert(s) to be associated with the projects and a letter from organization authorizing Project Leader and expert/expert(s) to undertake the study as proposed.
c) Objective that will be achieved and scope of the project clearly highlighting the need of such study and what would be the final deliverable;
d) Methodology (sampling size if applicable) to be adopted for the proposed study with a clear road map and time plan for completion of the project;
e) Details of infrastructure facilities available for the project, in the institution and

additional facilities required (if any) for carrying out research.

f) Stage wise timelines for the completion of the project

7.3 The Head of the concerned institution while forwarding the application and nominating the project leader shall certify that:

a) the core facilities (land, buildings, laboratory, manpower and other infrastructure etc.) are available and will be provided to the Project Leader to work on the proposed project,
b) the organization will discharge all its obligations, particularly in respect of management of the financial assistance given, and
c) no other funding is being received/sought for the project proposed to be sanctioned by BIS.

8 PROCEDURE FOR APPROVAL WITHIN BIS

8.1 There shall be a Research Evaluation Committee (REC) to evaluate the proposals received, the composition of which shall be as follows:

DDG (PRT)	: Chairperson
Head (CMD) concerned	: Member
Head (LPPD)	: Member
Head of the Technical Department concerned	: Member
Director Finance	: Member
Two Experts from the Sectional Committee concerned	: Members
Head (SCMD)	: Member Secretary

*The experts shall be nominated by the Sectional Committee and the nominated members shall give a declaration to the effect that there is no conflict of interest with respect to the project.

8.2 The evaluation and selection will be as per Quality and Cost Based Selection (QCBS) method (Rule 192, GFR 2017) which is explained in **Annex C**.

8.3 The criteria for evaluation of technical proposal shall be as under:

Sl No.	**Criteria**	**Max. Marks**	**Score by REC**
1	Profile of key individual/individuals to be associated with the research project	**10**	
2	Experience of the individual/organisation in conducting research projects in the relevant discipline	**20**	
3	Understanding of Scope, Objectives and deliverables	**15**	
4	Methodology	**30**	
5	Work plan/Execution strategy	**15**	
6	Chapterisation, contents and lay out of the proposed report	**10**	

TOTAL	**100**	

Note: REC may call for a presentation by the proposers if deemed necessary.

8.4 The minimum qualifying marks shall be 70. All the proposals with marks below 70 shall be considered rejected.

8.5 REC may refer back, advise changes for reconsideration or reject any proposal.

8.6 REC shall open the financial proposals (bids) within 7 days from completion of technical evaluation.

8.7 A final score sheet of all the proposers shall be made as detailed in **Annex C** and the proposer getting the highest combined score shall be selected for awarding the project.

8.8 The member secretary (REC) shall send the selected proposals to DG/DDG Standardization concerned, as per their delegated powers, for consideration and approval for sanction of the project.

8.9 After the approval of project, the member secretary (REC) shall inform the concerned technical department and the proposer regarding the decision.

9 AWARD OF PROJECT

9.1 After the approval of project, the member secretary (REC) shall inform the concerned technical department and the proposer regarding the decision along with the format of the Consent Letter (Annex D) to be signed by the proposer.

9.2 After receipt of duly signed consent letter from the proposer, the first instalment of the total approved project cost shall be released. The project would be considered to have commenced from the date the first instalment is released.

9.3 In case the proposer to whom the project is awarded declines to take up the project, the Research project shall be awarded to the proposer getting the next highest combined score among the qualified proposers.

10 FUNDING

10.1 The mode of payment for Research & development projects shall be as follows:

a) First instalment of 30 percent of the total approved project cost would be released after approval of the project.
b) Second instalment to the extent of 50 percent of the approved estimated cost would be released on the submission of progress report along with the report on utilization of the

75 percent of the fund and acceptance of the same by the Sectional Committee.

c) The balance amount shall be released after submission of the final project report along with utilization certificate for the fund released and its acceptance by the Sectional Committee.

10.2 Release of each instalment is subject to satisfactory progress, required stage - wise deliverables and submission of the Utilization Certificate (UC) as per Form GFR12-A of GFR 2017 along with the statement of expenditure (SoE) issued by the Competent Authority.

11 PROGRESS REPORT AND MONITORING OF PROJECT

11.1 The relevant Sectional Committees of BIS will monitor the progress of project to ensure that the project is progressing as per the planned arrangement. However, member secretary of the concerned Sectional Committee under overall coordination of HoD would be the controlling/link officer for Research & Development projects and would constantly monitor the progress of the project every 30-45 days. Any delay in implementation of project should be duly justified by the Project leader and shall be put up to the sectional committee for approval.

11.2 The Sectional Committee shall review and give its acceptance of the progress reports submitted, within 3 weeks.

12 SUBMISSION OF FINAL PROJECT REPORT (FPR)

12.1 The FPR must be detailed and should include information about:

a) the original objective(s) of the project,
b) how far these objective(s) have been achieved, and
c) how the results will benefit the development of the national standard(s) and
d) a copy of final working draft of the concerned standard(s) (wherever applicable)
e) include clear inferences, recommendations regarding their use in the proposed standards,
f) all references used, raw data of surveys, sampling, testing and experiments,
g) undertaking that all the information presented is authentic.

12.2 FPR received in BIS would be put up to the concerned Sectional Committee, which will take necessary action for preparation/revision of standard appropriately. The Project leader shall assist in the disposal of comments received on the research project, draft standard and for the preparation of the finalized draft, as may be desired by the Sectional Committee.

12.3 The proposer shall submit the Project Completion Report (PCR), within one month of completion of project along with the Utilization Certificate of the fund released as per Form GFR 12-A of GFR 2017 and the statement of expenditure (issued by the Competent Authority -in case of Govt. organization / Charted Accountant in case of private organization).

13 RESULTS OF RESEARCH & DEVELOPMENT

13.1 Project Leader(s) would be encouraged to publish the results of research & development. While doing so, acknowledgement to the effect that financial assistance was received from BIS

should be made in the research paper(s) published. BIS should be acknowledged in similar type of other published work/press reports.

13.2 One re-print of each research paper(s) published as a result of the work done under the BIS funds shall be sent to BIS as and when published.

14 INTELLECTUAL PROPERTY RIGHTS

14.1 Ownership of any intellectual property, including but not limited to confidential information, know-how, patents, copyrights, design rights, rights relating to computer software, and any other industrial or intellectual property rights, developed solely by Proposer shall be vested with that Party.

14.2 Ownership of any intellectual property, including but not limited to confidential information, know-how, patents, copyrights, design rights, rights relating to computer software, and any other industrial or intellectual property rights, developed solely by the Bureau shall be vested with that Party.

14.3 The Intellectual Property arising out as an outcome of research project undertaken under these guidelines shall be vested with Bureau.

14.4 The proposer shall indemnify BIS from any legal and/or financial encumbrance arising out of any infringement of IPR/licensing of IPR/technology transfer/commercialization.

15 OPERATION OF FUNDS

15.1 The utilization certificate of the funds received in previous instalment (if any) to BIS should be annexed with the Statement of all equipment, books, etc purchased out of the funds certified by the Head of the organization. The name, description of the equipment, cost in rupees, date of purchase, and the name of the supplier to be given in the list. The main purpose/function of the equipment may also be mentioned against each item.

15.2 Any unspent balance lying with the organization should be refunded to BIS after the finalization of the draft immediately, by means of demand draft or online transfer.

15.3 The Head of the concerned standardization department of BIS shall ensure that the project leader submits the utilization certificate in the manner prescribed in Form GFR 12-A of GFR 2017.

15.4 Head of the Standardization department shall also ensure that the operation of funds is monitored strictly as specified in **Annex E**. Further the Project Leader is also fully aware and shall adhere to the obligations of his/her as given in this procedure.

16 OTHER REQUIREMENTS

16.1 Organizations receiving financial assistance for research & development projects from BIS would have to maintain separate accounts for each research project.

16.2 In the event of a Project Leader's absence from his normal place of duty for two months at a stretch, the Head of the organization would need to immediately nominate an Alternate Project Leader(s) to supervise the implementation of the project and such a name has to be approved in advance by BIS. In any event, a Project Leader shall give prior notice to BIS of his intention to stay away from the project.

16.3 Items of equipment, etc should be purchased on the basis of the established rules and procedures of the entity/organization.

16.4 Stock register of all equipment, books, etc purchased out of the funds shall be maintained.

16.5 Any capital-intensive equipment/devices purchased using financial assistance from BIS for research & development projects shall be allowed to be retained by the proposer for their research activity etc.

16.6 The organization shall have to ensure that expenditure with respect to TA/DA are made only as per their own norms but under no circumstances the executive/business class air travel or stay in a five-star hotel is made. The overhead expenses should not be more than 20 percent of the cost of the project.

16.7 The Project Leader must ensure that the concerned organization's newsletter would carry information on the activities and accomplishments of the various projects funded by the BIS.

17 TERMINATION OF PROJECT

The research & development project can be terminated in case of any of the following:

a) the approval of research & development project may be treated as withdrawn, if the sanctioned research & development project does not commence within one month from the date of receipt of the sanction letter, unless otherwise authorized by BIS;
b) A Proposer may request for the withdrawal of a research & development project even after commencement of the project. In such case the entire fund given till that date shall be refunded to the Bureau; and
c) if the Proposer fails to submit Progress report/Final Project report within the prescribed timelines.

The REC shall take decision on all cases of termination.

18 RESOLUTION OF DISPUTES

Dispute Resolution: In case of any dispute that cannot be resolved amicably, it shall be referred to Sole Arbitrator appointed by the Director General of the Bureau of Indian standards, whose decision shall be final and binding upon both the parties. The provisions of the Arbitration and Conciliation Act, 1996, as amended from time to time, shall be applicable.

ANNEX A

TECHNICAL PROPOSAL

1. Name of the Proposer and Organization	
2. Project title	

3. Project leader

a) Title: Prof/Dr/Mr/Ms b) Name:		Sex M/F
c) Full official address		
Mobile/Telephone Fax E-mail		
d) Designation		
e) Date of birth		
f) Academic qualifications along with year of completion		
g) Experience		

4. Other members of the research team (give name, address, experience and academic qualifications for each member)

1. Name	Designation: Address: Experience: Academic Qualifications:
1. Name	Designation: Address: Experience: Academic Qualifications:

5. Research support availed/being availed/applied for by the Project leader from different sources, including BIS, during the last 5 years:

Funding agency	Title of the project and reference number	Duration (from mm/yyyy to mm/yyyy)	Percentage of time devoted /being devoted/to be devoted, in man months	Amount in lakh Rs.

6. Details of facilities available with the institute/organization w.r.t. the research & development project

Facilities	Relevance to project
1.	

7. Aims and significance of the project
(Include the current status of work in area, both in India and abroad, with appropriate reference list at the end; identify lacunae, define question to be investigated; list briefly specific objectives of investigation. ethical clearance be enclosed where necessary).

8. The CV of the Project leader and expert/expert(s) to be associated with the projects and a letter from organization authorizing Project leader and expert/expert(s) to undertake the study as proposed.

9. Objective that will be achieved and scope of the project clearly highlighting the need of such study and what would be the final deliverable.

10. Methodology (sampling size if applicable) to be adopted for the proposed study.
11. Road map (Stage wise timelines for the completion of the project) and time table for completion of the project
12. Plan of work, methods and techniques to be used.
13. List of awards and honours conferred on the Project leader with dates.
14. Deliverables
15. Declaration and attestation:

I certify that all the details declared here are correct and complete. Signature of Project leader	Date:

12. Certificate of the institution:

This is to certify that

a) we have read the terms and conditions of the BIS Research & Development Guidelines necessary for the compliance of the same.
b) the necessary institutional facilities are available and will be provided for the implementation of this research proposal being submitted to the BIS for funding.
c) Full account of expenditure will be rendered by the institution.

	Name of the head: of the institution Signature with date: Seal:

ANNEX B
FINANCIAL PROPOSAL FORMAT

[To be submitted on letterhead wherever applicable]

To:

Bureau of Indian Standards

Manak Bhavan, 9 Bahadur Shah Zafar Marg
New Delhi – 110002, India

Sub: Financial Proposal for Research & development Project on (Title: _____)
for Bureau of Indian Standards (Research guidelines document no._____dated---------- ____).

Dear Sir,

We are pleased to submit our Financial Proposal for Research & Development Project on (Title: _____) for Bureau of Indian Standards as per the terms and conditions of the Research & Development guidelines document (Ref No.: _____dated: ___-___-___).

1. We hereby declare that our financial proposal is unconditional in all respects.
2. Our financial proposal is as follows:

3. Cost of the Project:

Sl no.	Budget items	Amount
1	Manpower cost	
2	Consumables [Chemicals, samples, testing glassware, stationery, books etc, information search (from databases)]	
3	Equipment	
4	Travel	
5	Any other/Overhead expenses	
	Total project cost	

*Please write NA in case any item is not applicable

a) The prices should be quoted in Indian Rupees above by the proposer.
b) The quoted price should be inclusive of all applicable taxes and charges.
c) Fund shall be released after deducting TDS as per applicable provisions of GST and income tax.
d) Justification of cost (for each item of equipment, consumables and travel. Quotation(s) for equipment should also be enclosed).

Yours faithfully,

Date: (Signature of the Project leader)

Place: (Name and Designation of the proposer)

Name and Signature of the head of the institution

(Rubber seal of the proposer/institution/organization, as applicable)

ANNEX C

Stage 1: Evaluation of Technical Proposal:

a) The proposal will be evaluated against the criteria defined at clause **8.3** in these Guidelines. The proposer may be required to provide additional details as deemed necessary by the REC.

b) Upon technical evaluation of each proposal, "Technical marks" out of 100 marks will be assigned to every proposal.

c) The proposals with score 70 or more marks in technical evaluation, will qualify for the evaluation of the financial proposal.

d) The proposer with the highest marks in technical proposal will be awarded 100 "Technical Score" and subsequently other proposers will also be awarded "Technical Score" relative to the highest technical marks for the final composite score calculation purpose e.g., if the highest technical marks is 90 then "Technical Score" is (90/90) × 100 = 100, hence the proposer with highest technical marks will score 100"Technical Score". Similarly, another proposer who scored 80 marks, will get (80/90)x 100 = 88.88 "Technical Score". Following formula will be used for the "Technical Score" (TS) calculation:

$$\text{Technical Score (TS)} = \left[\frac{\text{Proposer's Technical Marks}}{\text{Highest Technical Marks}}\right] \times 100$$

Stage-2 Evaluation of Financial Proposal

a) The evaluation will be carried out if financial proposals are complete and computationally correct.

b) Upon financial evaluation of each proposal, the lowest financial proposal will be awarded 100 "Financial score". The "Financial Score" of other proposer(s) will be computed by measuring the financial proposal against the lowest financial proposal. Following formula will be used for calculating "Financial Score":

$$\text{Financial Score (FS)} = \left[\frac{\text{Lowest Financial proposal}}{\text{Proposer's Financial Proposal}}\right] \times 100$$

Stage-3 Computation of Combined Score

The "Combines Score" is a weighted average of the Technical and Financial Scores. The ratio of Technical and Financial Scores is 70:30 respectively. The Combined Score will be derived using the following formula:

$$\text{Combined Score} = [(\text{TS} \times 0.70) + (\text{FS} \times 0.30)]$$

The responsive proposers(s) will be ranked in descending order according to the Combined Score, which is calculated based on the above formula. The highest-ranking proposer asper the Combined Score will be selected for award of Research Project.

ANNEX D

CONSENT LETTER

This has reference to award of the following R&D Project in favour of the undersigned.

Project Code	Project Title	Proposer	Financial Proposal (in lakh Rs)

I/We hereby give consent to the execution of the above project, which shall be governed by the following:

i) Terms of Reference (ToR) of the project mentioned above;
ii) Guidelines for R&D Projects (SCMD/R&D Guidelines/20240522);
iii) Proposal submitted by us.

I/we understand that the first instalment (30 percent of the approved financial proposal) shall be released after submission of this consent by us. The amount may please be transferred to the following account:

a) Name of the Account Holder
b) Account No.
c) IFS Code
d) Name & branch of the Bank.

Thanking you,

To be signed by
(Proposer/Project Leader)

Name and Signature of the head of the institution

(Rubber seal of the proposer/institution/organization, as applicable)

ANNEX E

OPERATION OF FUNDS AND PROGRESS REPORT

1. Title of the Project:	Project number:
2. Name & Address of Project leader:	Date of Commencement: dd/mm/yyyy

3. Details of Equipment Purchased (if any):

Name of equipment	Cost	Supplier	Date of purchase/ placing order for each item of equipment
NOTE - The equipment fund once fixed cannot be enhanced. Project leaders are advised to give authenticated estimates of the cost of equipment. Equipment should invariably be purchased within 1 month from the date of receipt of the fund and/or sanction letter.			

4. Fund received_____.
5. Expenditure made in Rupees: (Please provide the details)

Expenditure	Amount	Taxes (as applicable)	Total
Manpower cost			
Consumables			
Equipment			
Travel			
Others			
Grand Total			

6. Amount saved (if any) from the last instalment: Rs_____.

7. Date on which scheme will complete its normal tenure of months _____.

8. Whether extension beyond normal tenure has been requested. Yes /No.

If yes, justification for extension and programme of work to be completed. Also mention as to why the work could not be completed as per the original plan.

{Extension beyond normal tenure should be requested at the Project Monitoring Session before end of tenure (as given in ToR)}.

9. Constraints (if any) faced in the progress of work and suggestions to overcome them.

10. Any deviation from original plan with its nature and cause.

11. List of publication giving full bibliographic details accrued from this project (copies of the paper (s) should be enclosed).

12. Summary of work done (200 words).

13. Proposed programme of work for the next month (1000 words).

14. Detailed Progress Report enlisting the objectives in beginning briefly (up to five pages maximum).

Signature of Project leader
Date:

Note: No column should be left blank; write not applicable (NA), wherever applicable.

TERM OF REFERENCE FOR RESEARCH AND DEVELOPMENT PROJECT

1) **Term of Reference (ToR)** for Working draft for Specification of Surgical Sutures (Absorbable and Non-Absorbable)

2) **Title of the project:** —Working draft for Specification of Surgical Sutures (Absorbable and Non-Absorbable)

3) **Background:-**

i) **Technical Committee:** TXD 36 Technical Textiles for Medtech Applications sectional committee under Textile Division council.

ii) Technical Textiles for Medtech Applications TXD 36 of BIS has identified the subject of surgical sutures (absorbable and non-absorbable). In order to take holistic view on the subject and to formulate an indigenous Indian Standard, a detailed study of Surgical Sutures (Absorbable and Non-Absorbable) on raw material and performance parameter is required.

iii) Briefly explain the rationale for the commissioning of the project.

In India, a wide variety of surgical sutures, including absorbable and non-absorbable sutures, are used across different medical specialties such as orthopaedic, cardiovascular, alimentary, ophthalmic, laparoscopic, and other surgical procedures. In recent years, suturing techniques have gained increasing significance in minimal access surgeries (MAS) due to their potential to reduce post-operative discomfort, shorten hospital stays, and expedite patient recovery. As a result, the demand for surgical sutures is steadily rising in India. The domestic surgical sutures market is projected to experience a compound annual growth rate

of approximately 4.55%, ultimately reaching an estimated value of $220.0 million by 2028, according to Mordor Intelligence.

Given this growing demand, and diverse applications, it becomes essential to formulate standards that describes the material (such as polypropylene, nylon, polyamide, linen, silk), structure (monofilament or multifilament), length, diameter, knot strength/breaking load, needle attachment, extractable color, sterility, and other safety and performance requirements for various types of sutures. These specifications not only assist manufacturers in producing high-quality sutures and provide patients with a reliable product but also contribute to elevating the quality of locally manufactured surgical sutures to meet international standards.

4) Scope: -

The project aims to bring out a working draft for surgical sutures with specific reference to absorbable and non-absorbable sutures supported by technical information, scientific data, inhouse test report, third party report, International Practice.

The project involves generation and collection of technical data for raw material, general requirement, specific requirement/value and test method for performance parameters like length, diameter, tensile strength, needle attachment strength, breaking strength retention test, biocompatibility evaluation, extractable colour etc.

5) Expected Deliverables: -

i) Detailed information for sutures used in India, their manufacturers and contact details, availability of testing facility and testing laboratories with contact details, List of users/stakeholders and their contact details
ii) Relevant supportive technical documents, test reports, technical and research paper, International Standards, Govt. Technical Regulation, Applicable guidelines as per medical device rules.
iii) To provide the data for the technical and performance requirements of absorbable, non-

absorbable surgical sutures such as length, diameter, tensile strength, needle attachment strength, breaking strength retention test, biocompatibility evaluation, extractable colour etc

iv) To prepare a working draft after incorporating the scope, raw material, manufacture, general requirement, performance requirement, method of test, sampling, packing and marking.

v) Any other important requirement for surgical suture may also be incorporated in the draft standard if required.

6) Research Methodology:-

i) To collect the data for the raw material, varieties, performance parameter, test methods and other requirements of surgical sutures through desktop study, books, magazines, national and international standards/regulation, technical information available with manufactures (small, medium and large scale), laboratories, academia or any other source.

ii) Identifying the stakeholders, including manufacturer, laboratories, etc. for surgical sutures to understand the manufacturing process and collect relevant technical data and information.

iii) Visiting of surgical sutures industries (Large, Medium and small scale) and testing labs to collect information, regarding raw materials, varieties, performance parameters, manufacturing and packaging practices, sampling and testing methods or any other important requirement of surgical sutures (if required).

iv) To purchase/collect one sample from large, medium and small-scale industries of each variety of surgical sutures and carry out tests from NABL Accredited lab equipped with the necessary capabilities for the performance requirement(s) either using Indian Standard/ISO International standards or those specified by the manufacturer on the product labelling. These results are to be tabulated and examined to determine the final values which has to be incorporated in the standard.

v) Visiting, consulting or taking feedback from atleast 5 reputed govt./private hospitals regarding the issues faced related to quality of sutures and including the specific requirement and characteristics in the draft standard. For taking user feedback, the preference shall be given for taking feedback through telephonic discussion, emails, virtual/online meeting or visiting locally available hospitals.

vi) To provide data in tabulated/presentable form and prepare working draft on Specification of Surgical Sutures (Absorbable and Non-Absorbable).

7) Requirement for the CVs:-

Graduate in Textile Technology/Textile Engineering with minimum 5 years of experience

in testing or certification or manufacturing of sutures.

8) Timeline and Method of progress Review :- 5-6 Months

Time line	Method of progress
0 to 45 days	Literature review/Desktop Study Collecting the references (books/magazines/ national and international standards/regulation) and studying these standards to execute the project with appropriate knowledge on the subject. Visiting of surgical sutures industries (Large, Medium and small scale industry) and testing labs to collect information
45 to 90 days	To purchase/collect one sample from Large, Medium and small scale industry) of each variety of surgical sutures Carry out tests from NABL Accredited lab with necessary capability
90 to 135 days	Visiting/Consulting or Taking feedback from atleast 5 Govt/Private hospitals Examining the results of samples tested, Analysing data collected through visit and literature survey/desktop Study
135 to 180 days	Consolidation of data, Submission of working draft of the project.

9) Support BIS will Provide:-

All the relevant Indian Standards/ISO Standards or any other standards required during the project will be provided by BIS.

ANNEX 17
(Item 4.1)

REVIEW OF R&D PROJECT - Project Number: TXD 0035 Study of safety, performance and constructional requirement for surgical sutures (absorbable and non-absorbable)

ANNEX E

OPERATION OF FUNDS AND PROGRESS REPORT

1. Title of the Project: Study of safety, performance and constructional requirements for surgical sutures (absorbable and non-absorbable)	Project number: TXD 0035
2. Name & Address of Project leader: Hemant Sonawane, Johnson and Johnson Pvt. Ltd. Arena Space, Behind Majas Bus Depot. Off JVLR, Jogeshwari (E), Mumbai-400060, India	Date of Commencement: 27/09/2024

3. Details of Equipment Purchased (if any): Not applicable

Name of equipment	Cost	Supplier	Date of purchase/ placing order for each item of equipment
Not Applicable	Not Applicable	Not Applicable	Not Applicable
NOTE - The equipment fund once fixed cannot be enhanced. Project leaders are advised to give authenticated estimates of the cost of equipment. Equipment should invariably be purchased within 1 month from the date of receipt of the fund and/or sanction letter.			

4. Fund received: Not Applicable
5. Expenditure made in Rupees: (Please provide the details): Not applicable

Expenditure	Amount	Taxes (as applicable)	Total
Manpower cost	N/A	N/A	N/A
Consumables	N/A	N/A	N/A
Equipment	N/A	N/A	N/A
Travel	N/A	N/A	N/A
Others	N/A	N/A	N/A
Grand Total	N/A	N/A	N/A

6. **Amount saved (if any) from the last instalment: Rs:** Not Applicable

7. **Date on which scheme will complete its normal tenure of months:** 27/03/2025

8. **Whether extension beyond normal tenure has been requested.** ~~Yes~~ /No.

If yes, justification for extension and programme of work to be completed. Also mention as to why the work could not be completed as per the original plan.

{Extension beyond normal tenure should be requested at the Project Monitoring Session before end of tenure (as given in ToR)}.

9. Constraints (if any) faced in the progress of work and suggestions to overcome them.
Project team have identified following constraints:

- ToR Section 4 d)- Undertake 2 visits to each of small, medium and large-scale manufacturer and collect the information.
    - **Constraint-** BIS facilitated the communication with manufacturer to allow J&J to visit their manufacturing sites, however the confirmation is waited for allowing the visit.
    - **Proposed suggestion-** With the permission of BIS, we will connect with manufacturer via email/over phone and try to collect the required information.

- ToR Section 4 f) Collection of 2 samples from each from large, medium and small-scale industries
    - **Constraint-** Samples was supposed to be collected from small, medium and large-scale manufacturers during site visits, however the visits are not confirmed, following suggestion is proposed.
    - **Proposed suggestion-** Suture samples of relevant manufacturer can be purchased from the market with valid invoices.

10. Any deviation from original plan with its nature and cause.

- Potential deviation - as stated in point no. 9

11. List of publication giving full bibliographic details accrued from this project (copies of the paper (s) should be enclosed).

- Not Applicable.

12. Summary of work done (200 words).

As per of Terms of Reference document, the project team has worked on deliverables mentioned under scope section of TOR. As of now, the project team had made significant progress on following key deliverables:

- ToR Section 4a: The Literature review report is developed by undertaking the review of the existing literature including international standards and regulation, review of Journals and research papers, guidelines published by Health Authority and relevant published information.
- ToR Section 4b: As sutures are regulated under Medical Device Regulation in India, hence their manufacturing sites are registered with CDSCO. The manufacturer information has been collected from the database published on CDSCO Portal. Similarly, Suture Testing Laboratory details have been collected from the list of notified Medical Device Testing Laboratories (MDTL) published by CDSCO.
- ToR Section 4c: The Import and Export data is collected for Sutures. Also reviewed the standards and regulation followed by domestic and foreign manufacturers and completed the comparative analysis.

13. Proposed programme of work for the next month (1000 words).

Project team is planning to execute following key deliverables in the next month:

- ToR Section 4d: With BIS permission collect the required information from manufacturer via email/phone. (Refer Section No. 9.)
- ToR Section 4e: Undertake 2 visits to users (one Govt and one private NABH accredited Hospital) and 2 visits to testing labs (one Govt/ and one private NABL accredited lab) to collect information as per ToR.
- ToR Section 4f: Collection of 2 samples of each variety of surgical sutures and carry out testing from 2 NABL accredited lab for parameters defined in ToR.

14. Detailed Progress Report enlisting the objectives in beginning briefly (up to five pages maximum).

The Progress Report against the deliverables is enclosed as Annexure-I

Signature of Project leader Date:
19 Dec 2024

Progress Report

- **Aim:** Study of safety, performance, and constructional requirements for both absorbable and non-absorbable surgical sutures
- **Objective**: To collect the technical data and scientific evidence for safety, performance and constructional requirement of surgical sutures (absorbable and non-absorbable) from primary and secondary sources.
- **Progress Update**:

ToR Section	Deliverable	Progress
4a	Undertake study and analysis of the existing literature	The Literature review report is developed by undertaking the review of the existing literature including international standards and regulation, review of Journals and research papers, guidelines published by Health Authority and relevant published information.
4b	Collection of the database for manufacturers (small, medium, and large-scale), testing infrastructure and users in the country.	As sutures are regulated under Medical Device Regulation in India, hence their manufacturing sites are registered with CDSCO. The manufacturer information has been collected from the database published on CDSCO Portal. Similarly, Suture Testing Laboratory details have been collected from the list of notified Medical Device Testing Laboratories (MDTL) published by CDSCO.
4c	Collection of import and export data, type of standards and regulations being followed by domestic/foreign manufacturers, comparative analysis of these standards and regulations	The Import and Export data is collected for Sutures. Also reviewed the standards and regulation followed by domestic and foreign manufacturers and completed the comparative analysis.

ToR Section	Deliverable	Progress
4d	Undertake 2 visits to each of small, medium, and large-scale manufacturers and collect the information as per scope mentioned in technical proposal	Refer Section 9 of Annex E. 'OPERATION OF FUNDS AND PROGRESS REPORT'
4e	Undertake 2 visits to users (one Govt and one private NABH accredited Hospital) and 2 visits to testing labs (one Govt/ and one private NABL accredited lab) to collect. Information to be included as per scope mentioned technical proposal	In discussion with Users and Suture testing Labs and visits are being planned in next month
4f	Collection of samples from each from large, medium, and small-scale industries of each variety of surgical sutures and carry out testing from 2 NABL accredited labs (1 Govt Lab and 1 Pvt. Lab) for parameters like but not restricted to length, diameter, knot strength/breaking load, needle attachment, extractable color, sterility. The biocompatibility evaluation data for each type of material used shall be collected from the manufacturers.	Refer Section 9 of Annex E. 'OPERATION OF FUNDS AND PROGRESS REPORT'
4g	Preparation of a comprehensive project report covering all the above information.	Final report will be prepared basis above deliverables.

ANNEX 18

(Item 8.1)

INTERNATIONAL ACTIVITIES

ISO/TC 338 **N 135**

ISO/TC 338 "Menstrual products"
Secretariat: SIS
Committee manager: **Acaralp Jenny Mrs**

ISO TC 338 Plenary meeting agenda December 2024

Document type	Related content	Document date Expected action
Meeting / Agenda	Meeting: VIRTUAL 11 Dec 2024	2024-10-14

DRAFT AGENDA **N 135**

ISO/TC 338 MENSTRUAL PRODUCTS
5th meeting
Virtual meeting December 11, 2024

Number and title of Committee ISO/TC 338 Menstrual products	
Secretariat Swedish Institute for Standards, SIS	**Meeting** Meeting dates: 11 December 2024 10.00-13.00 CET
Host **SIS**	**Place** **Zoom**
Zoom link Meeting: https://sis.zoom.us/j/85226623105?pwd=T2b4afb4JH6bFHYv6iZEizZiTpqovq.1 Meeting ID: 852 2662 3105 Password: 045617	

Registration for the meeting is open in the ISO Meeting tool: https://sd.iso.org/meetings/151424

P-and O-members are invited to inform the secretariat of the committee concerned, within one month of the receipt of this notice of meeting, of their intention to be represented at the meeting, the approximate number of their delegates and their need for interpretation.

Whenever possible, the names of delegates (or observers) and the name of the head of the delegation should also be sent to the secretariat of the committee concerned at least one month before the opening of the meeting.

Les membres (P) et (O) sont invités, dans un délai d'un mois à partir de la réception de la présente convocation, à faire connaître au secrétariat du comité concerné leur intention d'être représentés à la réunion, le nombre approximatif de leurs délégués et leur besoin en matière d'interprétation.

Dans la mesure du possible, une liste indiquant les noms des délégués (ou observateurs), ainsique le nom du chef de la délégation, devrait également parvenir au secrétariat concerné unmois au moins avant l'ouverture de la réunion.

#	Items	Action (e.g for vote for discussion	N-Doc Number*	Time allocated (min)

		for information)		
1	Opening of the meeting (at 10.00 CET)			5
2	Roll call of delegates			15
3	Work environment: Presentation on the ISO Code of Ethics and Conduct Direct link to the ISO Code of Ethics and Conduct			5
4	Adoption of the agenda		N 135	5
5	Appointment of the resolution drafting committee			5
6	Report of the Committee Manager/Chair			5
7	SIS information on Twinning			5
8	SIS information on Sponsorships			5
9	Report - WG 1 Safety, performance and general requirements of menstrual products			10
10	Report - AHG 1 Terminology			10
11 11.1 11.2	Any items from organisations in liaison UNOPS – introduction Liaison with ISO/TC 283 Occupational health and safety management (menopause)			10 5
12	Status of all items of the portfolio and actions to be taken • Current work programme • Update on target dates for work in progress			5
13 13.1 13.2	**Presentation** Metals in Tampons: A Potential Risk to Women's Health Kathrin Schilling, Columbia University Single Use Menstrual Products Determination of Absorption Properties Dr. Jinglei Xie			15 15
14	Establishment of Task Group 2 "Outreach & communication"			10
15 15.1 15.2	Requirements concerning a subsequent meeting Next meeting in Kenya 2025 Offers to host 2026			10
16	Approval of resolutions			15
17	Closure of meeting (at 13.00 CET)			5

Additional relevant information on meetings can be found:

- My ISO job
- TMB/SMB Guidance on effective virtual and hybrid meetings
- ISO Helpdesk knowledge base
- ISO/IEC Directives, Part 1, Clause 4 and Annex SK

For BIS Use Only

BUREAU OF INDIAN STANDARDS

MINUTES

Briefing meeting of Indian Delegation for plenary meeting of ISO/TC 338 scheduled to be held on 11 December 2024

Date of Briefing/Pre-Meeting	Time	Venue
04 December 2024 (Wednesday)	1100 h	Video Conference through CISCO Webex

ATTENDEES:

a) Nominated Experts

i) Shri E. Santhini, Coimbatore
ii) Shri Nirav Mehta, M/s Dima Products (ITTA), Mumbai
iii) Ms. Roocha Khedkar, Kenvue [JNTL Consumer Health (India) Pvt. Ltd.)], Mumbai
iv) Ms. Shivani Swamy, Livinguard Technology Pvt. Ltd., Mumbai
v) Smt. Tanya Mahajan, MHAI/The Pad Project (NGO), India, New Delhi
vi) Shri Dharmbeer, Scientist D and Member Secretary, TXD 36

b) Invitees

i) Dr. R. Radhai, SITRA, Coimbatore
ii) Dr. Sadhana Srivastava, Indian Council of Medical Research, New Delhi
iii) Smt. Shradha Dongre, The Synthetics & Art Silk Mills Research Association, Mumbai
iv) Dr. Namrata Makkar, AIIMS, New Delhi
v) Shri Prashant Jadhav, P & G Mumbai
vi) Shri Mithun Shah, Anabio Technologies Pvt Ltd. Bengaluru
vii) Smt. Rupande Sampat, Chemco Group, New Delhi
viii) Ms. Paradhi Mantri, Soothe Healthcare, Noida
ix) Ms. Saloni Mayekar, Nua Woman (Lagom Labs Private Limited), Mumbai

c) Regret

i) Shri S. Sivakumar, SITRA, Coimbatore

Item 0 WELCOME AND INTRODUCTORY REMARKS

Shri Dharmbeer, Scientist D and Member Secretary, TXD 36 extended a hearty welcome to the experts and members nominated in ISO/TC 338. He emphasized on active participation of the members and requested for the precise inputs so as to decide the India's point of view for the plenary meeting.

Item 1 SALIENT OUTCOMES OF THE BRIEFING MEETING

1.1 Member Secretary informed that the following New Work Item Proposals (NWIP) from India which are under consideration by ISO TC 338 and issued for voting of member bodies: -

i) ISO/TC 338, N 130, ISO/PWI 25130, Menstrual products — General and safety requirements (Under WG 1, Shri S. Sivakumar, Convenor, Last Date of Voting 24 December, 2024)

ii) ISO/TC 338, N 136, ISO/PWI 25071, Menstrual Products — Vocabulary (Under Adhoc Group, Smt. Tanya Mahajan, Convenor, Last Date of Voting 04 February, 2025)

The experts/member also reviewed the agenda of ISO/TC 338 plenary meeting, comments received from Smt Roocha Khedkar, Kenvue, Shri S. Sivakumar, SITRA and discussed the progress report, India's point of view and future action plan of Working Group (WG 1) and Adhoc group.

ITEM 1.1.1 ISO/TC 338/WG 1 Safety, performance and general requirements of menstrual products

After the deliberation, the following was decided: -

i) Shri S. Sivakumar, SITRA, Convenor of WG 1 shall present the status report of WG 1 during plenary meeting highlighting – the work done / progress report by WG 1 since 4th plenary meeting/WG 1 meeting, provide the next meeting date of WG 1/completion of the document, challenges and support required from ISO/TC 338 secretariat/Sub group leaders/WG 1 experts, future action plan/roadmap for completion of the document.

ii) A presentation of 10-12 minutes shall be prepared by Convenor. The ppt shall include the work allotted, progress report on positive work carried out since last plenary meeting, next WG 1 meeting, challenges faced and way forward.

iii) Shri S. Sivakumar, SITRA, Convenor shall clarify the comments received from experts of other National Standards Body on working document (if required/raised during meeting). He may request views of subgroup leader for further clarification. It was suggested not to repeat the issues/comments which have already been resolved.

iv) Shri S. Sivakumar shall review the comments received on Preliminary Work item, ISO/PWI 25130 General and safety requirements of menstrual products after completion of voting and prepare his notes/view point in advance. He may request the sub group leader to share

the brief summary on outcomes, unresolved issues/comments, proposal to overcome them and way forward, timelines to complete task assigned.

v) It was recommended that India should approve ISO Ballot on ISO/TC 338, N 130, ISO/PWI 25130, Menstrual products — General and safety requirements with comments. The experts were again requested to share their comments on ISO/TC 338, N 130, ISO/PWI 25130 latest by 15 December, 2024.

a) It was also discussed that the majority of menstrual products used in India include disposable sanitary pad and reusable sanitary pad. The other products like tampon, menstrual cups are not being used widely in India due to cultural issues, lack of awareness, education and accessibility etc.

b) The main apprehension raised in ISO/PWI 25130 document was that excess/additional safety requirement for internally used products like tampon and menstrual cups which may not be relevant to externally used products like disposable sanitary pad and reusable sanitary pad. The convenor, subgroup leaders and other experts were requested to take note of such requirements and strongly put forward India's point of view.

c) It was agreed that in case of technical matters, the requirement given in IS 5405:2019 Disposable sanitary napkin and IS 17514: 2021 Reusable sanitary napkin shall be referred. In case of additional requirements or against India's point of view, it shall be specified in the respective clause of that product category preferably on raw material stage, recommendary/guidance or optional. There should be separate table for each type of product category.

vi) Any specific safety parameter like anti-microbial, flushable, biodegradable, compositable may be included as an optional requirement/other requirement and adequate technical data should be provided. If the widely accepted test method is not available then the proposer shall be requested to provide the test method in the form of annexure.

vii) As majority of menstrual products in India are disposable type, environmental safety should be included in the working document. The safe disposal of menstrual products may be as per the National regulation and law.

viii) It was suggested that we may agree for exposure-based assessment (EBRA) but in India there are Micro, Small and Medium Industry, NGO which are not located globally so it was

also suggested to put material-wise guidance table of chemical and biological safety parameters along with test method.

ix) The testing method for safety parameter like biocompatibility evaluation -cytotoxicity, skin irritation and sensitization, chemical safety -phthalate, pesticide, heavy metal, dioxin/furan shall be ISO, EN, ASTM etc. and the requirement shall be objective as far as possible. If the widely accepted test method is not available then the proposer shall be requested to provide the test method in the form of annexure.

x) The testing method for biocompatibility evaluation -cytotoxicity, skin irritation and sensitization shall be in accordance of ISO 10993 series which are globally being used for medical device and similar type of products. In case if some experts have apprehension on animal testing, it was requested to ask them the inputs/separate annextures for test methods which are accepted widely. In absence of widely accepted test method, we should go for ISO 10993 series.

xi) Menstrual products in India are also manufactured by micro, small Industries, NGO and so microbiological requirement along with general menstrual hygiene practice should be included in working document.

xii) The upcoming working group meeting (WG 1)/Subgroup Group meeting shall be utilized by convenor/sub group leaders to resolve the comments received on ISO/TC 338, N 130, ISO/PWI 25130, Menstrual products — General and safety requirements and to build consensus on different clauses of the document. In case of any assistance, they shall send communication to TXD BIS with a copy to convenor WG1. Avoid discussion from experts again on the clauses which have been already discussed/finalized.

xiii) In the working group/subgroup meeting, the convenor/sub group leader shall utilize the time effectively, go well prepared in advance and avoid the discussion on the technical clauses/comments which have been already resolved.

xiv) If any expert/delegate does not agree with relevant content/information in clause, ask her/him to not only highlight the issues but also share the specific proposal or ask her/him to rewrite the sentence. It is collective responsibility. It is not only convenor/sub group leader job. It is not necessary to agree with all the comments raised by experts if you have strong justification on your view point. If after giving reasonable time, the technical inputs are not available then you should go ahead with the working document with your view point.

xv) The repetitive reference of National standards/regulation on different clauses of working document on safety aspects should be avoided. Since we are trying to formulate International Standard, we should come out with minimum requirement/information that can be incorporated for respective clause in the working document.

xvi) The Convenor/subgroup leaders shall take views of developing countries/Asian Countries/Countries using similar types of products in support of India's argument.

xvii) Indian expert may take leadership role as convenor/project leader or as an expert if separate subgroup is/are created for new work item proposal on performance requirement or any other subject dealing with disposable sanitary pad, reusable sanitary pad, tampon, menstrual cup etc.

xviii) The other experts shall support Convenor/Sub group leader on above matter.

ITEM 1.1.2 Adhoc group Terminology

After the deliberation, the following was decided: -

i) Smt. Tanya Mahajan, Convenor of Adhoc group shall present the status report of Adhoc group during plenary meeting highlighting – the work done/progress report by Adhoc group since 4th plenary meeting/Adhoc group meeting.

ii) A presentation of 10-12 minutes shall be prepared by Convenor. The ppt shall include the work allotted, progress report since last plenary meeting/adhoc group meeting, next Adhoc group meeting, challenges faced and way forward.

iii) The experts were again requested to share their comments on ISO/TC 338, N 136, ISO/PWI 25071, Menstrual Products — Vocabulary **latest by 31 December, 2024.**

iv) The Convenor shall take views of developing countries/Asian Countries/Countries using similar types of products in support of India's argument.

v) If a member country suggest any additional term/definition, then the same shall be added in subsequent stages.

vi) Smt. Tanya Mahajan, Convenor shall clarify the comments received from experts of other National Standards Body on 'ISO/PWI 25071, Menstrual Products — Vocabulary' (if required/raised during meeting).

vii) vii)Smt. Tanya Mahajan agreed to continue as a Convenor if a working group/separate working group is required to be established for NWIP on ISO/PWI 25071, Menstrual Products — Vocabulary. It was proposed that the existing adhoc group shall be converted to full-fledged working group if agreed by ISO/TC 338 secretariat and experts. In case if the subject is allotted to existing working group WG1 then Smt. Tanya Mahajan will be the project Leader from India.

viii) Smt. Tanya Mahajan shall review the comments received on ISO/TC 338, N 136, ISO/PWI 25071, Menstrual Products — Vocabulary after closing of the voting results and shall prepare her notes/view point in advance before next working group meeting.

ix) The other experts shall support Convenor on above matter.

1.2 The Convenor, subgroup leaders and other experts shall prepare their report/notes/inputs (usefulness, work carried out and benefits accrued for India) on outcomes of the plenary and working group meeting so that Textiles Department can submit report to IRD-BIS within 07 days.

1.3 The experts agreed to nominate Shri Jitender Gupta, Scientist E and Head, Textiles as the Head of delegation to represent final view point of India.

1.4 Smt. Tanya Mahajan and/or Shri Dharmbeer, Scientist D, TXD shall be the part of drafting committee of resolution.

1.5 It was also agreed that Smt. Tanya Mahajan may be nominated as a Convenor/Group leader for task group of Low- and Middle-Income Countries (LMIC) for disseminating the work of ISO/TC 338 Menstrual Products.

1.6 It was suggested to nominate one subject expert from MHD on menstrual cup in ISO/TC 338 WG1.

1.7 There being no other business, the meeting ended with a hearty vote of thanks to the *convenor/experts and members*.

N 144 Resolutions ISO TC 338 5th Plenary meeting 2024

Document type	Related content	Document date	Expected action
Meeting / Other	Meeting: VIRTUAL 11 Dec 2024	2024-12-11	

Resolutions taken at the 5th plenary meeting of ISO/TC 338, 11 December 2024

Resolution 33 - 2024

ISO/TC 338 agrees to adopt the draft agenda N 135, with the addition of LMIC coordination task group under item 12.

Resolution 34 - 2024

ISO/TC 338 agrees that the secretariat of ISO/TC 338 together with Joakim Falk and Tanya Mahajan to be appointed to the resolutions drafting committee.

Resolution 35 - 2024

ISO/TC 338 agrees that all reports included in the agenda presented at the meeting, to be accepted. That includes the reports of AHG 1 Terminology, WG 1 Safety, performance and general requirements, and organizations in liaison.

Resolution 36 - 2024

ISO/TC 338 agrees to start a ballot for creating a Task Group for Low- and middle-income countries (LMIC) coordination, with the following purpose:

- Strengthen the perspective of LMICs in the standardization work within ISO/TC 338.
- Develop a cohesive viewpoint and improve the awareness of LMIC challenges with respect to recommended inputs to the standard, amongst all other stakeholders
- Share their experiences with the TC
- Propose areas where capacity building is relevant for LMIC and explore potential pathways
- Support the LMIC participants to advocate for this field of standardization in their respective countries and regions
- Explore potential solutions for adoption challenges by SMEs operating in LMICs
- Identify standardization needs relevant to developing countries and making proposals to the TC;

The secretariat to prepare the full resolution including Background, Terms of Reference, proposed leadership Tanya Mahajan (BIS), and launch a 4-week Committee Internal Ballot including Call for experts.

Resolution 37 - 2024

ISO/TC 338 agrees to create a liaison to ISO/TC 283 Occupational health and safety management (menopause), with the TC 338 secretariat to be contact point for the time being, but welcome proposals for liaison officer from ISO/TC 338.

Brief report of 5th plenary meeting of ISO/TC 338 Menstrual Products held on 11 December 2024 through virtual mode

The 5th plenary meeting of ISO/TC 338 'Menstrual Product' was held on 11 December 2024 through virtual mode. Since the subject matter being dealt by ISO/TC 338 are important from India's perspective, critical and sensitive in nature so a strong representation at the plenary meeting was proposed to represent India during the meeting.

The following delegation of experts participated in the 5th plenary meeting in virtual mode to represent India's point of view: -

9) Shri S. Sivakumar, (Head, Medical Textiles), SITRA, Coimbatore
10) Smt. Tanya Mahajan, MHAI/The Pad Project, New Delhi
11) Ms. Shivani Swamy, Livinguard Technologies Pvt. Ltd., Mumbai
12) Dr. E. Santhini, SITRA, Coimbatore
13) Shri Nirav Mehta, Dima Products, Mumbai
14) Ms. Roocha Khedkar, Kenvue, Mumbai
15) Shri J.K. Gupta, Scientist E & Head, Textiles (**Head of Delegation**)
16) Shri Dharmbeer, Scientist D, Textiles, Member Secretary TXD 36

The important outcomes of the ISO/TC 338 Plenary meeting are as follows: -

i) The progress reports presented by Shri S. Sivakumar for WG 1 Safety, performance and general requirements and Smt. Tanya Mahajan on adhoc group for terminology were accepted by the committee and leadership roles (Convenorship) of India have been continued in the Working Group 1 /Adhoc group AHG1.

ii) During presentation, Shri S. Sivakumar, Convenor ISO TC 338 WG 1 also highlighted the following comments/suggestion received from sub group leaders and requested experts for their technical inputs and information to resolve the matter: -

Points	**Remarks**
List of chemicals and allergens to be tested and their limit values for each type of products	There is concern among LMIC and MSME manufacturers that the list is exhaustive and might increase the cost of compliance and hence that of the product. The members may suggest a brief list of common compounds based on the risk involved.
Test methods and the list of analytes for the above	ISO test methods, if available, may be chosen as the first choice. We need try and avoid USP in this standard.
Sampling size	The members need to consider the different products and suggest sampling size.

Max. duration of use of the product based on the impact assessment	It is referred in Clause 8.2 of the revised working draft. Further elaboration needs to be discussed.
Typical safety assessment report	Aligned with the input from SG1. Incorporated in revised draft. Any difference of opinion may be discussed.
Flushability and Biodegradability of products and the test methods	Flushability seem to be irrelevant for reusable products. Further discussion is required on biodegradability.
Environmental aspects	Detailed inputs are requested.
Agreement on use of a common term for Shelf life	Definition is available in AHG1 Terminology document. Need to decide on the usage of this term in different sections particularly for reusable products.
Revised working draft	Proof reading to be done from the angle of regulators.

iii) It was informed that the new subject proposed by BIS India ISO/PWI 25130, Menstrual products — General and safety requirements and ISO/PWI 25071, Menstrual Products — Vocabulary are currently out for voting, any comments to the proposals should be submitted via the ballot.

iv) ISO/TC 338 agrees to start a ballot for creating a Task Group for Low- and middle-income countries (LMIC) coordination to improve the awareness, strengthen the perspective of LMIC, capacity building, implementation and adoption challenges of standard by SMEs.

v) It was agreed to nominate Smt Tanya Mahajan from BIS India as a proposed Leader for task group and to launch a 4-week Committee Internal Ballot including call for experts.

vi) ISO/TC 338 agrees to create a liaison to ISO/TC 283 Occupational health and safety management (menopause),

ANNEX 19

(Item 9.1)

COMMENTS ON PUBLISHED STANDARDS

IS 17787 : 2021, Medical Textiles — Nonwoven Wipes — Specification and IS 17788 : 2021 Medical Textiles — Nonwoven Fabric for Wipes — Specification

a) Shri Pronab Nandi, Ginni Filaments Limited

Suggestions/Comments for Modification in requirements in IS 17788:2021 and IS 17787:2021

1. As per IS 17788:2021 (Clause 6.1), **IS 15891 (Part 18**) is mentioned for strength testing. But, **IS 15891 (Part 18)** is Grab Tensile Test method and it is not suitable for Nonwoven fabric.

For Nonwoven fabric, **IS 15891 (Part 3**) which is a Strip Tensile test method and it is widely used for Nonwoven fabric and it is equivalent to **ISO 9073-3:2023**, **EDANA202-89.** So, we would request you to please remove IS 15891 (Part 18) from IS 17788:2021 (Clause 6.1) and please replace with **IS 15891 (Part 3)**.

2. As per IS 17787:2021 (Clause 6.1), the requirement of length and width (mm) is mentioned as agreed to between the buyer and seller with a tolerance of ± 1 mm. As Nonwoven spunlace fabric is highly stretchable, it is not possible to maintain it with a tolerance of ± 1 mm. Hence, we recommend the tolerance of ± 5 mm.

b) **Ms. Monika Sathe and Ms. Roocha Khedkar, R&D, JNTL Consumer Health (India) Pvt. Ltd.**

DOCUMENT NO: IS 17788: 2021 Medical Textiles — Nonwoven Fiber for Wipes — Specification.

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Specific Proposal (Draft clause to be add/amended)	Remarks	Technical References and justification on which (2), (3), (4) are based
(1)	(2)	(3)	(4)	(5)

Table 1 Performance Requirement for Nonwoven Fabric (Clause 6.1) i) Fabric identification	For the requirement of "at least 20 percent of cotton or/and viscose fibre", the test method mentioned is IS 667. IS 667 "Identification of Textile Fibres" is qualitative method.	Meets the requirements for cotton or/and viscose fibre. For percent content, check the requirement through manufacturing process records.	IS 667 "Identification of Textile Fibres" is qualitative method and not quantitative hence percent content of cotton or/and viscose fibre cannot be verified.	

Ms. Monika Sathe and Ms. Roocha Khedkar, R&D, JNTL Consumer Health (India) Pvt. Ltd.

DOCUMENT NO: IS 17787: 2021 Medical Textiles — Nonwoven Wipes — Specification.

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Specific Proposal (Draft clause to be add/amended)	Remarks	Technical References and justification on which (2), (3), (4) are based
(1)	(2)	(3)	(4)	(5)
Table 1 Performance Requirement for Nonwoven Wipes (Clause 6.1) ii) Length and width, mm	The tolerance limit to be modified from ± 1 mm	As agreed to between the buyer and the seller with a tolerance of ± 5 mm	The wipes are made of spun lace fabric which has elongation properties, therefore gets stretched during manufacturing.	
ii) pH	Revise the limit	3.5 – 7.5		OEKO-TEX® STANDARD 100: New regulations 2023 Wet wipes The pH-footnote was added to the OEKO-TEX ® STANDARD 100 to allow an exception

				in the pH range for wet wipes. The new accepted pH range for wet wipes is 3.5 - 7.5.
8 MARKING Section l) Anti-bacterial if claimed; and	Section 1.1 mentions - This standard does not cover wet wipes impregnated/coated with alcohol and other wipes with germicidal claim (numerical germ kill, disinfection etc.).	Modify as below: Anti-bacterial if claimed (other than bactericidal mode of action)		

a) Shri Rohit Srivastava, Unicharm India

IS 17787:2021

Medical Textiles Nonwoven Wipes –Specification

6.1 i) Tolerance ±1mm - Request to changeNeed change to ± 10mm

Reason for Change

There are 2 process which are involved in dimensions of Wipes.

Process 1) Mother Roll Slitting - Spunlace Mother roll is slitted as per requiredSlit Width for the Wet wipes machine.

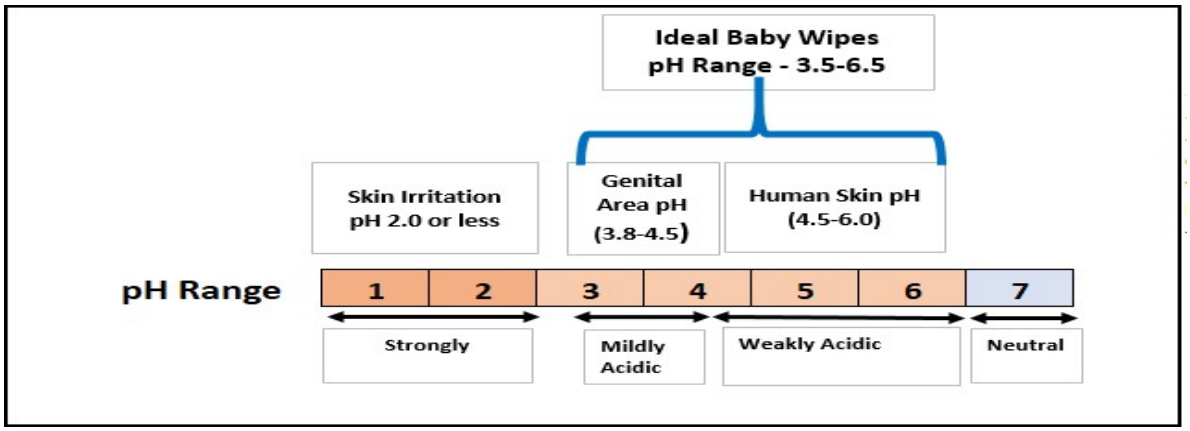
The tolerance is ± 5mm

Process 2) Machine In line Slit of Finished Goods - Once Spunlace desired Slitted roll is kept on wet wipes machine the machine itself cuts the fabric intodesired length. The tolerance is ± 5mm needed as material is moving during production time.

Hence Considering Condition of Process 1 and Process 2 Overall Toleranceshould be considered ± 10mm.

6.1 ii) pH 4.5-7.5 Request to change

Need change to pH 3.5 - 6.5



1) The skin's natural part like hand, foot and other body has pH slightly acidic,ranging from 4.5 to 6.0.

2) The genital area like pubic/vaginal area has pH 3.8-4.5.

3) Below pH 2 or less is consider as Skin corrosive/irritation pH.

4) Wipes especially baby wipes are used to clean urine and stool which covers delicate area and also used to clean other body parts like hand, foot and otherbody part. Our main target is to have hygiene around genital area hence considering all factors we have considered the mildly acidic range with 3.5-6.5.

Conclusion - Our Wipes are designed to match the actual baby wipespH range 3.5-6.5.

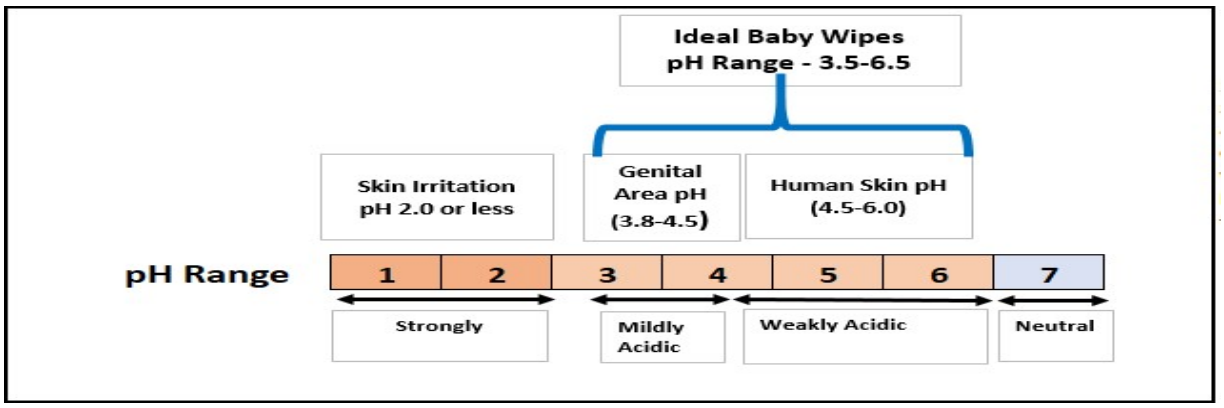
IS 17788:2021, Medical Textiles Nonwoven Fabric for Wipes – Specification

4 Material; Cotton or Viscose Fiber at least 20% or more Request to Change Need change to No Design limitation

Reason for Change

Currently based on Standard shared Unicharm wipes could meet the standard but we shouldn't limit wipes to minimum 20% viscose/cotton as Wipes design spec depends on Consumer requirement and demand of Stiffness in fabric and fluffiness requirement. Hence, we shouldn't restrict wipes specification as we limiting product design.

6.1 vi) pH 5.5-8.0 Request to change Need change PH 3.5- 6.5



1) The skin's natural part like hand, foot and other body has pH slightly acidic, ranging from 4.5 to 6.0.

2) The genital Area like pubic area has pH 3.8-4.5

3) Below pH 2 or less is consider as Skin corrosive/irritation pH.

4) Wipes especially baby wipes are used to clean urine and stool which covers delicate area and also used to clean other body parts like hand, foot and other body part. Our main target is to have hygiene around genital area hence considering all factors we have considered the mildly acidic range with 3.5-6.5.

Conclusion - Hence Wipes are designed to match the actual baby pH range 3.5-6.5.

ANNEX 20

(Item 9.2)

COMMENTS ON PUBLISHED STANDARDS

IS 17349:2020 Medical textiles — Shoe covers — Specification

Ms Ankhi Chakraborty, BIS EROL Kolkata

As per IS 17349: 2020, "Cleanliness- Microbial (CFU /100 cm^2)" explicitly does not specify regarding the specific type of microorganisms (bacteria and fungus) to be considered to calculate the Microbial count. Thus the term "Cleanliness- Microbial (CFU /100 cm^2)" may be rephrased as 'Cleanliness – Total Microbial count (Total number of bacteria and fungi in CFU /100 cm^2)".

Reference has been drawn from the following Standards wherein bacterial and fungal bio-burden has been separately mentioned.

1) IS 17514:2021 Reusable Sanitary Pad/Sanitary napkin Clause 9.3 stating "Total viable count (total number of bacteria and fungi) shall not be more than 1000 cfu/gm and *Staphylococcus aureus* shall be absent."
2) IS 5405:2019 Sanitary napkin-specification Clause 7.3 stating "Total viable count (total number of bacteria and fungi) shall not be more than 1000 cfu/gm and *Staphylococcus aureus* shall be absent."
3) IS 17508:2020- Disposable Adult Incontinence Diaper — Specification" Clause 7.3 stating "Total viable count (total number of bacteria and fungi) shall not be more than 1000 cfu/gm and *Staphylococcus aureus* shall be absent."
4) IS 17509:2021- Disposable Baby Diaper — Specification Clause 7.3 stating "Total viable count (total number of bacteria and fungi) shall not be more than 1000 cfu/g and *Staphylococcus aureus* shall be absent".

Table 1 - Requirements for Shoe Covers (Clause 5.2)
Sl.No.(1) (i)
Characteristics(2)-Cleanliness – **Total Microbial count (Total number of bacteria and fungi)** (CFU /100 cm^2)

ANNEX 21

(Item 9.3)

COMMENTS ON PUBLISHED STANDARDS

IS 17508: 2020, Disposable Adult Incontinence Diaper – Specification

Shri Shubham, BIS Rajkot Branch Office

Figure 1 illustrates the dimensions of a Adult Incontinence Diaper. While the figure effectively represents the overall size and key measurements using alphabetic labels, it lacks specific designations for the diaper crotch and core crotch width.

It is recommended that the figure be revised to include clear labels for diaper crotch and core crotch width, enhancing its clarity and comprehensiveness.