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## BUREAU OF INDIAN STANDARDS

### MINUTES

Technical Textiles for Medtech Applications  
Sectional Committee, TXD 36

25<sup>th</sup> Meeting

Date	Time	Venue
05 January 2024 (Friday)	1430 h	Video Conference through CISCO Webex

### Attendance

Sl No.	Name of Member	Organization
1.	<b>Dr. Prakash Vasudevan (Chairman)</b>	<b>Director, SITRA</b>
2.	Shri Kulveen Sing Bali	3 M India Limited, New Delhi
3.	Smt. Prabha Hegde	-do-
4.	Shri Arnab	Aakar Innovation, Mumbai
5.	Shri Apurva Ranka	Alpha Foam Ltd., Pune
6.	Smt. Rama Venugopal	Association of Indian Medical Device Industry (AiMeD), New Delhi
7.	Shri Amit Kumar	-do-
8.	Shri Shyamni Sasidharan	Central Drugs Standard Control Organisation, New Delhi
9.	Shri R Krishana Kumar	Cologenesis Healthcare Pvt. Ltd, Salem
10.	Dr. Vikas B Thakare	Defence Research & Development Establishment (DRDE), Gwalior
11.	Surg Capt S.S Dalawayi	DGAFMS, Ministry of Defence, New Delhi
12.	Shri Arnab Das	DGQA (Ministry of Defence), New Delhi
13.	Shri S S Kashyap	-do-
14.	Shri Nirav Mehta	Dima Products, Mumbai
15.	Dr. Naresh Panchal	Director General of Health Services, New Delhi
16.	Dr. B.S Charan	-do-
17.	Shri Sumit Marwah	Dispoline India Private Limited, Bangalore
18.	Dr. Mukesh Kumar Sinha	DMSRDE, Kanpur
19.	Shri Manish Sabharwal	Dr. Sabharwals Manufacturing Labs Pvt Ltd, Panchkula
20.	Shri Dhruv Sabharwal	-do-
21.	Ms. Vedika	Eco Femme, Kerala
22.	Dr. Sanjiv Rehlan	Federation of Indian Chambers of Commerce & Industry, New Delhi

23.	Ms Tulsi	-do-
24.	Shri Gurmeet Singh	Ginni Filaments Limited, Noida
25.	Shri Chiranjit	Goonj, New Delhi
26.	Dr. Sadhana Srivastav	Indian Council of Medical Research, New Delhi
27.	Dr. Anup Rakshit	Indian Technical Textile Association
28.	Ms. Roocha Khedkar	JNTL Consumer Health (India) Pvt Ltd. (Kvenue), Mumbai
29.	Smt. Monika Sathe	-do-
30.	Shri Rakesh Sahni	-do-
31.	Shri Mayur Vasani	-do-
32.	Smt. Sonal Shidhore	-do-
33.	Dr Priti Thakor	-do-
34.	Shri Mehul Tyagi	Johnson and Johnson, Mumbai
35.	Shri Hemant Sonawane	-do-
36.	Shri Bhuwan Singla	-do-
37.	Smt. Komal Sharma	Kimberly-Clark Corporation, Mumbai
38.	Shri Abhijit Joshi	-do-
39.	Shri T. Balaji	KOB Medical Textiles Pvt Ltd, Palladam
40.	Dr J. Jayalakshmi	Kovai Medical Center and Hospital, (KMCH), Coimbatore
41.	Ms. Shivani Swamy	Livinguard Technologies Pvt. Ltd., Mumbai
42.	Dr. Lalit Gupta	Maulana Azad Medical College, New Delhi
43.	Shri Anothony D' Costa	Medline Healthcare Industries Pvt. Ltd, Pune
44.	Smt. Sneha Gupta	Nobel Hygiene, Mumbai
45.	Shri Joy Devassy	-do-
46.	Shri Kamal Johari	-do-
47.	Shri Kaushik Johari	-do-
48.	Shri Sivakumar S.	Office of Textile Commissioner, Mumbai
49.	Dr. Vijay Tadia	PGIMER, Chandigarh
50.	Shri Pankaj Arora	-do-
51.	Shri Prashant Jadhav	Procter and Gamble Co., Mumbai
52.	Shri Girish Parhate	-do-
53.	Shri Prajwal	-do-
54.	Shri Karthik	Real Relief, Tamilnadu
55.	Smt. Paridhi	Soothe Healthcare Pvt. Ltd., Noida
56.	Shri Sharad Khise	-do-
57.	Dr. E. Santhini	South India Textile Research Association, Coimbatore
58.	Shri S. Sivakumar	-do-
59.	Shri Khalil Khan	Surya Textech, Chandigarh
60.	Smt Meeta Singla	Testtex India Laboratories Pvt Ltd, Mumbai
61.	Dr. P. Ravichandran	Textiles Committee, Mumbai
62.	Shri Ashwini Govekar	The Bombay Textile Research Association, Mumbai
63.	Smt.Prasanta K. Panda	-do-
64.	Smt. Tanya Mahajan	The Pad Project (NGO), India

65.	Smt. S. S. Dongre	The Synthetics & Art Silk Mills Research Association, Mumbai
66.	Dr Manisha Mathur	-do-
67.	Shri Rohit Shrivastava	Unicharm India, Gurgaon
68.	Shri Samir Gupta	-do-
69.	Shri Harshal Patil	Venus Safety and Health Pvt Limited, Navi Mumbai

## **BIS DIRECTORATE GENERAL**

1.	Shri Dharmbeer, Scientist D/Joint Director (Textiles) & (Member Secretary)	Bureau of Indian Standards, New Delhi
2.	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** The committee decided to include Dr. Priti Thakor Kenvue (JNTL Consumer Health (India) Private Limited), Mumbai in the attendance list of 24<sup>th</sup> meeting of TXD 36. The committee further decided that the other comments received from Ms. Roocha Khedkar R&D JNTL Consumer Health (India) Pvt. Ltd. are not related to the accuracy of recording of 24<sup>th</sup> minutes of TXD 36 meeting. These are the technical comments on IS 5405 : 2019/IS 17514 : 2021 which will be taken up for discussion under agenda Item **5.1**.

**1.1** In view of no other comments on accuracy of recording of minutes, the Committee **CONFIRMED** the minutes of 24<sup>th</sup> meeting of TXD 36 committee held on 07 November, 2023 through CISCO Webex Video conferencing as circulated vide email dated 16 November, 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 2** to the agenda and **DECIDED** as follows:

- a) The updated nomination of the following organizations be as under: -
  - i) DGQA (Ministry of Defence), New Delhi will be represented by Shri S.S. Kashyap as a Principal Member and Shri Arnab Das as an Alternate Member.

- ii) JNTL Consumer Health (India) Pvt Ltd. (Kvenue), Mumbai will be represented by Smt. Monika Sathe as a Principal Member and Ms. Roocha Khedkar as an Alternate Member.
- iii) Central Drugs Standard Control Organization, New Delhi will be represented by Dr. Aseem Sahoo as a Principal member and Shri Shyamni Sasidharan as an Alternate Member.
- iv) Dima Products, Mumbai will be represented by Shri Nirav Mehta as a Principal Member and Shri Raghavan Adiyodi as an Alternate Member.
- v) Livinguard Technologies Pvt. Ltd., Mumbai will be represented by Ms. Shivani Swamy as a Principal Member and Shri Shashank Morje as an 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 24<sup>th</sup> meeting of TXD 36 as given in **Annex 3** of the agenda.

### **Item 4 RESEARCH AND DEVELOPMENT PROJECT**

#### **4.1 New Subject - Surgical Sutures (absorbable and non-absorbable)**

**4.1** The committee noted the information given in finalized term of reference (ToR) for Surgical Sutures (absorbable and non-absorbable).

### **Item 5 COMMENTS ON PUBLISHED STANDARDS**

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

The committee considered the testing results received from Dima Products, P & G, Kenvue (JNTL Consumer Health) and Kimberly Clark Pvt. Ltd as given in **Annex 5** of the agenda.

The committee also considered the comments received from Feminine and Infant Hygiene Association (FIHA) and P &G Mumbai as given in **Annex 6** of the Agenda.

After deliberation, the committee decided that the following changes shall be incorporated in draft amendment 4 to IS 5405 and IS 17514: -

- i) The range of pH shall be changed from ‘5.5-8.0 to 3.5-7.5 for both disposable and reusable sanitary napkins.
- ii) To remove the declaration of material and chemical ingredient.

The draft amendments after incorporating the above changes are given in **Annex 1 to Minutes (Pages 8-9)**.

The committee further decided that the matter is urgent and the wide circulation of the above amendments be waived off under Rule 22 (4) of BIS Rules 2018 notified vide GSR 584(E) dated 25 June 2018; and draft amendments be held to have been FINALIZED for publication.

BIS may carry out the editorial changes in the finalized draft, if required.

The committee requested Kenvue, P & G and other stakeholders to contact BIS Branch Office/CMD 2 department for certification/product manual related queries for IS 5405, IS 17514 and IS 17509.

## **5.2 IS 17509: 2021, Disposable Baby Diaper — Specification**

The committee considered the comments received from P &G, Mumbai as given in **Annex 8** of the agenda.

After deliberation, the committee decided that the following changes shall be incorporated in draft amendment 1 to IS 17509: -

- i) The requirement of biocompatibility shall be made optional.
- ii) To remove the declaration of material and chemical ingredient.
- iii) The information whether the material of the product is biocompatible is to be included on marking clause.
- iv) A tolerance of 0.1 percent on the total weight of rigid cover plate in clause **B 2.2** may be permitted.

The draft amendment after incorporating the above changes is given in **Annex 2 to Minutes (Page 10)**.

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 be held to have been FINALIZED for publication. BIS may carry out the editorial changes in the finalized draft, if required.

The committee also considered the request from P & G, Nobel Hygiene, Unicharm India to review the requirement of pH test, Rate of absorption per gush (s), weight of rigid cover plate (B 2.2) in IS 17509 : 2021.

The committee decided that the following manufacturers/stakeholders shall send atleast 5 samples (wood pulp or superabsorbent polymer or combination in absorbent core) any size/lot of baby diaper for testing of pH test as per IS 1390 : 2022/ISO 3071 : 2020 and Rate of absorption per gush (s) to each lab i.e Testtex, SASMIRA and SITRA separately for testing within 07 days :-

- i) Shri Prashant Jadhav, P & G, Mumbai
- ii) Shri Kamal Johari, Nobel Hygiene, Mumbai
- iii) Shri Rohit Shrivastava, Unicharm India, Gurgaon

The cost of testing above samples shall be borne by above manufacturer.

The committee also requested P & G, Nobel Hygiene, Unicharm India to share the International standard and regulation, scientific evidence and technical data, Inhouse testing report, Third Party Report supporting their comments.

Based on the testing results and technical data, BIS shall prepare the draft amendment to IS 17509 : 2021 and the same shall be issued in wide circulation for **30 days**. BIS may carry out the editorial changes in the draft amendment if required.

### **5.3 IS 17508: 2020, Disposable Adult Incontinence Diaper - Specification**

The committee considered the proposed amendment 1 to IS 17508 (similar to IS 17509 Baby diaper, IS 5405 Sanitary Pad) after including the phthalate test as given in **Annex 10** of the agenda.

After deliberation, the committee decided that the following changes shall be incorporated in draft amendment 1 to IS 17508: -

- i) Phthalate test (similar to IS 17509 Baby diaper, IS 5405 Sanitary Pad) shall be included.
- ii) The requirement of biocompatibility shall be made optional.
- iii) To remove the declaration of material and chemical ingredient.
- iv) The information whether the material of the product is biocompatible is to be included on marking clause.

The draft amendment after incorporating the above changes is given in **Annex 3 to Minutes (Page 11)**.

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 be held to have been FINALIZED for publication. BIS may carry out the editorial changes in the finalized draft, if required.

### **5.4 IS 17354: 2020, Medical Textiles — Dental Bib / Napkins — Specification**

The considered the comments received from CMD-II, BIS as given in **Annex 11** of Agenda.

After deliberation, the committee decided to finalize the draft amendment 1 to IS 17354 : 2020 as given in **Annex 12** of Agenda.

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 be held to have been FINALIZED for publication.

## **5.5 IS 863: 2023, Medical Textiles - Cotton bandage cloth - Specification (third revision)**

The committee considered the comments received from CMD-2 of BIS on above standard.

After deliberation, the committee decided that Dr. Manish Sabharwal, Dr. Sabharwal Manufacturing Labs Pvt Ltd, Panchkula shall provide the requirement and test method for Bioburden level or objective criteria for establishing conformity to sterility test.

Based on the technical inputs, BIS shall prepare the draft amendment on above standard and the same shall be issued in wide circulation for a period of 30 days for eliciting technical comments from stakeholders. BIS may carry out the editorial changes in the draft if required.

### **Item 6 INTERNATIONAL ACTIVITIES**

The committee **NOTED** the information.

### **Item 7 REVIEW OF PRE-2000 STANDARDS**

In view of no technical inputs, the committee decided to archive the standards given in agenda (except IS 10829 : 1993).

### **Item 8 DATE AND PLACE OF NEXT MEETING**

**8.1** The Committee **DECIDED** to hold the next meeting in consultation with Chairman TXD

36.

### **Item 9 ANY OTHER BUSINESS**

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

**ANNEX 1 TO MINUTES  
(Item 5.1)**

**Doc: TXD 36 (xxxxx)**

*Draft* **AMENDMENT NO. 4**

**TO**

**IS 5405 : 2019 SANITARY NAPKINS — SPECIFICATION  
(Second Revision)**

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*(Page 2, clause 7.1)* — Substitute the following for the existing: -

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

*(Page 3, clause 7.4, second paragraph, second line)* — Substitute ‘non-cytotoxic’ for ‘none.’

*(Page 5, clause 2, Annex A)* — Substitute ‘IS 1390 : 2022/ISO 3071 : 2020 Textiles — Determination of pH of aqueous extract (*third revision*)’ for ‘1390 : 2019 Textiles — Determination of pH of aqueous extracts (*second revision*)’

NOTE — 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.

**Doc: TXD 36 (xxxxx)**

*Draft* **AMENDMENT NO. 4**

**TO**



**IS 17514 : 2021 REUSABLE SANITARY PAD / SANITARY NAPKIN / PERIOD  
PANTIES — SPECIFICATION**

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*(Page 2, clause 9.1)* — Substitute the following for the existing: -

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.

*(Page 3, clause 9.4, second paragraph, second line)* — Substitute ‘non-cytotoxic’ for ‘none.’

*(Page 6, clause 2, Annex A)* — Substitute ‘IS 1390 : 2022/ISO 3071 : 2020 Textiles — Determination of pH of aqueous extract (*third revision*)’ for ‘1390 : 2019 Textiles — Determination of pH of aqueous extracts (*second revision*)’

NOTE — 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.

**ANNEX 2 TO MINUTES  
(Item 5.2)**

**Doc: TXD 36 (xxxxx)**

*Draft* **AMENDMENT NO. 1**

**TO**

**IS 17509 : 2021 DISPOSABLE BABY DIAPER — SPECIFICATION**

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

*(Page 3, clause 7.4, first sentence)* — Substitute the following for the existing:

‘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.’

*(Page 3, clause 7.4, second paragraph, second line)* — Substitute ‘non-cytotoxic’ for ‘none.’

*(Page 5, clause 9.1)* — Insert the following at the end:

‘g) 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).’

*(Page 6, clause B 2.2)* — Insert the following new note at the end :

‘A tolerance of 0.1 percent on the total weight of rigid cover plate may be permitted if agreed between the buyer and seller.’

**ANNEX 3 TO MINUTES  
(Item 5.3)**

**Doc: TXD 36 (xxxxx)**

*Draft* **AMENDMENT NO. 1**

**TO**

**IS 17508 : 2020 DISPOSABLE ADULT INCONTINENCE DIAPER — SPECIFICATION**

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*(Page 4, clause 7.6)* — Insert the following new clause at the end: -

**‘7.7 Phthalate Test**

The amount of phthalate present in adult incontinence diaper 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.’

*(Page 3, clause 7.4, subtitle)* — Substitute the following for the existing:

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

*(Page 3, clause 7.4, first sentence)* — Substitute the following for the existing:

‘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.’

*(Page 3, clause 7.4, second paragraph, second line)* — Substitute ‘non-cytotoxic’ for ‘none.’

*(Page 5, clause 9.1)* — Insert the following at the end:

‘g) 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).’