

BUREAU OF INDIAN STANDARDS

MINUTES

**Technical Textiles for Medtech Applications
Sectional Committee, TXD 36**

22nd Meeting

Date	Time	Venue
09 June 2023 (Friday)	1100 h	Video Conference through CISCO Webex

Attendance

Sl No.	Representative	Organization
1.	Dr. Prakash Vasudevan (Chairman)	Director, SITRA, Coimbatore
2.	Ms Apurva Ranka	Alpha Foam Ltd.
3.	Shri Arihant Jain	B. Braun, India
4.	Shri Sven Worst	-do-
5.	Shri Antoigin	-do-
6.	Dr. Anmol Kumar Ray	-do-
7.	Smt. Anjali	Business Coordination House, New Delhi
8.	Shri Ajai Basil	CDSCO, New Delhi
9.	Shri Arvind Hiwale	-do-
10.	Dr. Suraj Khanna	CSIR-National Physical Laboratory, New Delhi
11.	Shri Suraj Bharati	DRDE, Gwalior
12.	Surg Capt S.S. Dalawayi	Directorate General Armed Forces Medical Service (DGAFMS), New Delhi
13.	Shri Harkesh Chandra	-do-
14.	Dr. Naresh Panchal	DGHS, New Delhi
15.	Shri N Senthil Kumar	DGQA, New Delhi
16.	Shri Nirav Mehta	Dima Products, Mumbai
17.	Shri Sumit Marwah	Dispoline India Private Limited, Bangalore
18.	Dr. Manish Sabharwal	Dr. Sabharwals Manufacturing Labs Pvt Ltd, Chandigarh
19.	Shri Gurmeet Singh	Ginni Filaments Ltd., Noida
20.	Shri Arun Nag	-do-
21.	Ms. Aditi Sharma	Goonj, New Delhi
22.	Shri Raajjesh	Healthium Medtech Ltd
23.	Dr. Ashwini Agarwal	Indian Institute of Technology, New Delhi
24.	Ms. Roocha Kedkar	Johnson and Johnson, Mumbai

- | | |
|------------------------------|---|
| 25. Shri Aditya Vats | Johnson and Johnson, Mumbai |
| 26. Shri Mehul Tyagi | -do- |
| 27. Shri Puneet Kanodia | Kansons Overseas Ltd. (Medi Karma) |
| 28. Shri Vishwanath Patil | Kenvue |
| 29. Shri T. Balaji | KOB Medical Textiles Pvt Ltd, Coimbatore |
| 30. Ms. Shivani Swamy | Livinguard Technology Pvt. Ltd., Mumbai |
| 31. Shri Dhaval Ghughe | Medline Healthcare Industries Pvt. Ltd, Pune |
| 32. Dr. Prabha Hegde | 3 M India |
| 33. Dr. Pankaj Arora | PGIMER, Chandigarh |
| 34. Dr. Vijay Tadia | -do- |
| 35. Dr. Sanjiiv | PWMAI, New Delhi |
| 36. Ms. Shradha Dongre | SASMIRA, Mumbai |
| 37. Shri Khalil Khan | Surya Textech |
| 38. Shri D. Veerasubramaniam | The South India Textile Research Association,
Coimbatore |
| 39. Dr. R. Radhai | -do- |
| 40. Shri Sivakumar S. | Textile Commissioner Office, Mumbai |
| 41. Shri Narottam Kumar | -do- |
| 42. Dr. P. Ravichandaran | Textile Committee, Mumbai |
| 43. Shri Navketan Gaikwad | Venus Safety & Health Pvt. Ltd. Mumbai |
| 44. Shri Harshal Patil | -do- |
| 45. Shri Ravi Sindhe | -do- |

BIS DIRECTORATE GENERAL

- | | | |
|-----|--|---------------------------------------|
| 45) | Shri Dharmbeer
Scientist D (Textiles) &
(Member Secretary) | Bureau of Indian Standards, New Delhi |
| 46) | Shri Ranga Banothu
Scientist B (Textiles) | – do – |

Item 0 WELCOME & INTRODUCTORY REMARKS

Dr. Prakash Vasudevan, Chairman extended a hearty welcome to the members of TXD 36. He emphasized for active participation from the members and requested for the precise inputs so as to arrive at consensus.

Member secretary has also welcomed the Chairman and all other members.

Item 1 CONFIRMATION OF THE MINUTES OF THE PREVIOUS MEETING

In view of no comments, the Committee **CONFIRMED** the minutes of the 21st meeting of the TXD 36 committee held on 27 March, 2023 through CISCO Webex Videoconferencing as circulated vide email dated 06 April 2023.

Item 2 SCOPE AND COMPOSITION OF TXD 36

2.1 The Committee REVIEWED the present scope and composition of the Committee TXD 36 as given in **Annex 1** to the agenda and DECIDED as follows:

- a) Updated Nomination/Fresh nominations to be sought from the following organization:
 - i) Ministry of Textiles (NTTM), New Delhi

Item 3 ISSUES ARISING OUT OF PREVIOUS MEETING OF TXD 36

3.1 The committee noted the summary of actions taken on various decisions of the 21st meeting of TXD 36 as given in **Annex 2** of the agenda.

Item 4 DRAFT STANDARD FOR FINALIZATION

4.1 The committee considered the following draft standard as given in **Annex 3** of the agenda:

-

- 1) Textiles — Determination of Antibacterial Activity of Textile Products [(First revision of IS/ISO 20743) (Doc : TXD 36 (22151)]

After deliberations, the committee decided that the above draft standard as given in agenda is **FINALIZED** for publication as Indian Standard. BIS may carry out the editorial changes in the finalized draft, if required.

Item 5 DRAFT AMENDMENT FOR WIDE CIRCULATION

5.1 IS 19022: 2023, Medical Textiles — Barrier Face Covering — Specification

The committee considered the comments/suggestion received from CMD-II and SITRA as given in **Annex 4** and **Annex 5** respectively in the agenda.

The committee also considered the proposed amendment 1 to IS 19022 : 2023 as given in **Annex 6** of the agenda.

After deliberations, the committee decided that the following changes shall be incorporated in amendment 1 to IS 19022 : 2023 [Doc: TXD 36 (22649)] :-

(Page 2, Clause 6, second line) — Substitute the following for the existing:

‘Reusable barrier face coverings shall withstand at least 5 washing and drying cycles when tested using reference washing machine Type A (wash procedure no. 4 N, 40 ± 3 °C) or using reference washing machine Type B (wash procedure 4B, 41 ± 3 °C) using reference detergent 2 and drying procedure (as per care instruction) as specified in IS 15370.’

(Page 2, Clause 8 third line) — Substitute the following for the existing: -

'The laces, elastic strips, fabric tie etc. used as fastening mechanism shall withstand a minimum force of 10 N (for single use face covering) or 50 N (for reusable face covering) when subjected to a tensile force for 10s with the face covering mounted on a dummy head. The schematic diagram for reference is provided as follows :-

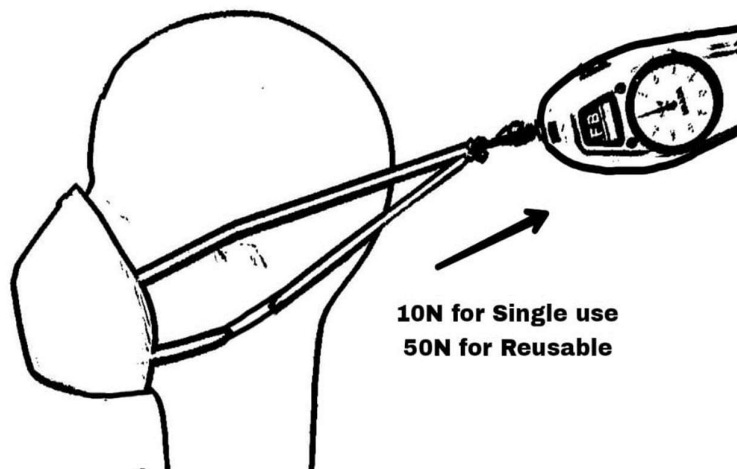


FIG. 1 SCHEMATIC DIAGRAM FOR TIE AND ATTACHMENT STRENGTH TEST (FOR GUIDANCE ONLY)

[Page 3, Clause 7.1, Table 1, Sl no (iv)] — Insert the following note at the end:

'NOTE — 'Reusable barrier face coverings shall withstand at least 5 washing and drying cycles when tested using reference washing machine Type A (wash procedure no. 4 N, 40 ± 3 °C) or using reference washing machine Type B (wash procedure 4B, 41 ± 3 °C) using reference detergent 2 and drying procedure (as per care instruction) as specified in IS 15370.'

[Page 6, Clause 9.1, Table 2, Sl no (i), Annex B] — Substitute 'FIG. 2' for 'FIG 1.'

[Page 6, Clause 9.1, Table 2, Sl no (i), B-2] — Substitute the following for the existing:

'Suitable breathing resistance test apparatus for measurement of pressure differential equipped with flow meter, pressure gauges etc. (such as the apparatus given in Fig. 2).

NOTE —Equivalent automated instruments validated against the test method prescribed may also be used.'

[Page 7, Clause 9.1, Table 2, Sl no (ii), Annex C] — Substitute 'polystyrene latex' for 'latex'.

[Page 7, Clause 9.1, Table 2, Sl no (ii), C-1] — Insert the following note at the end:

'NOTE — Instead of aerosol containing suspended polystyrene latex (PSL) spheres, NaCl aerosol may also be used.'

[Page 7, Clause 9.1, Table 2, Sl no (ii), C-2] — Insert the following note at the end:

'NOTE — Equivalent automated instruments validated against the test method prescribed may also be used.'

[Page 3, Clause 9.1, Table 2, Sl no (iii)] — Delete.

The committee further decided that the matter is urgent and the wide circulation of the above amendment be waived off under Rule 22 (4) of BIS Rules 2018 notified vide GSR 584(E) dated

25 June 2018; and draft amendment 1 to IS 19022 : 2023 be held to have been **FINALIZED** for publication. BIS may carry out the necessary editorial changes in the finalized draft, if required.

5.2 IS 17354 : 2020, Medical Textiles — Dental Bib / Napkins — Specification

The committee considered the suggestion received from SITRA on suitable liquid for testing of dental bib as given in **Annex 7**.

After deliberation, the committee decided that an amendment incorporating following changes shall be issued:-

- i) [(Page 1, Table 1, Sl no. (iv), a)] — Substitute ‘Liquid absorbency time’ for ‘Sinking time’.
- ii) [(Page 1, Table 1, Sl no. (iv), b)] — Substitute ‘Liquid absorptive capacity’ for ‘water holding capacity’.
- iii) The informative annex on test liquid for dental bib is to be included and the inputs are to be suggested by SITRA.
- iv) (Page 2, Clause 7.1) — Insert the following information at the end:-
 - f) Declared shelf-life of the product

The draft amendment so prepared may be issued in **wide circulation** for **2 months** for eliciting technical comments from stakeholders. BIS may carry out the editorial changes in the draft if required.

Item 6 PRELIMINARY DRAFT FOR APPROVAL FOR WIDE CIRCULATION

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

The committee considered the performance table for non-woven gauze swab and the test report received from M/s Ginni filament as given in **Annex 8** of the agenda.

After deliberation, the committee decided that the performance requirement as given in the following table shall be included in the existing draft (as given in 21st meeting agenda): -

Table 1 Performance Requirements for Nonwoven Gauze

(Clause 5)

Sl. No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Fibre identification	At least 20 percent of cotton or/and viscose /absorbent fibres	IS 667
ii)	Weight per square metre, g/m ² , <i>Min</i>	30	IS 15891 (Part 1)
iii)	Absorbency (with distilled water)		IS 15891 (Part 6)
	a) Liquid absorption time, s, <i>Max</i>	10	

	b) Liquid absorptive capacity, percent, <i>Min</i>	400	
iv)	Tensile strength in machine direction (Dry) in N/5cm, <i>Min</i>	20	IS 15891 (Part 3)
v)	Tensile strength in machine direction (Wet) in N/5cm, <i>Min</i>	20	IS 15891 (Part 3))
vi)	Total viable count (cfu/g), <i>Max</i> (Non-sterile)	100	ISO 11737 Part 1
vii)	pH value of aqueous extract	6.5 to 8.5	IS 1390
viii)	Water soluble substance, percentage, <i>Max</i>	1	IS 14944
ix)	Ether soluble substance percentage, <i>Max</i>	1	IS 14944
x)	Particle release [log ₁₀ (lint count)]	≤ 4.0	IS 15891 (Part 10)
viii)	Freedom from optical whitener	No fluorescence or not more than occasional point of fluorescence visible' when viewed under the ultra-violet (UV) light of wavelength 365 nm	Viewing under ultra-violet light
xi)	Cytotoxicity	Non-Toxic (Reactivity as none)	IS/ISO 10993-5

In case of any additional clarification and technical information for preparation of preliminary draft, BIS may co-ordinate with

- i) Shri Gurmeet Singh, M/s Ginni Filaments, Noida.
- ii) Shri Rajiv Ranka, M/s Alpha Foam Pvt. Ltd., Pune
- iii) Shri Sunil Kumar Rathi, M/s Welspun India

The preliminary draft so prepared shall be issued in wide circulation for 2 months for eliciting technical comments from stakeholders. BIS may carry out the editorial changes in the draft if required.

Item 7 NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD

The committee considered the technical inputs received from Dr. Sabharwal Wound Care on new subject - IV Dressings (Film/Non-Woven), Synthetic Orthopaedic Cast Bandage, Synthetic Orthopaedic Cast Splint, Burn Sheet, Medical Wipes as given in **Annex 9**.

After deliberation, the committee requested the following member to share the additional inputs on scope, raw material/fabric, workmanship and finish, performance requirement, sampling, packing and marking on the above subjects :-

- 1) Dr. Manish Sabharwal, Dr. Sabharwal Wound Care, Baddi
- 2) Dr. Prabha Hegde, 3 M India, Bengaluru
- 3) Shri Khalil Khan, Surya Textech,
- 4) Shri T. Balaji, KOB Medical Textiles

Based on the technical inputs, BIS shall prepare the preliminary draft on above subjects for discussion in next meeting of TXD 36.

The committee further decided that the following committee members/stakeholders shall provide their technical inputs on the remaining subjects within 30 days :-

Sl No.	Field	Subjects	Stakeholder Identified
1	Medtech	Medical wipes	Dr. Manish Sabharwal, Dr. Sabharwal Wound Care Shri Prashant Jadhav, P & G
3	Medtech	Dental floss	Shri Prashant Jadhav, P & G Representative of Colgate Palmolive
4	Medtech	Scrub suit/patients clothing	Dr. Sanjiiv, PWMAI Ms. Shivani Swamy, Livinguard Mr. Apurva Ranka/Mr. Rajiv Ranka, Alpha Foam Ltd Shri Khalil Khan, Surya Textech, Shri Sumit Marwah, Dispoline India Pvt. Ltd. Representative of Arvind Mills
6	Medtech	Sterilization wrap	Shri D. Veerasubramanian, SITRA Shri Dhaval Ghuge/Shri Anthony D'costa, Medline Healthcare Industries Pvt. Ltd Shri Sumit Marwah, Dispoline India Pvt. Ltd.
7	Medtech	Tampons	Ms. Roocha Khedkar, Johnson and Ms. Tanya Mahajan, The Pad Project India

			Shri Rahesh Shah/Representative, Feminine and Infant Hygiene Association
8	Medtech	Maternity napkins/pads	Shri Nirav Mehta, Dima Products Ms. Tanya Mahajan, MHAI/The Pad Project Shri Rahesh Shah/Representative, Feminine and Infant Hygiene Association Ms. Roocha Khedkar, Johnson and Johnson Ms. Shivani Swamy, Livinguard Shri Kamal Johari, Nobel Hygiene
9	Medtech	Antistatic Healthcare Textiles	SHI Medicare Shri Khalil Khan, Surya Textech,
10	Medtech	Advanced wound dressings - Hydrogel, film and foam-based dressings, multilayer, tissue engineer based wound dressings etc.	Dr. Prabha Hegde, 3 M India Shri T. Balaji, KOB Medical Textiles Dr. Manish Sabharwal, Dr. Sabharwal Wound Care Shri R. Krishnakumar, Cologensis Healthcare Private Limited
12	Medtech	Synthetic orthopaedic cast / sling / splint, Mopping Pad, Leukodepletion filter or textiles used for blood purification, Hernia mesh, Umbilical tape	Shri R. Krishnakumar, Cologensis Healthcare Private Limited Shri Aditya Vats/Shri Mehul Tyagi, Johnson and Johnson

The committee also requested BIS to co-ordinate with other stakeholder/manufacturers (who are not represented in the committee) for their technical inputs on above subjects.

Item 8 COMMENTS ON PUBLISHED STANDARDS

8.1 IS 5405 : 2019, Sanitary Napkins — Specification (Second Revision) and IS 17514 : 2021, Reusable Sanitary Pad / Sanitary Napkin / Period Panties — Specification

The committee considered the working draft for test method for determination of volatile organic compounds along with comments received from SGS, Chennai as given in **Annex 10** and **Annex 11** of the agenda respectively.

After deliberation, the committee decided that the development of test method for determination of volatile organic compounds (VOCs) shall be taken up with Chemical Methods of Test Sectional Committee, TXD 05 on top priority. Once the test method of VOCs is developed by TXD 05, then the chemical compound/substances, frequency and requirement of VOC test may be deliberated in TXD 36 for needful action in IS 5405 : 2019 and IS 17514 : 2021.

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

The committee considered the agenda and minutes of panel meeting held on 18 May 2023 as given in **Annex 12** of the agenda.

After deliberation, the committee decided that the recommendation of panel meetings dated 24 November 2022 and 18 May 2023 shall be incorporated in the revised draft of IS 17334.

The committee further decided that the following aspects/comments shall be discussed in next meeting of TXD 36 : -

- i) The remaining comments of SITRA on test procedure and reporting of (Hydrostatic resistance test, Particle release test and Biocompatibility test), requirement of dry and wet microbial penetration.
- ii) Any other aspects.

Item 9 INTERNATIONAL ACTIVITIES

9.1 The committee noted the information given in the agenda item. It was also requested to TXD 36 members/nominated experts to participate and share their views on working documents/agenda items for working group meeting of Adhoc Group/Task Group/WGs under ISO/TC 338.

9.2 Committee Internal Ballot (CIB) - ISO TC 338 N 38 Menstrual Products — Terminology

The committee considered the Committee Internal Ballot (CIB) - ISO TC 338 N 38 Menstrual Products — Terminology as given in **Annex 17** of the agenda.

After deliberation, the committee requested TXD 36 members/nominated experts to go through the document and share their suggestion/comments latest by **31 July 2023**.

Item 10 REVIEW OF PUBLISHED STANDARDS

10.1 The committee considered the standards due for review and pre-2000 standards as given in the agenda.

After deliberation, the committee decided to reaffirm the following Indian Standards for further period of 5 years: -

- 1) IS 16111 : 2013, Elastic bandage
- 2) IS 6237 : 1971, Specification for handloom cotton cloth for plaster of Paris bandages and cut bandages
- 3) IS 757 : 1971, Specification for handloom cotton lint, absorbent, bleached, non-sterilized (first revision)

The committee requested Shri T. Balaji, KOB Medical Textiles and Dr. Manish Sabharwal, Dr. Sabharwal Wound Care, Baddi to review the requirement of GSM, Stretch Length and Extensibility due to wider range in the draft standard of IS 16111 : 2013, Elastic bandage as given in the agenda and provide their comments within 15 days.

The committee further decided that BIS shall prepare the draft revision of above standards based on review performa and comments received from stakeholders. The draft revision so prepared shall be issued in wide circulation for **2 months** for eliciting technical comments from stakeholders. BIS may carry out the editorial changes in the draft if required.

The committee also decided that following Indian Standards shall be reviewed by expert members for their comments and suggestion: -

SI No	IS No.	Title	Allotted To
1	IS 5405 : 2019	Sanitary napkins – Specification (second revision)	Amendment 3 to IS 5405 : 2019 under WC Ms. Sharada Dongre, SASMIRA, Mumbai
2	IS 17243 : 2019	Medical textiles – Test methods for compresses for wound management and surgical procedures	Shri D. Veerasubramaniam, SITRA Coimbatore
3	IS 17334 : 2019	Medical textiles – Surgical gowns and surgical drapes – Specification	Dr. E. Santhini, SITRA Coimbatore

The members requested to give additional time for 30 days to send their comments and the committee agreed for the same.

Pre-2000 Standards

Sl No	IS No.	Title	Allotted To/Review
1	IS 10829 : 1993	X-Ray detectable gauze swabs and laparotomy sponges – Specification (first revision)	Dr. Manish Sabharwal, Dr Sabharwal Medicals Pvt Ltd, Chandigarh
2	IS 11046 : 1984	Specification for towel, operating	-do-
3	IS 12839 : 1989	Wool/polyamide blended flannel, hospital, grey - Specification	Dr. Sanjiiv, FICCI/PWMAI
4	IS 14274 : 1995	Bandage, T - Shaped, calico - Specification	Dr. Manish Sabharwal, Dr Sabharwal Medicals Pvt Ltd, Chandigarh
5	IS 14306 : 1995	Bandage, triangular, calico – Specification	-do-
6	IS 14316 : 1995	Swabs, small, in bag of 50 - Specification	-do-
7	IS 1681 : 1998	Textiles – Hospital blankets, woollen, dyed – Specification (third revision)	Dr. Sanjiiv, FICCI/PWMAI

The committee requested DGAFMS to provide their suggestion/comments on IS 14274 : 1995 Bandage, T - Shaped, calico - Specification and IS 14306 : 1995 ‘Bandage, triangular, calico – Specification’.

The committee also requested experts/committee member to send their comments and suggestion for pre-2000 standards in 60 days.

The committee further decided that based on the suggestion/recommendation of expert members, BIS shall fill the Performa for review and prepare the preliminary draft for revision of above Indian Standards. The preliminary draft so prepared shall be issued in **wide circulation** for **2 months** for eliciting technical comments from stakeholders. BIS may carry out the editorial changes in the draft if required.

Item 11 NEW INITIATIVES IN STANDARDIZATION

11.1 The committee NOTED the Rolling Annual Action Plan for the year 2023-24, Annual calendar of Technical Committee meetings, Research Projects to be taken up, List of National and International events to be participated, Scientific journals and periodicals to be subscribed, Process Reforms proposed in standardization activity etc. as given in **Annex 19** and **Annex 20**.

Item 12 DATE AND PLACE OF NEXT MEETING

12.1 The Committee DECIDED to hold the next meeting in consultation with Chairman TXD 36 in first week of **July 2023**.

Item 13 ANY OTHER BUSINESS

13.1 The member secretary placed the technical inputs received from Shri Aaditya Vats, Johnson & Johnson Pvt. Ltd., during the meeting. After deliberation, the committee decided that the working draft shall be circulated to TXD 36 members for 15 days for their study and comments. Based on the comments/suggestion, the matter shall be discussed in next meeting of TXD 36.

13.2 There being no other business, the meeting ended with a hearty vote of thanks to the *Chair*.