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## BUREAU OF INDIAN STANDARDS

### MINUTES

Technical Textiles for Medtech Applications  
Sectional Committee, TXD 36

16<sup>th</sup> Meeting

| Date                     | Time   | Venue                                |
|--------------------------|--------|--------------------------------------|
| 28 June 2021<br>(Monday) | 1430 h | Video Conference through CISCO Webex |

### ATTENDEES:

- 1) **Dr. Prakash Vasudevan** (Chairman) Director, SITRA, Coimbatore
- 2) Shri Kulveen Bali 3 M India Limited, Bangalore
- 3) Dr. Prabha Hegde -do-
- 4) Shri Prasanta Panda BTRA, Mumbai
- 5) Dr. Ravikant Sharma CDSCO, New Delhi
- 6) Shri R. Krishnakumar Cologenesi Healthcare Pvt Ltd, Coimbatore
- 7) Surg Cmde Dilip Raghavan DGAFMS, New Delhi
- 8) Shri Nirav Mehta Dima Products, Mumbai
- 9) Dr. Anil Kumar Director General of Health Services, New Delhi
- 10) Dr. Bina R Sahney -do-
- 11) Shri Sumit Marwah Dispoline India Private Limited, Bangalore
- 12) Dr. Manish Sabharwal Dr. Sabharwals Manufacturing Labs Pvt Ltd,
- 13) Shri Hari Dynamic Techno Medical Pvt. Limited, Kerala
- 14) Dr. Sanjeev Rehlan FICCI, New Delhi (Shalex Overseas)
- 15) Ms Tulsi - do -
- 16) Shri Pramod Sharma Ginni Filaments Ltd, Noida
- 17) Shri Gurmeet Singh - do -
- 18) Shri Anshu Gupta Goonj, New Delhi
- 19) Ms. Sneha Dey -do-
- 20) Shri Ravikant Dwivedi -do-
- 21) Ms. Smita Singh -do-
- 22) Dr. Prakmya Gupta ICMR, New Delhi
- 23) Dr Anup Rakshit Indian Technical Textile Association, Mumbai
- 24) Shri Vivek Bansal J&J Ltd., Mumbai
- 25) Shri Arun Buchade KOB Medical Textiles Pvt. Limited, Coimbatore
- 26) Shri T. Balaji - do -
- 27) Ms. Shivani Swamy Livinguard Technology Pvt. Ltd., Mumbai
- 28) Shri Dnyaneshwar Jonghale -do-

|                            |   |
|----------------------------|---|
| 29) Smt. Tanya Mahajan     | MHAI Alliance, New Delhi                                    |
| 30) Shri Prashant Jadhav   | P&G Ltd., Mumbai  |
| 31) Shri Paresh Patel      | Surgicotfab Textile Pvt. Ltd. Ahmedabad                     |
| 32) Dr E Santhini          | The South India Textile Research Association,<br>Coimbatore |
| 33) Shri Veera Subramaniam | - do -  |
| 34) Shri Kartikeyan Dhanda | Textiles Committee, Mumbai                                  |
| 35) Dr. P. Ravichandran    | - do -  |
| 36) Shri Rajkumar Sontakke | -do-  |
| 37) Dr. Manisha Mathur     | SASMIRA, Mumbai   |
| 38) Ms. Shradha Dongre     | - do -  |
| 39) Shri Mahesh Kudhav     | Venus Safety and Health Pvt. Ltd., Mumbai                   |
| 40) Shri Harshal Patil     | - do -  |
| 41) Shri Sandeep           |   |

## **BIS DIRECTORATE GENERAL**

|  |                                       |
|--|---------------------------------------|
| 42) Shri Dharmbeer<br>Scientist C (Textiles) &<br>(Member Secretary) | Bureau of Indian Standards, New Delhi |
| 43) Shri Sourabh Awasthi<br>Young Professional (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 15<sup>th</sup> meeting of the TXD 36 committee held on 18 January 2021 through CISCO Webex Videoconferencing as circulated vide email dated 27 January 2021.

## **Item 2 SCOPE AND COMPOSITION OF TXD 36**

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

- a) Nomination/Fresh nominations to be sought from the following organizations:
  - i) Coimbatore Medical College & Hospital, Coimbatore
  - ii) Govt. Medical College & ESI Hospital, Coimbatore

- iii) Kamal Healthcare Pvt. Limited, Tamilnadu
- iv) Lady Irwin College, New Delhi
- v) Maulana Azad Medical College, 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 15<sup>th</sup> meeting of TXD 36 as given in **Annex 2** to the agenda.

### **Item 4 DRAFT AMENDMENT FOR FINALIZATION**

#### **4.1**

#### **1) TXD 36 (16331), Draft Amendment No. 1 to IS 17350 : 2020, Medical Textiles — Abdominal Binder — Specification**

The Committee considered the draft amendment as given in **Annex 3** to the agenda along with the comments received from Shri Hari, M/s Dynamic Techno Medicals Pvt. Ltd. during the meeting.

After deliberations, the committee decided that the Shri Hari, Dynamic Techno Medicals Pvt. Limited will share technical details of test method and requirement for breaking strength and elongation at break, dimensional stability to washing and colorfastness to washing. The committee also decided to keep biocompatibility evaluation — cytotoxicity, irritation and skin sensitization requirement as an optional requirement as per agreement between buyer and seller.

The revised amendment shall be prepared by BIS in consultation with M/s Dynamic Techno Medicals Pvt. Ltd, Kerala. The committee further decided that draft amendment so prepared shall be issued under wide circulation for eliciting technical comments from stakeholders for a period of **one month**. BIS may carry out the necessary editorial changes in the draft, if required.

### **Item 5 DRAFT STANDARD FOR APPROVAL FOR PRELIMINARY DRAFT**

The Committee considered the technical inputs and working draft standard from M/s Venus Safety and Health Pvt. Ltd. as given in **Annex 4** to the agenda.

After detailed deliberations, the committee decided the following: -

- i) Most of the manufacturers of surgical face mask are from MSME sector so inputs/suggestion from these stakeholders/associations shall be sought for further action regarding proposed revision of IS 16289 surgical face masks and inclusion of medical respirator requirements.
- ii) Contact details of at least 5-6 manufacturers of medical respirator and testing laboratories where the complete testing facility are available shall be provided by M/s Venus Safety and Health Pvt. Ltd., Mumbai.
- iii) Technical Data and test reports to support the requirement given in the draft for medical respirators for other 2 classes i.e., IN 80 and IN 99 will be provided by M/s Venus Safety and Health Pvt. Ltd., Mumbai.

- iv) Any other necessary information/requirement.

Based on the technical inputs and comments received, the matter shall be taken up for discussion in next meeting of TXD 36.

## **Item 6 NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD**

### **6.1 Dental Floss and Eye Patch/Dressing**

The committee considered the technical inputs from Dr. Prabha Hegde, 3 M India on Dental Floss and Eye Patch Dressing as given in **Annex 5** to the agenda.

#### **i) Dental Floss**

The committee observed that the technical inputs are mainly for integrated dental floss and handles (based on ISO 28158 : 2010) and does not cover the textile component of dental floss. The committee requested Dr. Manish Sabharwal, Dr. Sabharwal Medical Pvt. Limited Chandigarh and Dr. Manisha Mathur, SASMIRA, Mumbai to share the contact details of manufacturers of dental floss so that BIS can approach them for technical inputs for preparation of working draft on dental floss.

#### **ii) Eye Patch Dressing**

The committee decided that the subject will be taken up for formulation of standards if at least 5-6 manufactures and testing facility are available for the product in India and the need for formulation of the standard is justified for safety of user.

The committee further decided that the following technical inputs/ information along with revised working draft shall be provided by Dr. Prabha Hegde, 3 M India and Dr. Manish Sabharwal, Dr Sabharwal Medicals Pvt Ltd, Chandigarh to BIS within 15 days: -

- i) Foreword, need and justification for formulation of the standard.
- ii) Review requirement of fibre composition, adhesiveness, fabric weight of adhesive fabric, tensile strength of base fabric and add the parameter where applicable.
- iii) Exclude biocompatibility requirement.
- iv) Technical document/test reports to support the requirement given in the working draft.
- v) Contact details of the laboratory in India where the complete test facilities are available
- vi) Contact details of at least 5-6 manufacturers of eyepatch dressing in India.
- vii) Any other necessary information/requirement.

The committee also decided that the working draft [Sl no. (i), (ii)] so prepared may be circulated to TXD 36 members for technical comments for 15 days. BIS may carry out the editorial changes in the draft if required.

### **6.2 Elastic Bandage and Elastic Crepe Bandage**

The committee considered the technical information and working draft from KOB Medical Textiles Pvt. Limited as given in **Annex 6** to the agenda.

After deliberation, the committee decided that most of the requirement of elastic crepe bandage specified in draft proposal of KOB Medical Textiles Pvt. Limited are similar to IS 16111 : 2013 'Elastic Bandage' and has been already covered in IS 16111 : 2013. So, there is no need of separate standard for Elastic Crepe Bandage.

### **6.3 Community Face Mask**

The Committee considered the request for formulation of standard on Community Face Mask from SITRA as given in **Annex 7** to the agenda.

After detailed deliberations, the committee decided that Dr. E. Santhini, SITRA shall co-ordinate with following stakeholder for their technical inputs (if any): -

- i) Shri Harshal Patil, VENUS Safety & Health Pvt Ltd., Mumbai
- ii) Dr. Manisha Mathur, SASMIRA Mumbai
- iii) Ms. Shivani Swamy, Livinguard Technology Pvt. Ltd., Mumbai

& provide the following information to BIS within 15 days: -

- i) Working Draft (including the foreword, need of the standard, use and significance of the product).
- ii) Technical document/test reports to support the requirement given in the working draft.
- iii) Contact details of the laboratory in India where the complete test facilities are available.
- iv) Contact details of at least 5-6 manufacturers of community face mask in India.
- v) Any other necessary information/requirement.

The committee further decided that the working draft so prepared shall be circulated to TXD 36 members for technical comments for 15 days. BIS may carry out the editorial changes in the draft if required.

## **Item 7 COMMENTS ON PUBLISHED STANDARDS**

### **7.1 Comments on IS 5405 : 2019, Sanitary Napkins — Specification (second revision) and IS 17514 : 2021, Reusable Sanitary Pad / Sanitary Napkin / Period Panties — Specification**

The committee considered the recommendations of webinar and comments received through eBIS module as given in **Annex 8** to the agenda along with the comments received from Goonj, NGO as given in **Annex 9** to the agenda.

After deliberation, the committee decided the following: -

- i) Biocompatibility evaluation — cytotoxicity, irritation and skin sensitization test is very expensive, time consuming and involved in-vivo testing on animals which makes it difficult to comply for MSME sector and the cost of production will increase substantially. In view of this, the committee decided to keep biocompatibility evaluation as an optional requirement in IS 5405 and IS 17514 for

- sanitary pad/reusable cloth pad on raw material stage as per the agreement between buyer and seller.
- ii) The requirement of 'Biodegradability and Compostability' shall be reviewed in IS 5405 to exclude oxy-degradability as this is a misleading term for the consumers.
  - iii) In IS 5405, Clause 7.1, delete word 'cold method, as there is no such method in IS 1390 : 2019 for determination of pH.
  - iv) Any other editorial changes in the standards.

The committee further decided that the draft amendment no. 1 to IS 5405 and IS 17514 shall be prepared by BIS and the same shall be issued in wide circulation for a period of **one month** for eliciting technical comments from stakeholders.

**7.2** The committee requested Dr. Sanjiiv, FICCI, New Delhi to share the technical inputs/specific proposal for sampling plan on the respective standard of medical textiles published under TXD 36 and the same shall be taken up for discussion in the next meeting of TXD 36.

**7.3** The committee considered the standards published on similar type of products e.g., Bandage, Gauze and swab as given in **Annex 10** to the agenda and requested the following stakeholder to give their suggestion and comments to BIS within 30 days for amalgamation, revision, amendment or withdrawal: -

- i) Dr. Manish Sabharwal, Dr Sabharwal Medicals Pvt Ltd, Chandigarh
- ii) Shri D. Veerasubramaniam, SITRA Coimbatore
- iii) Mr. Paresh Patel, Surgicotfab Textile Pvt. Ltd. Ahmedabad
- iv) Mr. Arun Buchade, KOB Medical Textiles Pvt Ltd, Coimbatore

The committee requested Member Secretary to provide soft copies to members within 07 days.

Based on the technical inputs and comments, the matter shall be taken up for discussion in next meeting of TXD 36.

## **Item 8 REVIEW OF PUBLISHED STANDARDS**

**8.1** The committee considered the standards due for review as given in **Annex 11** to the agenda.

After deliberation, the committee constituted the following panel of members for thorough study of the Indian standards under review and give their comments/technical inputs to BIS within 15 days: -

- 1) Dr. Manish Sabharwal, Dr Sabharwal Medicals Pvt Ltd, Chandigarh (**Convenor**)
- 2) Shri E. Santhini, SITRA Coimbatore
- 3) Shri Jitendra Sachchade/Representative, AiMed, New Delhi
- 4) Mr. Paresh Patel, Surgicotfab Textile Pvt. Ltd. Ahmedabad
- 5) Mr. Hari, M/s Dynamic Techno Medicals Pvt. Ltd, Kerala
- 6) Mr. Arun Buchade, KOB Medical Textiles Pvt Ltd, Coimbatore
- 7) The panel may co-opt the members/experts as required
- 8) Shri Dharmbeer, Member Secretary, TXD 36, BIS New Delhi

The committee requested Member Secretary to provide soft copies (preferably in word format for ease in incorporation of changes) to panel members within 07 days. The committee also decided that based on the technical inputs received from the panel on the review of Indian standards, the standards shall be taken up for revision/amendment/withdrawal.

#### **Item 9 DATE AND PLACE OF NEXT MEETING**

**9.1** The Committee DECIDED to hold the next meeting on Priority after completing all the actions arising out of this meeting in consultation with Chairman TXD 36.

#### **Item 10 ANY OTHER BUSINESS**

**10.1** The committee decided that Dr. Sumit Marwah, Dispoline India Private Limited, Bangalore and Dr. Sanjiiv, FICCI, New Delhi (Shalex Overseas) shall thoroughly review the published standard 'IS 17334 : 2019 'Medical Textiles — Surgical Gowns and Surgical Drapes — Specification' and send their comments with justification to BIS within 15 days for further necessary action.

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