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**BUREAU OF INDIAN STANDARDS**

**Resolution**

**Technical Textiles for Medtech Applications 27th Meeting**

**Sectional Committee, TXD 36**

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

**Attendees :-**

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| **Sl No.** | **Name of Representative** | **Organization** |
|  | **Dr. Prakash Vasudevan** **(Chairman)** | **Director, SITRA** |
|  | Smt. Prabha Hegde | 3 M India Limited, New Delhi |
|  | Shri Apurva Ranka | Alpha Foam Ltd., Pune |
|  | Shri Mithun A. Shah | Anabio Technologies Pvt Ltd., Bengaluru |
|  | Capt. Baban Rai | Association of Healthcare Providers (India), New Delhi |
|  | Dr. Sunil Khetarpal | -do- |
|  | Smt. Pallavi Shukla | All India Institute of Medical Sciences, Delhi |
|  | Smt. Aiswarya Sudhakar | Bella Premier Happy Hygiene Care Pvt Ltd., Tamil Nadu |
|  | Shri Ajai Basil | Central Drugs Standard Control Organization (CDSCO), New Delhi |
|  | Shri Rupande Sampat | Chemco Group, Mumbai |
|  | Shri R Krishana Kumar | Cologenesis Healthcare Pvt. Ltd, Salem |
|  | Dr. B.S Charan  | Director General of Health Services, New Delhi |
|  | Shri Sumit Marwah | Dispoline India Private Limited, Bangalore |
|  | Shri Arnab Das | DGQA (Ministry of Defence), New Delhi |
|  | Shri Nirav Mehta | Dima Products, Mumbai |
|  | Shri Raghavan Adiyodi | -do- |
|  | Dr Manish Sabharwal | Dr. Sabharwals Wound Care, Baddi Himachal Pradesh |
|  | Ms Tulsi | Federation of Indian Chambers of Commerce & Industry(Shalex Medtech), New Delhi |
|  | Shri Gurmeet Singh | Ginni Filaments Limited, Noida |
|  | Shri Pronab Nandi | -do- |
|  | Shri Ayan Chakraborty | -do- |
|  | Shri Mayank Rohatagi | Healthium Medtech Ltd., Bengaluru  |
|  | Dr. Sadhana Srivastava | Indian Council of Medical Research, New Delhi  |
|  | Prof. Bipin Kumar | Indian Institute of Technology Delhi (IIT Delhi), New Delhi |
|  | Smt. Ashwani Agarwal | -do- |
|  | Dr. Anup Rakshit | Indian Technical Textile Association, Mumbai |
|  | Smt. Ruchita Gupta | -do- |
|  | Smt. Monika Sathe | Kenvue, Mumbai |
|  | Ms. Roocha Khedkar | -do- |
|  | Smt. Komal Sharma | Kimberly-Clark Corporation, Mumbai |
|  | Shri T. Balaji | KOB Medical Textiles Pvt Ltd, Palladam  |
|  | Ms. Shivani Swamy | Livinguard Technologies Pvt. Ltd., Mumbai  |
|  | Shri Lalit Gupta | Maulana Azad Medical College, New Delhi |
|  | Shri Anthony D’Costa | Medline Healthcare Industries Pvt Ltd., Pune |
|  | Smt. Damini Sagar | -do- |
|  | Shri Ajay Pandit | Ministry of Textiles, New Delhi |
|  | Smt. Neeta Anand  | National Accreditation Board for Hospitals & Healthcare Providers, New Delhi |
|  | Shri Joy Devassy | Nobel Hygiene, Mumbai |
|  | Smt. Sneha Gupta | -do- |
|  | Shri Kaushik Johari | -do- |
|  | Shri Kamal Johari | -do- |
|  | Shri Pankaj Arora | PGIMER, Chandigarh |
|  | Shri Vijay Tadia | -do- |
|  | Shri Prashant Jadhav | Procter and Gamble Co., Mumbai  |
|  | Shri Girish Parhate | -do- |
|  | Shri Prajwal | -do- |
|  | Shri Leda Uy | -do- |
|  | Shri Napat | -do- |
|  | Shri Yao Ying | -do- |
|  | Shri Ujjawal Kedia | -do- |
|  | Shri Ayush Upadhyay | Soothe Healthcare Pvt Ltd., New Delhi |
|  | Smt. Pardhi Mantri | -do- |
|  | Shri Mohit Chhoker | Surgeine Health Care Pvt Ltd.(AIMED), New Delhi |
|  | Shri Shubham Kumar | -do- |
|  | Shri Kavivnder Kumar  | Solis Hygiene Pvt. Ltd., Madhya Pradesh |
|  | Shri Kulveen Singh Bali | Solventum India |
|  | Shri Ashish Naik | Swara Baby Products Pvt Ltd., Madhya Pradesh |
|  | Dr. P. Ravichandran | Textiles Committee Mumbai |
|  | Shri Neeraj Mehra | Tynor Orthotics Pvt Ltd., Mohali |
|  | Smt. Tanya Mahajan | The Pad Project (NGO), India |
|  | Shri S. Sivakumar | The South India Textile Research Association, Coimbatore — 641014 |
|  | Dr. E. Santhini | -do- |
|  | Shri Veerasubramanian | -do- |
|  | Dr Manisha Mathur | The Synthetics & Art Silk Mills Research Association, Mumbai |
|  | Smt. Shradha Dongre | -do- |
|  | Shri Rohit Shrivastava | Unicharm India Pvt Ltd., Gurugram  |
|  | Smt. Dipti Sharma | -do- |
|  | Shri Tanuj | -do- |
|  | Shri Lal Singh | -do- |
|  | Shri Babaroa Narotepatil | Welspun Living Ltd., Mumbai |
|  | Shri Nitin Goyal | -do- |
|  | Shri Sandeep Jalit | -do- |
|  | Shri Basudev Basu | -do- |
|  | Shri Shrish Narwade | -do- |
|  | Shri Rajeev Chauhan | -do- |

**BIS DIRECTORATE GENERAL**

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| --- | --- | --- |
| 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:

1. 3 M India Limited, New Delhi will be represented by Smt. Prabha Hegde as Principal Member and Smt. Kavitha Kulkarni as an Alternate Member.
2. 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.

1. Amendment No. 2 to IS 17509 : 2021 Disposable Baby Diaper — Specification [Doc: TXD 36 (25701)]
2. Amendment No. 1 to IS 758 : 2023 Medical Textiles — Absorbent Cotton Gauze — Specification (Fifth Revision) [Doc: TXD 36 (25704)]
3. 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 : -

1. The weight of X Large category is to be updated as ‘13-15 kg’.
2. The value of rewet under load (gm), Max for all size is to be updated as ‘3’.
3. 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 : -

1. 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: -

1. 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.
2. 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’.

1. **Dr. Sanjiiv Rehlan, FICCI, New Delhi (Shalex Medtech/PWMAI) (Project Leader)**
2. Dr. Sidhartha Satpathy, AIIMS, New Delhi
3. Dr. Pankaj Arora, PGIMER, Chandigarh
4. Dr. Lallu Joseph, Consortium of Accredited Health Care Organizations (CAHO), New Delhi
5. Dr. Sunil Khetarpal, Director, AHPI New Delhi
6. Dr Kashipa Harit, National Accreditation Board for Hospitals & Healthcare Providers (NABH), New Delhi
7. Dr. Vivek Kulkarni (Personal Capacity)
8. 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 5409 : 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:-

1. 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 :-
2. Shri Ayan Chakraborty, Ginni Filament, Haridwar
3. Smt. Roocha Khedkar, Kenvue Mumbai
4. Shri Basudev Basu, Welspun India Limited, Gujarat
5. 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.

1. 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 consideredthe 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: -

1. The committee requested experts/committee member to send their comments and suggestion for standards due for review/pre-2000 standards within 15 days.
2. 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.
3. 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.
4. If the pre-2000 standards are not is use/limited use, they shall be archived for the time being.
5. 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.