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BUREAU OF INDIAN STANDARDS

MINUTES

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

27th Meeting

Date	Time	Venue
16 July 2024 (Tuesday)	1030 h	Video Conference through CISCO Webex

Attendees :-

Sl No.	Name of Representative	Organization
1.	Dr. Prakash Vasudevan (Chairman)	Director, SITRA
2.	Smt. Prabha Hegde	3 M India Limited, New Delhi
3.	Shri Apurva Ranka	Alpha Foam Ltd., Pune
4.	Shri Mithun A. Shah	Anabio Technologies Pvt Ltd., Bengaluru
5.	Capt. Baban Rai	Association of Healthcare Providers (India), New Delhi
6.	Dr. Sunil Khetarpal	-do-
7.	Smt. Pallavi Shukla	All India Institute of Medical Sciences, Delhi
8.	Smt. Aiswarya Sudhakar	Bella Premier Happy Hygiene Care Pvt Ltd., Tamil Nadu
9.	Shri Ajai Basil	Central Drugs Standard Control Organization (CDSCO), New Delhi
10.	Shri Rupande Sampat	Chemco Group, Mumbai
11.	Shri R Krishana Kumar	Cologenes Healthcare Pvt. Ltd, Salem
12.	Dr. B.S Charan	Director General of Health Services, New Delhi
13.	Shri Sumit Marwah	Dispoline India Private Limited, Bangalore
14.	Shri Arnab Das	DGQA (Ministry of Defence), New Delhi
15.	Shri Nirav Mehta	Dima Products, Mumbai
16.	Shri Raghavan Adiyodi	-do-
17.	Dr Manish Sabharwal	Dr. Sabharwals Wound Care, Baddi Himachal Pradesh
18.	Ms Tulsi	Federation of Indian Chambers of Commerce & Industry(Shalex Medtech), New Delhi
19.	Shri Gurmeet Singh	Ginni Filaments Limited, Noida
20.	Shri Pronab Nandi	-do-

21.	Shri Ayan Chakraborty	-do-
22.	Shri Mayank Rohatagi	Healthium Medtech Ltd., Bengaluru
23.	Dr. Sadhana Srivastava	Indian Council of Medical Research, New Delhi
24.	Prof. Bipin Kumar	Indian Institute of Technology Delhi (IIT Delhi), New Delhi
25.	Smt. Ashwani Agarwal	-do-
26.	Dr. Anup Rakshit	Indian Technical Textile Association, Mumbai
27.	Smt. Ruchita Gupta	-do-
28.	Smt. Monika Sathe	Kenvue, Mumbai
29.	Ms. Roocha Khedkar	-do-
30.	Smt. Komal Sharma	Kimberly-Clark Corporation, Mumbai
31.	Shri T. Balaji	KOB Medical Textiles Pvt Ltd, Palladam
32.	Ms. Shivani Swamy	Livinguard Technologies Pvt. Ltd., Mumbai
33.	Shri Lalit Gupta	Maulana Azad Medical College, New Delhi
34.	Shri Anthony D'Costa	Medline Healthcare Industries Pvt Ltd., Pune
35.	Smt. Damini Sagar	-do-
36.	Shri Ajay Pandit	Ministry of Textiles, New Delhi
37.	Smt. Neeta Anand	National Accreditation Board for Hospitals & Healthcare Providers, New Delhi
38.	Shri Joy Devassy	Nobel Hygiene, Mumbai
39.	Smt. Sneha Gupta	-do-
40.	Shri Kaushik Johari	-do-
41.	Shri Kamal Johari	-do-
42.	Shri Pankaj Arora	PGIMER, Chandigarh
43.	Shri Vijay Tadia	-do-
44.	Shri Prashant Jadhav	Procter and Gamble Co., Mumbai
45.	Shri Girish Parhate	-do-
46.	Shri Prajwal	-do-
47.	Shri Leda Uy	-do-
48.	Shri Napat	-do-
49.	Shri Yao Ying	-do-
50.	Shri Ujjawal Kedia	-do-
51.	Shri Ayush Upadhyay	Soothe Healthcare Pvt Ltd., New Delhi
52.	Smt. Pardhi Mantri	-do-
53.	Shri Mohit Chhoker	Surgeine Health Care Pvt Ltd.(AIMED), New Delhi
54.	Shri Shubham Kumar	-do-
55.	Shri Kavivnder Kumar	Solis Hygiene Pvt. Ltd., Madhya Pradesh
56.	Shri Kulveen Singh Bali	Solventum India
57.	Shri Ashish Naik	Swara Baby Products Pvt Ltd., Madhya Pradesh
58.	Dr. P. Ravichandran	Textiles Committee Mumbai
59.	Shri Neeraj Mehra	Tynor Orthotics Pvt Ltd., Mohali
60.	Smt. Tanya Mahajan	The Pad Project (NGO), India
61.	Shri S. Sivakumar	The South India Textile Research Association, Coimbatore — 641014
62.	Dr. E. Santhini	-do-

63.	Shri Veerasubramanian	-do-
64.	Dr Manisha Mathur	The Synthetics & Art Silk Mills Research Association, Mumbai
65.	Smt. Shradha Dongre	-do-
66.	Shri Rohit Shrivastava	Unicharm India Pvt Ltd., Gurugram
67.	Smt. Dipti Sharma	-do-
68.	Shri Tanuj	-do-
69.	Shri Lal Singh	-do-
70.	Shri Babarao Narotepatil	Welspun Living Ltd., Mumbai
71.	Shri Nitin Goyal	-do-
72.	Shri Sandeep Jalit	-do-
73.	Shri Basudev Basu	-do-
74.	Shri Shrish Narwade	-do-
75.	Shri Rajeev Chauhan	-do-

BIS DIRECTORATE GENERAL

76.	Shri Dharmbeer, Scientist D/Joint Director (Textiles) and (Member Secretary)	Bureau of Indian Standards, New Delhi
77.	Ms. Shalini Shree, Executive Assistant	-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 also welcomed the Chairman and all other members.

Item 1 CONFIRMATION OF THE MINUTES OF THE PREVIOUS MEETING

1.1 In view of no comments, the Committee **CONFIRMED** the minutes of the 26th meeting of the TXD 36 committee held on 15 April 2024 through CISCO Webex videoconferencing which were circulated vide our reference TXD 36/A 2.26 email dated 27 April 2024.

Item 2 SCOPE AND COMPOSITION OF TXD 36

2.1 The committee **NOTED** the information.

2.2 The committee **NOTED** the information.

2.3 and 2.4 The committee **REVIEWED** the present scope and composition of the Committee TXD 36 as given in **Annex 1** to the agenda. After deliberation, the committee decided the following:

- i) 3 M India Limited, New Delhi will be represented by Smt. Prabha Hegde as Principal Member and Smt. Kavitha Kulkarni as an Alternate Member.
- ii) NABH was requested to share the nomination of Principal Member and Alternate Member.

2.4 The committee deliberated on the request for membership from M/s Tynor Orthotics Pvt. Ltd., Mohali and decided to co-opt in TXD 36. M/s Tynor Orthotics Pvt. Ltd., Mohali will be represented by Shri Neeraj Mehra as Principal Member and Shri Chetan Mittal as Alternate Member.

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 26th meeting of TXD 36 as given in **Annex 2** of the agenda.

3.2 The committee decided that Shri R Krishanakumar, Cologenesis Healthcare Ltd and Shri Saurabh, Axio Bio-Solutions Private Limited shall share the working draft on Chitosan Haemostatic Dressings based on inhouse technical data, scientific data and International Practice and share the same with BIS in 15 days.

Item 4 DRAFT AMENDMENTS FOR FINALIZATION

4.1 The committee considered the following draft amendments issued under wide circulation as given in Annex 3 to the agenda.

- i) Amendment No. 2 to IS 17509 : 2021 Disposable Baby Diaper — Specification [Doc: TXD 36 (25701)]
- ii) Amendment No. 1 to IS 758 : 2023 Medical Textiles — Absorbent Cotton Gauze — Specification (Fifth Revision) [Doc: TXD 36 (25704)]
- iii) Amendment No. 1 to IS 863 : 2023, Medical Textiles — Cotton Bandage Cloth — Specification (Third Revision) [Doc: TXD 36 (25705)]

The committee considered the comments received from M/s Swara Baby Products, P & G, Kimberly-Clark India Pvt. Ltd., Unicharm India on amendment No. 2 to IS 17509: 2021 as given at **Annex 4** to the agenda.

After deliberation, the committee decided that the following changes shall be incorporated in draft amendment 2 to IS 17509 :2021 : -

- a) The weight of X Large category is to be updated as '13-15 kg'.
- b) The value of rewet under load (gm), Max for all size is to be updated as '3'.
- c) Inner diameter of cylinder for X Large, XX Large and XXX Large is to be updated as '50 mm'

The committee also considered the comments received from M/s G Surgiwear Limited and CMD 2, BIS on Amendment 1 to IS 758 : 2023 and Amendment No. 1 to IS 863 : 2023 as given at **Annex 5** to the agenda.

After deliberation, the committee decided that the following changes shall be incorporated in draft amendment no. 1 to IS 758 : 2023 and amendment no. 1 to IS 863 : 2023 :-

- a) The method of test of Cleanliness–Microbial/ Bioburden Test for sterile and non-sterile products is to be updated as IS/ISO 11737 (Part 2) and IS/ISO 11737 (Part 1) respectively.

The committee further decided that the draft amendments as given in agenda after incorporating the above changes are **FINALIZED** for publication as amendment to Indian Standards. BIS may carry out the editorial changes in the finalized draft, if required.

Item 5 DRAFT AMENDMENT FOR APPROVAL FOR WIDE CIRCULATION

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

The committee considered the comments received from Shri N.K. Kansara, Ex-DDG, BIS vide email dated 18 March 2024 as given at **Annex 6** along with the technical inputs received from M/s Venus Safety and Health Pvt Limited as given at **Annex 7** to the agenda.

The committee also considered the proposed draft amendment 1 to IS 18266 : 2023 as given in **Annex 8** to the agenda.

After deliberation, the committee decided that the draft amendment as given in agenda shall be issued in **wide circulation** for **30 days** for eliciting technical comments from stakeholders. BIS may carry out the editorial changes in the draft if required.

Item 6 NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD

6.1 The committee considered the list of products as given at **Annex 9** along with the technical inputs received on New Subjects (Knee Cap, Lumbo Sacral Belt, Wrist and Forearm Splint, Ankle Binder, Wrist and Forearm Splint, Chest Binder) as given at **Annex 10** to the Agenda.

After deliberation, the committee requested Shri Neeraj Mehra, M/s Tynor Orthotics Pvt. Ltd., Mohali and Dr. Manish Sabharwal, Dr. Sabharwals Wound Care, Baddi (on Knee Cap) to share the working draft on the above subjects based on inhouse technical data, scientific data and International Practice and share the same with BIS in 15 days.

Based on the technical input/working draft, the matter shall be discussed in next meeting of TXD 36.

Item 7 INTERNATIONAL ACTIVITIES

7.1 The committee **NOTED** the following important outcomes of the ISO/TC 338 Plenary meeting: -

- i) ISO/TC 338 agrees to extend the task of AHG1 to propose an interim draft of the Terminology document within 30 days after WG 1 finalized its preliminary draft. Based on this proposal a NWIP ballot will be prepared and launched by the committee manager

with the intention of developing the document as an international standard in a working group that is to be established if the NWIP is approved.

- ii) ISO/TC 338 requests BIS to prepare a New Proposal Form 4 for ISO/PWI 25130 General and safety requirements of menstrual products latest by September 30, 2024. If approved, this project will be allocated to WG1 – Safety, performance and general requirements of menstrual products.

7.2 The committee **NOTED** the information. It was informed that the following working panel was constituted/approved by TXD 36 for participation in next meeting of ISO/TC 304/Working Group (in virtual mode) to represent India’s point of view for proposal of NWIP on “Guidelines for Processing of Multiple-Use Healthcare Textiles’.

- a) **Dr. Sanjiiv Rehlan, FICCI, New Delhi (Shalex Medtech/PWMAI) (Project Leader)**
- b) Dr. Sidhartha Satpathy, AIIMS, New Delhi
- c) Dr. Pankaj Arora, PGIMER, Chandigarh
- d) Dr. Lallu Joseph, Consortium of Accredited Health Care Organizations (CAHO), New Delhi
- e) Dr. Sunil Khetarpal, Director, AHPI New Delhi
- f) Dr Kashipa Harit, National Accreditation Board for Hospitals & Healthcare Providers (NABH), New Delhi
- g) Dr. Vivek Kulkarni (Personal Capacity)
- h) Head (Textiles) and/or Member Secretary, TXD 36, BIS New Delhi

The above experts from India may be registered in ISO global directory for ISO/TC 304 committee/Working Group for ISO/NP 25199, Guidelines for Processing of Multiple-Use Healthcare Textiles, once the project is approved by ISO TC 304.

Item 8 COMMENTS ON PUBLISHED STANDARDS

8.1 IS 5405 : 2019, Sanitary Napkins — Specification (Second Revision)

The committee considered the comments received from SITRA, Dima Products, Kenvue, P &G, ICMR, Soothe Healthcare and Anabio Technologies as given at **Annex 16** of the agenda.

After deliberation, the committee decided that an amendment incorporating following minor editorial changes shall be issued in IS 5405 : 2019 :-

- 1) (*Page 1, clause 6.1*, fourth line) — Substitute ‘pre-glued or without glue’ for ‘pre-glued’.

The committee further decided that the matter is urgent or non-controversial 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 be held to have been FINALIZED for publication.

The committee also decided to constitute a panel of the following members to discuss the comments received on IS 5405 and provide its recommendation for amendment and/or revision of standard within 30 days: -

- 1) Ms. Shradha Dongre, SASMIRA, Mumbai (**Convenor**)
- 2) Dr. Sadhana Srivastava, ICMR New Delhi
- 3) Dr. E. Santhini, SITRA, Coimbatore
- 4) Shri Nirav Mehta/Smt. Roocha Khedkar, Representing Indian Technical Textile Association/ Feminine and Infant Hygiene Association, Mumbai
- 5) Smt. Tanya Mahajan, The Pad Products (NGO), India
- 6) Shri Mithun Shah, Anabia Technologies, Bengaluru
- 7) 2-3 expert's subject experts/Doctors
- 8) Member Secretary, TXD 36

Based on the technical inputs/recommendation received, the matter shall be discussed in next meeting of panel/TXD 36 committee.

8.2 The committee considered the comments received from Ginni Filaments, Kenvue and Unicharm India on IS 17787 : 2021 and IS 17788 : 2021 as given at **Annex 17** of the agenda.

1	IS 17787 : 2021	Medical Textiles — Nonwoven Wipes — Specification
2	IS 17788 : 2021	Medical Textiles — Nonwoven Fabric for Wipes — Specification

The member secretary placed the comments received from M/s Welspun India Limited during the meeting.

After deliberation, the committee decided as follows:-

- 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 within 15 days :-
 - 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 within 15 days.

- 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 within 15 days.

Based on the inhouse data and test report, the matter shall be discussed in next meeting of TXD 36

Item 9 REVIEW OF PRE-2000 STANDARDS/DUE FOR REVIEW

9.1 The committee considered the list of standards due for 5-year review as given at **Annex 18** along with the list of pre-2000 standards given at **Annex 19** to the agenda. After deliberation, the committee decided the following: -

- i) The committee requested experts/committee member to send their comments and suggestion for standards due for review/pre-2000 standards within 15 days.
- ii) BIS should approach other stakeholder who are not represented in TXD 36 committee/working groups/panel for their feedback and suggestion for changes required in the these standards.
- iii) BIS shall prepare the review performa and circulate the same to committee members for 15 days through BIS Standards Portal. If no comments received after 15 days, the standards shall be reaffirmed for a further period of 5 years.
- iv) If the pre-2000 standards are not is use/limited use, they shall be archived for the time being.
- v) Based on the suggestion/comments of experts where amendment and revision are required in the published standard, BIS shall fill the Performa for review and prepare the draft amendment/draft revision. The draft amendment/draft revision standard so prepared shall be issued in wide circulation for **30 days** for eliciting technical comments from stakeholders. BIS may carry out the editorial changes in the draft if required.

Item 10 DATE AND PLACE OF NEXT MEETING

10.1 The Committee DECIDED to hold the next meeting in consultation with Chairman TXD 36 on Top Priority.

Item 11 ANY OTHER BUSINESS

11.1 There being no other business, the meeting ended with a hearty vote of thanks to the Chair and members present in the meeting.