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BUREAU OF INDIAN STANDARDS

AGENDA

Technical Textiles for Medtech Applications Sectional Committee, TXD 36 **25th Meeting**

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

CHAIRMAN: **Dr. Prakash Vasudevan, Director**
The South India Textile Research Association, Coimbatore

MEMBER SECRETARY: **Shri Dharmbeer, Scientist D/Joint Director, 'Textiles'**
Bureau of Indian Standards, New Delhi

Item 0 WELCOME & INTRODUCTORY REMARKS

Item 1 CONFIRMATION OF THE MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the 24th meeting of the TXD 36 committee held on 07-11-2023 through CISCO Webex videoconferencing were circulated vide our reference TXD 36/A 2.24 email dated 16 November 2023.

The comments received from Ms. Roocha Khedkar R&D JNTL Consumer Health (India) Pvt. Ltd. are given in **Annex 1 (Pages 5-8).**

1.1.1. The committee may **REVIEW** and **APPROVE** the minutes as circulated.

Item 2 SCOPE AND COMPOSITION OF TXD 36

2.1 The present scope and composition of the committee is given at **Annex 2 (Pages 9-11).**

2.1.1 The Committee may **REVIEW**.

2.2 Shri Venkeshtesh A, M/s Viridian Testing Laboratories LLP, Tirupur has requested for membership of TXD 36. He has done graduation in chemistry and have 18 years of experience in the laboratory testing.

2.2.1 The Committee may **DECIDE.**

Item 3 ISSUES ARISING OUT OF PREVIOUS MEETING OF TXD 36

3.1 Summary of actions taken on the various decisions of the 24th meeting is given at **Annex 3 (Pages 12-13).**

3.1.1 The Committee may **NOTE**.

Item 4 RESEARCH AND DEVELOPMENT PROJECT

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

The subject of surgical suture was identified in the Standards National Action Plan 2022-27 for the formulation of an Indian standard. The finalized ToR has been has been uploaded on BIS portal after approval of Review Committee of BIS. The copy of finalized ToR is also enclosed for reference of committee members at **Annex 4 (Pages 14-18).**

4.1.1 The Committee may **NOTE.**

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

In the last meeting of TXD 36, the committee decided that the following manufacturers/stakeholders shall send atleast 5 samples of any size of sanitary pad (as per IS 5405 : 2019) for testing of pH test as per IS 1390 : 2022/ISO 3071 : 2020 to SASMIRA and SITRA separately for testing :-

i) Shri Nirav Mehta, Dima Products, Mumbai
ii) Shri Prashant Jadhav, P & G, Mumbai
iii) Ms. Roocha Khedkar, Kenvue, Mumbai
iv) Smt. Komal Sharma, Kimberly Clark Pvt. Ltd., Mumbai

The testing results received from Dima Products, P & G, Kenvue (JNTL Consumer Health) and Kimberly Clark Pvt. Ltd are given at **Annex 5 (Pages 19-27).**

The comments received from Feminine and Infant Hygiene Association (FIHA) and P &G; Mumbai are given at **Annex 6 (Pages 28-37).**

The proposed amendments in IS 5405 and IS 17514 are given at **Annex 7 (Pages 38-39).**

5.1.1 The Committee may **DECIDE.**

5.2 IS 17509 : 2021, Disposable Baby Diaper — Specification

The comments received from P &G, Mumbai are given at **Annex 8 (Pages 40-46).**

The proposed amendment in IS 17509 is given at **Annex 9 (Pages 47).**

5.2.1 The Committee may **DECIDE.**

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

The proposed amendment 1 to IS 17508 (similar to IS 17509 Baby diaper, IS 5405 Sanitary Pad) after including the phthalate test has been prepared and given at **Annex 10 (Page 48-49).**

5.3.1 The Committee may **DECIDE.**

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

CMD-II, BIS provide comments on IS 17354 : 2020. The comments are given at **Annex 11 (Page 50).**

The proposed amendment in IS 17354 is given at **Annex 12 (Page 51).**

5.4.1 The Committee may **DECIDE.**

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

The comments received from CMD-2 of BIS on above standard are provided as follows :-

'For the optional test of sterility, the requirement specified is "complies with test" and the method given is IS 10150. IS 10150 is revised as IS/ISO 11737-1:2018 but this standard is only a guide for on the enumeration and microbial characterization of the population of viable microorganisms on or in a health care product and does not specify any bioburden level or objective criteria for establishing conformity to this requirement.

Bioburden level or objective criteria for establishing conformity to this requirement may be specified'

5.5.1 The Committee may **DECIDE.**

Item 6 INTERNATIONAL ACTIVITIES

6.1 The third plenary meeting of ISO/TC 338 'Menstrual Product' was held on 08th December 2023 in in virtual mode. The following delegation of experts participated in the 3rd plenary meeting in virtual mode to represent India's point of view:-

1) **Shri J.K. Gupta, Sc-E & Head, Textiles (Head of Delegation)**
2) Shri Dharmbeer, Sc-D, Textiles, Member Secretary TXD 36

3) Shri S. Sivakumar, (Head, Medical Textiles), SITRA, Coimbatore
4) Dr. E. Santhini, SITRA, Coimbatore
5) Smt. Tanya Mahajan, The Pad Project (NGO), India
6) Shri Nirav Mehta, Dima Products, Mumbai
7) Ms. Roocha Khedkar, Kenvue, Mumbai

The briefing meeting of Indian delegates and resolution and report of ISO/TC 338 plenary meeting are given at **Annex 13 (Pages 52-60).**

6.1.1 The Committee may **NOTE.**

Item 7 REVIEW OF PRE-2000 STANDARDS

In the last meeting of TXD 36, the committee requested following experts/committee member to send their comments and suggestion for pre-2000 standards. The inputs is yet to be received.

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 Wound Care, Baddi
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 14316 : 1995	Swabs, small, in bag of 50 - Specification	Dr. Manish Sabharwal, Dr. Sabharwal Wound Care, Baddi
5	IS 1681 : 1998	Textiles – Hospital blankets, woollen, dyed – Specification (third revision)	Dr. Sanjiiv, FICCI/PWMAI

7.1 The Committee may **DECIDE.**

Item 8 DATE AND PLACE OF NEXT MEETING

Item 9 ANY OTHER BUSINESS

ANNEX 1

(Item 1.1)

COMMENTS ON MINUTES OF 24TH MEETING OF TXD 36

NAME OF THE COMMENTATOR/ORGANIZATION: **Roocha Khedkar R&D JNTL Consumer Health (India) Pvt. Ltd.**

DOCUMENT NO: Minutes, Technical Textiles for Medtech Applications
24th Meeting Sectional Committee, TXD 36

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Specific Proposal (Draft clause to be add/amended)	Remarks	Technical References and justification on which (2), (3), (4) are based
(1)	(2)	(3)	(4)	(5)
Attendance	N/A	Add name – Dr. Priti Thakor Kenvue (JNTL Consumer Health (India) Private Limited), Mumbai	N/A	N/A
Item 6 COMMENTS ON PUBLISHED STANDARDS 6.1, The committee also considered the comments received from JNTL Consumer Health (India) Pvt Ltd, Mumbai; and Procter & Gamble, Mumbai as given in Annex 8.		Kenvue requested to revise the requirement for pH from 5.5-8 to 3.5-8 and had provided justification basis the 4 points. 1. Regulations across developed and developing nations. 2. Intimate area physiology and Post Marketing Safety Data (		

		3. Wood pulp technology 4. Access and Affordability As per request from BIS, Kenvue tested Sanitary pads with wood pulp at different BIS recognised labs. Kenvue shared that there is lot of variability in the results for the same product using same method across the different BIS recognised labs. This is an additional administrative reason to widen the range of pH, over and above the scientific considerations and evidence that acidic pH range which is closer to the physiological pH of the intimate area (~3.8 to 4.2) facilitates growth of commensal bacteria and limits the colonization of pathogenic bacteria. After deliberation, as there was no conclusion, it was suggested by		

		Dr. Prakash Vasudevan to take advice from expert outside TXD36 committee. Kenvue and P&G were also suggested to submit their proposal on sampling plan.		
Item 6 COMMENTS ON PUBLISHED STANDARDS 6.1, iii) IS 5405 : 2019 and IS 17514 : 2021, The manufacturer shall declare the material of top sheet, middle layer and bottom sheet of the product along with chemical ingredient on the label if agreed between the buyer and seller.	**N/A**	We do not agree with this blanket statement to include material along with chemical ingredients on the label, however, as discussed and aligned in previous meeting of TXD 36, in case this information is requested by the buyer to the seller, it can be provided to the buyer by the seller	**N/A**	**N/A**
6.1 V) The committee also considered the request from Kenvue Mumbai to review the requirement of pH test in IS 5405 : 2019 for wood pulp-based material used in absorbent core. The committee decided that the following manufacturers/stakeholders shall send at least 5 samples of any size of sanitary pad (as per IS 5405 : 2019) for testing of pH test as per IS 1390 : 2022/ISO 3071 :	**N/A**	The manufacturers to send only sanitary pads with 100% wood pulp as absorbent core material for testing and not the same in combination of tissue, cotton, wood pulp, other absorbent and super absorbent materials	**N/A**	**N/A**

2020 to SASMIRA and SITRA separately for testing within 07 days				

ANNEX 2
(Item 2.1)

Scope and Composition of Technical Textiles for Medtech Applications, TXD 36

Scope: To formulate Indian Standards for terminology, testing and specifications for technical textiles for medtech applications such as healthcare and hygiene textile products, implantable and non-implantable and extra corporeal textile products.

Meeting(s) held	**Date & Place**
23rd Meeting	04 August 2023 (Through VC)
24th Meeting	07 November 2023 (Through VC)

SL NO.	ORGANIZATION REPRESENTED	NAME OF THE REPERESENTATIVE PRINCIPAL/(ALTERNATE)	ATTENDANCE
1.	**Director, SITRA**	**Dr. Prakash Vasudevan** (Chairman)	2/2
2.	3 M India Limited New Delhi	Shri Kulveen Singh Bali (Smt. Prabha Hegde)	1/2
3.	Alpha Foam Ltd., Pune	Shri Rajiv Ranka (Shri Apurva Ranka)	2/2
4.	Association of Indian Medical Device Industry (AiMeD), New Delhi	Shri Amit Kumar (Smt. Rama Venugopal)	1/2
5.	All Indian Institute of Medical Sciences, New Delhi	Dr. Vijaydeep Siddharth (Dr. Anoop Daga)	1/2
6.	Business Coordination House New Delhi	Shri Kanav Gupta Smt. Ritika Gupta	2/2
7.	Cologenesis Healthcare Pvt. Ltd, Salem	Shri R Krishana Kumar Shri K. Ramprasad	1/2
8.	Defence Research & Development Establishment (DRDE), Gwalior	Dr. Vikas B. Thakre (Shri Suraj Bharati)	2/2

9.	DGAFMS, Ministry of Defence, New Delhi	Surg Capt S.S Dalawayi (Surg Lt Cdr Kotian V. Gopal)	2/2
10.	DGQA (Ministry of Defence), New Delhi	Shri Senthil Kumar (Shri Arnab Das)	2/2
11.	Dima Products, Mumbai	Shri Nirav Mehta	2/2
12.	Director General of Health Services, New Delhi	Dr. Naresh Panchal (Dr. B. S. Charan)	2/2
13.	Dispoline India Private Limited, Bangalore	Shri Sumit Marwah	2/2
14.	DMSRDE, Kanpur	Dr. Mukesh Kumar Sinha	1/2
15.	Dr. Sabharwals Manufacturing Labs Pvt Ltd Panchkula	Shri Manish Sabharwal (Shri Dhruv Sabharwal)	2/2
16.	Federation of Indian Chambers of Commerce & Industry, New Delhi	Dr. Sanjiiv Rehlan (Ms Tulsi)	2/2
17.	Ginni Filaments Limited NOIDA	Shri Pramod Sharma	2/2
18.	Indian Council of Medical Research, New Delhi	Dr. Sadhana Srivastav	2/2
19.	Indian Institute of Technology, New Delhi	Prof Ashwini Agarwal (Prof Bipin Kumar)	2/2
20.	Indian Technical Textile Association	Dr. Anup Rakshit (Shri Mahesh Kudav)	2/2
21.	Johnson & Johnson Ltd. Mumbai	Ms. Roocha Khedkar	2/2
22.	KOB Medical Textiles Pvt Ltd, Palladam	Shri Arun Buchade (Shri T. Balaji)	2/2
23.	Livinguard Technologies Pvt. Ltd., Mumbai	Ms. Shivani Swamy (Shri Virendra Madiyar)	2/2
24.	Maulana Azad Medical College, New Delhi	Dr. Pawanindra Lal (Dr. Kirti Nath)	2/2
25.	Medline Healthcare Industries Pvt. Ltd, Pune	Mr. Anothony D' Costa (Shri Dhaval Ghuge)	2/2

26.	Ministry of Textiles (NTTM), New Delhi	Shri Ajay Pandit	1/2
27.	National Physical Laboratory, New Delhi	Dr. Suraj Khanna	1/2
28.	Nobel Hygiene, Mumbai	Shri Joy Devassy (Smt. Sneha Gupta)	2/3
29.	Office of the Drug Controller (CDSCO), Delhi	Dr. Aseem Sahoo (Mr. Arvind Hiwale)	1/2
30.	PGIMER, Chandigarh	Dr. Pankaj Arora (Dr. Vijay Tadia)	2/2
31.	Procter and Gamble Co., Mumbai	Shri Prashant Jadhav (Shri Girish Parhate)	2/2
32.	South India Textile Research Association, Coimbatore — 641014	Shri S. Sivakumar (Dr. E. Santhini)	2/2
33.	Surya Textech, Chandigarh	Shri Khalil Khan (Shri Yogesh Yadav)	2/2
34.	Textiles Committee Mumbai	Shri Kartikeyan Dhanda (Dr. P. Ravichandran)	2/2
35.	The Pad Project (NGO), India	Smt. Tanya Mahajan	1/2
36.	The Synthetics & Art Silk Mills Research Association, Mumbai	Dr Manisha Mathur (Mrs. S. S. Dongre)	2/2

ANNEX 3
(Item 3.1)

SUMMARY OF ACTIONS TAKEN ON THE MINUTES OF 24th MEETING OF TXD 36

Item No.	Decision	Action taken
2.1	Certain modifications were suggested in the composition of the committee.	Updated composition is given in **Annex 1**
4.1	**DRAFT AMENDMENTS FOR FINALIZATION** **4.1** Doc: TXD 36 (22466), Guidelines for Reprocessing of Multiple Use Healthcare Textiles The committee decided that the above draft standard after incorporating the changes is FINALIZED for publication as Indian Standard.	Under Publication
5.1	**RESEARCH AND DEVELOPMENT PROJECT** **New Subject - Surgical Sutures (Absorbable and Non-Absorbable)** The committee decided that the changes suggested shall be included in the existing ToR.	Coming for discussion under **agenda item 4.1.**
6.1	**COMMENTS ON PUBLISHED STANDARDS** **IS 5405 : 2019, Sanitary Napkins — Specification (Second Revision) and IS 17514 : 2021, Reusable Sanitary Pad / Sanitary Napkin / Period Panties — Specification** The committee decided that BIS shall prepare the draft amendment to IS 5405 : 2019/IS 17514 and the	Coming for discussion under **agenda item 5.1.**

	same shall be issued in wide circulation for comments.	
6.2	**COMMENTS ON PUBLISHED STANDARDS** **IS 758 : 2023, Medical Textiles — Absorbent Cotton Gauze — Specification (Fifth Revision)** The committee decided that Dr. Manish Sabharwal, Dr. Sabharwals Manufacturing Labs Pvt Ltd, Panchkula shall provide the requirement and test method for Bioburden level or objective criteria for establishing conformity to sterility test.	The inputs are awaited.
6.3	**COMMENTS ON PUBLISHED STANDARDS** **IS 17508 : 2020, Disposable Adult Incontinence Diaper – Specification** The committee decided that draft amendment as given in the agenda shall be issued in wide circulation for eliciting technical comments from stakeholders.	Coming for discussion under **agenda item 5.3.**
7.1	**INTERNATIONAL ACTIVITIES** **CIB (Committee Internal Ballot), N59 - Draft ISO TC 338 Strategic Business Plan for comments** The committee decided that the above Ballot shall be approved for voting.	Ballot Approved

ANNEX 4
(Item 4.*1*)

DRAFT STANDARD FOR FINALIZATION

TERMS OF REFERENCE FOR THE R&D PROJECT

[Technical Textiles for Medtech Applications Sectional Committee TXD 36 under Textiles Department of BIS]

1) **Title of the project:** — Study of safety, performance and constructional requirement for surgical sutures (absorbable and non-absorbable)
2) **Background:-**

2.1 Surgical sutures are used to close wounds and aid in tissue healing in a variety of different surgical procedures such as orthopaedic, cardiovascular, alimentary, ophthalmic, laparoscopic, and other surgical procedures. Surgical sutures are helpful to reduce post-operative discomfort, shorten hospital stays, and expedite patient recovery. Based on application and material, there are different varieties and size of surgical sutures for natural or synthetic textiles, single filament or multifilament or braided or twisted with or without a coating.

2.2 Surgical sutures are being manufactured in India as well as being imported, however there is no Indian standard on the subject. In absence of Indian Standard, majority of the stakeholders are following either United States Pharmacopeia (USP) or British Pharmacopeia (BP) or European Pharmacopeia. So, it becomes important to study safety, performance, and constructional parameters of surgical sutures for deciding the appropriate requirement in Indian context.

2.3 The outcome of this R &D project will serve as basis for developing Indian Standard on the subject which will ensure consumer protection and safeguard public health.

3) **Objective**

To collect the technical data and scientific evidence for safety, performance and constructional requirement of surgical sutures (absorbable and non-absorbable) from primary and secondary sources.

4) **Scope: -**

a) Undertake study and analyse the existing literature which include but not restricted to the following :-

- International standard and regulation,
- Journals and research papers,
- Standard operating procedures (SOPs)/guidelines of Ministry/regulator/users,
- Studies/research conducted by any organization
- Any other relevant published information.

b) Collection of the database for manufacturers (small, medium and large-scale), testing infrastructure and users in the country.
c) Collection of import and export data, type of standards and regulation being followed by domestic/foreign manufacturers, comparative analysis of these standards and regulation.
d) Undertake 2 visits to each of small, medium and large-scale manufacturer and collect the information on the following aspects :-

i) Types of raw material being used
ii) Data/compliance of biocompatible evaluation and other requirement for each type of raw material
iii) Manufacturing process
iv) Good manufacturing practice
v) In-process controls being exercised during manufacturing
vi) Varieties being manufactured
vii) Standards being followed
viii) Testing method being used
ix) Testing infrastructure available
x) Post manufacturing quality/in-house data for safety, performance and constructional parameter for all the varieties being manufactured
xi) Sampling plan being followed
xii) Sterilization method being used
xiii) Marking and labelling of the product
xiv) Packaging and storage conditions
xv) Sustainability practices [sustainable raw material, energy efficient processes and methodologies, renewable energy sources, 3Rs (Reduce, Reuse and Recycle), waste management and disposal mechanisms]
xvi) Focused group discussions with teams involved in production, testing, and R&D to address quality issues, discuss challenges faced, and gather suggestions for improvement

The feedback from other manufacturers (where visit is not carried out) shall be collected by circulating suitable questionnaire covering above information through email or any other digital means.

e) Undertake 2 visits to users (one Govt and one private NABH accredited Hospital) and 2 visits to testing labs (one Govt/ and one private NABL accredited lab) to collect information including but not restricted to the following: -

User

i) Standards and regulations being followed
ii) Compliance mechanism being followed (test certificate from supplier, third party testing)
iii) Focused group discussion on quality issues, challenges being faced and suggestions if any.

Lab

i) Standards and regulation being followed
ii) Testing methods being followed
iii) Testing infrastructure
iv) Focused group discussion on testing related issues, challenges being faced and suggestion

The feedback from other hospitals (Govt and private NABH accredited) and labs (Govt and private NABL accredited) where visit is not carried out shall be obtained through suitable questionnaire covering above information.

f) Collection of 2 samples from each from large, medium and small-scale industries of each variety of surgical sutures and carry out testing from 2 NABL accredited lab (1 Govt Lab and 1 Pvt. Lab) for parameters like but not restricted to length, diameter, knot strength/breaking load, needle attachment, extractable color, sterility.

The biocompatibility evaluation data for each type of material used shall be collected from the manufacturers .

g) Preparation of a comprehensive project report covering all the above information.

5) Research Methodology: -

a) Collect and analyse the data/information as specified in the scope [4 (a), (b) and (c)].
b) Visit manufacturers, users and labs and collect data/information as specified in the scope [4 (d) and (e)].
c) Collect and test the samples as specified in the scope 4 (f).
d) Analysis the data/information and prepare a comprehensive project report.

6) Expected Deliverables: -

a) Comprehensive report in soft/hard form of study covering all the aspects detailed in the scope of the R & D project.
b) Questionnaire feedback, testing report, focussed group discussion report, other relevant documents and information shall be appended to the project report.

7) Requirement for the CVs:-

Graduate in textile technology or textile engineering or textiles chemistry or fibre science and technology or manmade fibre technology or biomedical engineering or post graduate in microbiology.

8) Timeline and Method of progress Review :-

The duration of the project is **120 days** from the date of the award of the project. The stagewise indicative timelines are as follows:-

Indicative Time line	**Method of progress**
0 to 30 days	Literature review, desktop study, collection of data and information Note : - The sampling plan for visit and collection of samples shall be discussed and finalized with nodal officer after literature survey and desktop research.
31 to 75 days	

	Visit to manufacturer, user, testing lab Collection of data and information and collection of samples
76 to 105 days	Testing of samples (except long duration test with testing time more than 30 days) preparation and submission of first draft report
106 to 120 days	Submission of the final project report.

9) Support BIS will provide: -

a) All the relevant Indian Standards/ISO Standards or any other standards required during the project will be provided by BIS.
b) Facilitate/introduction of the project leader/organization to relevant Industry and industry association, testing lab, institute, acedamia, user, regulator/ministries.
c) Facilitate testing of samples in BIS Lab/BIS Recognized Lab.

10) Nodal Point

In case of queries/clarification, Shri Dharmbeer, Scientist D and Member Secretary of TXD 36 may be contacted on txd@bis.gov.in, 011-23231282, 9910825544.

ANNEX 5
(Item 5.*l*)

COMMENTS ON PUBLISHED STANDARDS

1) Kimberly Clark Hygiene Products Pvt Ltd

a) Testing results from SITRA

pH Values	**S2300377-1 Sanitary Napkin Sample-1-1**	**S2300377-2 Sanitary Napkin Sample-1-2**	**S2300377-3 Sanitary Napkin Sample-1-3**	**S2300377-4 Sanitary Napkin Sample-1-4**
Mean pH Value	6.33	6.35	6.32	6.34
pH of extracting solution	5.72	5.72	5.72	5.72
Temperature of the extracting solution	27.4°C	27.4°C	27.4°C.	27.4°C.
pH Values	**S2300377-5 Sanitary Napkin Sample-1-5**			
Mean pH Value	6.34			
pH of extracting solution	5.72			
Temperature of the extracting solution	27.4°C.			

b) Testing from SASMIRA

Test Report No : SASMIRAlTRNo.1580/23-24

Discipline: Chemical Product Group: Textile
Sample ID Mark: Fempad Grade:XL 320 MM DAY(1)

Sl No	Test Name	Method	Results
1	pH of aqueous extract pH Value of Aqueous Extract of the material pH of KCL Solution	IS 1390:2022	 6.54 6.53

Discipline: Chemical Product Group: Textile
Sample ID Mark: Fempad Grade:XL 320 MM DAY(2)

Sl No	Test Name	Method	Results
1	pH of aqueous extract pH Value of Aqueous Extract of the material pH of KCL Solution	IS 1390:2022	 6.57 6.53

Discipline: Chemical Product Group: Textile
Sample ID Mark: Fempad Grade:XL 320 MM DAY(3)

Sl No	Test Name	Method	Results
1	pH of aqueous extract pH Value of Aqueous Extract of the material pH of KCL Solution	IS 1390:2022	 6.48 6.53

Discipline: Chemical Product Group: Textile
Sample ID Mark: Fempad Grade:XL 320 MM DAY(4)

Sl No	Test Name	Method	Results
1	pH of aqueous extract pH Value of Aqueous Extract of the material pH of KCL Solution	IS 1390:2022	 6.41 6.53

Discipline: Chemical Product Group: Textile
Sample ID Mark: Fempad Grade:XL 320 MM DAY(5)

Sl No	Test Name	Method	Results
1	pH of aqueous extract pH Value of Aqueous Extract of the material pH of KCL Solution	IS 1390:2022	 6.60 6.53

Discipline: Chemical Product Group: Textile
Sample ID Mark: Grade: Large Wonder Pant (X-PAD) (1)

Sl No	Test Name	Method	Results
1	pH of aqueous extract pH Value of Aqueous Extract of the material pH of KCL Solution	IS 1390:2022	 6.30 6.53

Discipline: Chemical Product Group: Textile
Sample ID Mark: Grade: Large Wonder Pant (X-PAD) (2)

Sl No	Test Name	Method	Results
1	pH of aqueous extract pH Value of Aqueous Extract of the material pH of KCL Solution	IS 1390:2022	 6.43 6.53

Discipline: Chemical Product Group: Textile
Sample ID Mark: Grade: Large Wonder Pant (X-PAD) (3)

Sl No	Test Name	Method	Results
1	pH of aqueous extract pH Value of Aqueous Extract of the material	IS 1390:2022	 6.38

	pH of KCL Solution		6.53

Discipline: Chemical Product Group: Textile
Sample ID Mark: Grade: Large Wonder Pant (X-PAD) (4)

Sl No	Test Name	Method	Results
1	pH of aqueous extract	IS 1390:2022	
	pH Value of Aqueous Extract of the material		6.51
	pH of KCL Solution		6.53

Discipline: Chemical Product Group: Textile
Sample ID Mark: Grade: Large Wonder Pant (X-PAD) (5)

Sl No	Test Name	Method	Results
1	pH of aqueous extract	IS 1390:2022	
	pH Value of Aqueous Extract of the material		6.49
	pH of KCL Solution		6.53

2) Dima Products, Mumbai

Summary of pH Test Reports (External Lab) for Sanitary Napkins and Woodpulp. 14/Dec/2023

Trial Sr. No	Product		Wood Pulp		SAP	Top Sheet		Remarks	SITRA					SASMIRA				
	Item	type				Spunbond PP Non Woven	Perforated dry cover		Potacium Chloride		Distilled Water		Diff.	Potacium Chloride		Distilled Water		Diff.
									KCL solution pH	RESULT pH	Distilled Water pH	RESULT pH		KCL solution pH	RESULT pH	Distilled Water pH	RESULT pH	
DP-01	Sanitary Napkin	Thick Pad	Supplier A	Yes	-	✓	-	SN with only pulp	5.60	**4.06**	6.63	**4.90**	-0.84	6.10	**4.70**	6.00	**4.60**	0.10

DP-03	Sanitary Napkin	Thick Pad	Supplier A	Yes	-	-	√	SN with only pulp	5.60	**4.06**	6.63	**4.98**	-0.91	6.10	**4.60**	6.00	**4.40**	0.20
DP-05	Sanitary Napkin	Thick Pad	Supplier B	Yes	-	√	-	SN with only pulp	5.72	**5.03**	6.63	**6.43**	-1.40	6.10	**5.20**	6.00	**4.90**	0.30
DP-07	Sanitary Napkin	Thick Pad	Supplier B	Yes	-	-	√	SN with only pulp	5.72	**5.03**	6.63	**6.39**	-1.36	6.10	**4.90**	6.00	**5.60**	-0.70
DP-02	Sanitary Napkin	Thick Pad	Supplier A		Yes	√	-	SN with Pulp and SAP	5.60	**5.71**	6.63	**7.40**	-1.69	6.40	**6.50**	6.20	**6.60**	-0.10
DP-04	Sanitary Napkin	Thick Pad	Supplier A		Yes	-	√	SN with Pulp and SAP	5.60	**5.42**	6.63	**7.49**	-2.07	6.40	**6.50**	6.20	**6.70**	-0.20
DP-06	Sanitary Napkin	Thick Pad	Supplier B		Yes	√	-	SN with Pulp and SAP	5.72	**5.94**	6.63	**7.77**	-1.83	6.40	**6.40**	6.20	**6.60**	-0.20
DP-08	Sanitary Napkin	Thick Pad	Supplier B		Yes	-	√	SN with Pulp and SAP	5.72	**6.17**	6.63	**7.69**	-1.52	6.40	**6.90**	6.20	**6.90**	0.00
DP-09	Fluff Pulp (Woodpulp) Supplier A	Raw Material	Supplier A	50.00 g	-	-	-	Pure pulverised Wood pulp(USA make)	6.04	**4.07**	6.38	**5.18**	-1.11	6.20	**4.20**	6.00	**4.80**	-0.60
DP-10	Fluff Pulp (Woodpulp) Supplier B	Raw Material	Supplier B	50.00 g	-	-	-	Pure pulverised Wood pulp(USA make)	6.04	**5.01**	6.38	**6.26**	-1.25	6.20	**5.00**	6.00	**5.50**	-0.50
DP-11	Sanitary Napkin	Thin Pad	-	Airlaid Woodpulp	Yes	√	-	SN made from Airlaid material using Wood pulp and SAP	6.04	**6.30**	6.38	**7.51**	-1.21	6.20	**6.40**	6.00	**6.30**	0.10

Max	-2.07			Max	-0.70
Min	-0.84			Min	0.30
Average	-1.38			Average	-0.15

3) Kenvue, Mumbai

a) One of the actions from the TXD 36 meeting dated 7th Nov 2023 was to send samples of sanitary pads for testing of pH as per IS 1390 : 2022/ISO 3071:2020 to SASMIRA and SITRA laboratories separately. Accordingly, we had sent samples of sanitary pads for testing of pH as per IS 1390 : 2022/ISO 3071 : 2020 to SASMIRA and SITRA laboratories.

Note:

· We had sent two types of sanitary pads for testing. Samples of thick sanitary pads containing 100% fluff pulp as absorbent core and samples of thin sanitary pads containing a combination of fluff pulp and polymer as absorbent core.

· The pH result, pH of extracting solution (0.1M Potassium Chloride solution) and temperature during measurement is recorded by the labs and is documented in the test reports provided to us.

Please find the results from both these laboratories tabulated below :-

	Batch No.	**pH results from SITRA Laboratory**	**pH results from SASMIRA Laboratory**
Thick Napkin with 100% fluff pulp used in absorbent core	SF-DXL001	**3.79**	**4.10**
pH of Extracting Solution (KCL)	-	6.21	6.53
Temperature	-	27.3 °C	20 °C
Thin Napkin with combination of fluff pulp and super absorbent polymer used in absorbent core	SF-MDM001	**6.36**	**6.54**
pH of Extracting Solution (KCL)	-	6.21	6.53
Temperature	-	27.3 °C	20 °C

Conclusion:

- The current method for pH is IS1390:2022 effective March 2022 which describes 0.1M Potassium Chloride as extraction solvent. It is observed that the pH of the thick pads (with 100% fluff pulp) is towards the acidic side of the pH range, while the presence of super absorbent polymer in the thin pads shifts the pH towards higher side of the range.

- As one of the leading manufacturers of thick pads for our India market and in view of the submissions made earlier on the scientific attributes, we would like to reiterate that there is a need to widen the range of pH for sanitary napkins from 3.5 to 8.0. The thick pads made with fluff pulp tend to be on an acidic side of the spectrum, due to the intrinsic properties of the fluff pulp. The fluff pulp pads help in maintaining sustainability objectives on account of its biodegradability and are thus more environment friendly. The inclusion of super absorbent polymer in pads to meet pH requirements poses a challenge in meeting sustainability objective of reducing plastic and will add burden on municipal bodies in managing solid waste.

One of the actions from the TXD 36 meeting dated 7th Nov 2023 was to send samples of sanitary pads for testing of pH as per IS 1390 : 2022/ISO 3071:2020 to SASMIRA and SITRA laboratories separately. Accordingly, we had sent samples of sanitary pads for testing of pH as per IS 1390 : 2022/ISO 3071 : 2020 to SASMIRA and SITRA laboratories and results shared with you on Dec 18, 2023 (below trailing mail for reference).

We had also sent additional samples of sanitary pads from our different manufacturing locations for testing of pH as per IS 1390:2022/ISO 3071:2020 to SASMIRA and TESTTEX laboratories. Both these laboratories are BIS-recognized labs.

Note:

- We had sent different variants of sanitary pads for testing. Samples of thick sanitary pads containing 100% fluff pulp as absorbent core and samples of thin sanitary pads containing a combination of fluff pulp and polymer as absorbent core.
- The samples manufactured at our different sites (internal manufacturing and external manufacturing site) were sent for testing. Same batches of sanitary pads were sent for pH determination to both these labs except in one case.
- The pH result, pH of extracting solution (0.1M Potassium Chloride solution) and temperature during measurement is recorded by the labs and is documented in the test reports provided to us.
- Section 10 of the Test method IS1390:2022 titled 'Precision' states that reproducibility limit for inter-laboratory measurements is 1.1 pH units

b) Please find the results from both these laboratories tabulated below including observations :

Product Type	**Category**	**Manufacturing site**	**pH result from Sasmira lab** (pH of 0.1M KCl : 6.1 Temperature : 20°C)	**pH result from Testtex lab** (pH of 0.1M KCl : 6.5 Temperature : 22.6°C)
Sanitary pad product 1	Thick pads with 100% pulp	Internal manufacturing site	**Batch M5231211 : 4.7**	**Batch M6231213 : 6.6**

Sanitary pad product 2	Thick pads with 100% pulp	External manufacturing location 1	**Batch V3231114 : 6.2**	**Batch V3231114 : 6.9**
Sanitary pad product 3	Thick pads with 100% pulp	External manufacturing location 2	**Batch D12231019 : 4.3**	**Batch D12231019 : 6.8**
Sanitary pad product 4	Thick pads with 100% pulp	External manufacturing location 2	**Batch D7231119 : 6.0**	**Batch D7231119 : 6.8**
Sanitary pad product 5	Thick pads with 100% pulp	External manufacturing location 2	**Batch D3231116 : 4.2**	**Batch D3231116 : 6.4**
Sanitary pad product 6	Thin pads (Fluff Pulp+super absorbent polymer)	Internal manufacturing location	**Batch A7231004 : 6.4**	**Batch A7231004: 6.5**
Sanitary pad product 7	Thin pads (Fluff Pulp+super absorbent polymer)	Internal manufacturing location	**Batch A9231010 : 6.6**	**Batch A9231010 : 6.4**

Conclusion:

- The current method for pH is IS1390:2022 effective March 2022 which describes 0.1M Potassium Chloride as extraction solvent. It is observed that the pH of the thick pads (with 100% fluff pulp) is towards the acidic side of the pH range, while the presence of super absorbent polymer in the thin pads shifts the pH towards higher side of the range.
- In case of thick pads with 100% fluff pulp, out of the 5 different products sent for testing, pH results of 3 out of the 5 products show inter-lab variation of more than 1.1.pH units, the maximum being 2.5pH units. In these cases, one of the labs reports the pH result out of the current specification of 5.5 to 8.0 while the other lab reports the result within the limit.
- The significant variation in pH results from different laboratories for identical samples from same batch of thick pads with 100% fluff pulp further reiterates the need to widen the range of pH for sanitary napkins from 3.5 to 8.0.

4) P & G, Mumbai

Pls find test results for P&G samples below:

Conclusions:
1. Inconsistency observed between pH test results when tested at two laboratories
2. Having considered material nature (cellulosic pulp base) there is an urgent need to widen the existing pH limits (from 5.5-8 to 4.0 to 9.0).
3. Wider pH limits will be in line with widely used cellulose pulp based absorbent core properties without compromising innovations

1. SITRA Results

Sr. No.	Sample Name	pH	pH of Extracting Fluid
1	Whisper Choice (Cellulosic Pulp)	5.18	6.21
2	Whisper Choice XL (SAP)	4.42	6.21
3	Whisper Bindazzz Night (SAP)	4.49	6.21

2. SASMIRA Results

Sr. No.	Sample Name	pH	pH (aqueous extract)
1	Whisper Choice	6.69	6.97
2	Whisper Choice XL	6.69	6.17
3	Whisper Bindazzz Night	6.79	6.69

ANNEX 6
(Item 5.*1*)
COMMENTS ON PUBLISHED STANDARDS

1) P&G, Mumbai

Comments on IS 5405 (Sanitary Napkins - Specifications):

Sl No.	Item Clause/Reference	P&G Proposal	Justification
1.	**7.1 pH Value** The pH of the absorbent material shall be from 5.5 to 8.0 when tested by the method given in IS 1390 (cold method).	**To amend existing pH Limits 7.1 pH Value** The pH of the absorbent material shall be from 3.5 to 8.0 when tested by the method given in IS 1390 (cold method).	a. **Material consideration** (Majority of pads being sold today in India are based on Cellulosic Pulp which is acidic) b**. Physiology** and microenvironment of usage area c. **Ability to innovate in future &** inclusion of sustainable materials (largely from natural resources - e.g. banana fibres) which are predominantly acidic d. Previous justifications - discussed in detail in 24th TXD-36 meeting held on 06/11/2023) e. **Inter-labs (Govt. labs) variation** in pH Testing - to be deliberated in committee meeting
2.	**3 Materials** 3.1 Cover/Top sheet 3.2 Absorbent Core 3.3 Barrier or Bottom Sheet	To remove from Sanitary Napkins Manual	a. These are Raw materials tests and should not be clubbed with Finished product. In fact, this is not at all practiced anywhere. b. Raw material quality is checked prior to its acceptance for final manufacturing. On top, robust in process quality checks (IPQC) ensures quality throughout manufacturing process

			c. Being visual tests and general material expectations - these lack test methods and creates ambiguity to deploy and results interpretation
3.	8 SAMPLING AND CRITERIA FOR CONFORMITY	To remove from Sanitary Napkins	a. Presence of this clause contradicts sampling & test frequency plan in Sanitary Napkin product manual.
4.	**8.2.4** The manufacturer shall perform the hygiene testing for the final product every quarter for monitoring purpose and whenever there is a change in the raw material, manufacturing premises, and the supplier of the raw material.	To amend the existing text as given below: The manufacturer shall perform the hygiene testing for the final product every quarter for monitoring purpose.	a. The quarterly monitoring of hygiene is already factoring changes in the raw material, vendor occurred. b. This will facilitate manufactures without defeating core purpose of Hygiene Testing. c. If Finished product conformity is established then additional testing burden should not be added onto the manufacturers. d. Adherence to general GMP principle in the standard are key for reliable Hygienic manufacturing environment and product quality.
5.	**8.2** Number of Tests and Criteria for Conformity	Insert the following (or at appropriate sub-section) 8.2.7 Each type of sanitary napkin shall be tested at least monthly for the pH value and Ability to Withstand Pressure after Absorption.	a. This is a precision engineered product and higher testing frequency is not required. b. A monthly frequency is good enough for the purpose of BIS compliance. Nonetheless enforcement officials can check product conformity as per their will. C. To reduce unnecessary sample wastage, resources for no obvious benefit in terms of compliance and quality. d. Parametric release over time should be allowed and reflected in the sampling and criterion for conformity section or in the respective product manual.

6.	**IS 1390 & IS 5405**	Include separate pH Test method applicable for absorbent Hygiene product as a new Annex in 17509 **OR** Draft new pH test method applicable for Absorbent Hygiene products (Diapers, sanitary pads, adult diapers, light incontinence products etc.)	a. Current test method (IS 1390) is designed for Textile Material and not for diapers or absorbent hygiene products.
7.	**Note 3 (PM/5405/4 Nov 2023) PRODUCT MANUAL** FOR Sanitary Napkins The number of sanitary napkins to be selected from the control unit/lot shall depend on the size of the lot and shall be in accordance with column 2, column 3 and column 5 of Table 1 of IS 5405. Any sanitary napkin failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 4 of Table 1 of IS 5405. Otherwise, the lot shall be rejected. Out of the sample already found satisfactory according to the above, a	To remove This footnote from the sanitary napkin's manual	a. This contradicts the frequency specified in the Table 1 of the manual and introduces ambiguity for the compliance efforts.

	sub-sample as per column 5 of Table 1 of IS 5405 shall be taken. This sub-sample shall be further tested for the remaining requirements. The lot shall be considered as conforming to the requirements of the specification, if the total number of defective sanitary napkin found in the sample is less than or equal to the acceptance number as given in column 6 of Table 1 of IS 5405.		

2) P&G Mumbai

Comments on IS 1390 (Textiles — Determination of pH of Aqueous Extract):

Sl No.	Item Clause/Reference	Specific Proposal	Justification
1.	8.1 Preparation of the aqueous extract (IS 1390:2022, Textiles — Determination of pH of Aqueous Extract): Agitate the flask for a short period by hand to ensure that the textile material is properly wetted out, then shake it mechanically (6.2) for 2 h ± 5 min at 30rpm.	Agitate the flask for a short period by hand to ensure that the textile material is properly wetted out, then a. shake it mechanically (6.2) for 30 min ± 5 min at 300rpm OR b. stir with a magnetic stirrer for 30 min ±5 min at 150rpm	a. Current test method is designed for Textile Material and not for diapers or absorbent hygiene products. b. As confirmed by our R&D, there is no difference in measured pH value (30 min shaking Vs 2 hr shaking) c. allow flexibility in the mode is mixing. R&D has data that mechanical shaker and magnetic stirrer can mix well

			without any impact on the final pH measurements
2.	**7 Preparation of test Specimens (IS 1390:2022, Textiles — Determination of pH of Aqueous Extract):** Take a laboratory test sample representative of the bulk of the textile material	Specifically call out in method to cut out the centre of the diaper, inclusive of top and Backsheet.	a. to be more specific in the manual on location which is to retrieve sample from centre of the diaper.
3.	**IS 1390 & IS 17509**	**Include separate pH Test method** applicable for absorbent Hygiene product as a new Annex in 17509 **OR** Draft new pH test method applicable for Absorbent Hygiene products (Diapers, sanitary pads, adult diapers, light incontinence products etc.)	a. Current test method (IS 1390) is designed for Textile Material and not for diapers or absorbent hygiene products.

3) Feminine and Infant Hygiene Association ('FIHA')

Subject: Representation regarding a 9 months' extension of timeline for implementation of Medical Textiles (Quality Control) Order, 2023 dated 27th Sep 2023, for non-SMEs, from 1st April 2024 to 1st January 2025.

Dear Sir,

Feminine and Infant Hygiene Association ('FIHA') is a Section 25 company, incorporated in September 2009. FIHA is a group of large, medium and small-scale industries, engaged in the manufacture of adult and baby diapers and sanitary napkins. The members of FIHA include among others, large and medium scale consumer goods companies which manufacture product segment comprising of baby diapers, adult diapers & sanitary napkins. A list of FIHA members is attached herewith as **Annexure A**

Our Request

At the outset, FIHA and its members congratulate the government of India for providing rigorous standards that manufacturers must adhere to, for ensuring the safety and quality of products like sanitary napkins, disposable baby diapers etc. which is of great importance.

We acknowledge that products designed for feminine and baby hygiene should not only be effective, provide comfort, care but also should be safe to use and therefore we laud the intent behind notification of Medical Textiles (Quality Control) Order, 2023 dated 27th Sep 2023 ('QCO Order'), which is to safeguard the larger interests of the consumers. As your good self is aware, the implementation date of QCO Order for non-SME (Small and Micro Enterprises) has been set as 1st April 2024.

After detailed discussions between our members and their technical/product teams, we believe that it is neither possible nor practical for industries to implement the QCO Order by 1st April 2024, which requires compliance to IS standards is IS 5404:2019, IS 17509:2021 and IS 17514: 2021 ("concerned IS Standards"), for the reasons and stages enumerated below, which would require some more time by the industry to implement the same. Therefore, FIHA, on behalf of its members, hereby requests the government to consider an extension of 9 months' for the time period for implementation of QCO Order from 1st April 2024 to 1st January 2025. This would enable the member industries to implement the QCO Order, in compliance to its true nature, intent and purpose.

Industry assessment and concerns of the challenges in relation to implementation of QCO order by 1st April 2023, along with anticipated reasons for delays

1. Site readiness requiring more time, for securing BIS registration:

   a. In view of the QCO Order, the member industries of FIHA have been actively working towards preparing their multiple manufacturing sites for manufacturing of products (viz. Sanitary napkins, baby diapers etc.), for them to be compliant to the concerned IS Standards. This has involved immense review and efforts as well as close coordination across multiple manufacturing sites, spread not only across the Indian landscape but also overseas as well in case of imported products.

   b. As per the requirements of the QCO Order, each of these manufacturing sites will now be treated as individual manufacturing units for the purposes of Bureau of Indian Standards (BIS) certification. As a result, an assessment needs to be made for obtaining BIS certification/ license and all additional licenses and permits that may have become applicable due to the same. Therefore, additional time would need to be invested in reviewing the applicability of such licenses as well as procuring the same.

c. Further, to ensure holistic site readiness for BIS certification/ license, the member companies need to ensure the following amongst others:

- Relevant laboratories are identified or established,
- Changes in product design to comply with concerned IS Standards
- Robust Standard Operating Procedures (SOPs) for testing are developed,
- Effective test methods are deployed,
- Efficient dossiers are prepared and updated,
- Competent and qualified resources are hired,
- Requisite training is conducted to the relevant team/staff as per the protocols.
  This would entail significant investment of time and energy by the member industries and thus a considerable period of time shall be spent in ensuring the same.

2. Inability to seek BIS registration for thick pads, pending the ongoing discussions with BIS over amendment on existing IS standard 5405: 2019:

The existing IS 5405:2019 has a pH range of 5.5-8.0 currently. However, before the said standard is made mandatory by the said QCO Order, there is a need for revision in the pH specification range by making it 3.5-8.0. In the last few months, members of FIHA and their technical teams have undertaken an extensive assessment and submitted multiple representations related to the concerns on the current pH range of Sanitary Napkins basis the following factors:

1) International practices on regulating sanitary protection.
2) Key scientific considerations related to use of sanitary napkins (product safety and efficacy)
3) Wood Pulp Technology and Standard Consideration
4) Sanitary Protection access, affordability, and impact on sustainability goals in India

It may be relevant to mention in this context that as per the suggestion of TXD 36 Committee of BIS, the industry members had submitted representative samples of their products (Sanitary Napkins) for testing as per the current standards. It is noteworthy to mention that most of the pH testing results of thick pads manufactured by various industry players are below the current pH range notified by BIS i.e. in the range of 5.5 to 8.0.

We are expecting a favorable consideration by the BIS authorities by making the required amendment in pH Range in IS 5405:2019. Therefore, pending such resolution, the manufacturers of thick pads, which forms a majority of market size for the sanitary napkins, cannot even seek BIS registration. In other words, BIS registration for thick pad manufacturers, can only be taken once this issue is resolved and closed.

3. Infrastructural requirements for securing BIS registration:

a. An integral part of the BIS registration process is to submit test results of product samples from BIS accredited lab. As on date, 2 (two) BIS accredited labs have been notified and published at BIS website, for testing of baby diapers. While this is helpful, the onboarding of any such labs requires a lead time of about 6-8 weeks for FIHA members. This is so because the contracting process, quality audit and vendor creation for the payment mechanism, is a cumbersome process that requires time.

b. Additionally, for the Cytotoxicity and Bio-compatibility tests have been made mandatory for baby diapers would require factoring in of longer approval process, false positive results, animal testing requirements and costs challenges. It is worthy to mention that full testing infrastructure for Cytotoxicity and Biocompatibility is lacking today even in the recently empaneled BIS labs for diaper testing. Therefore, we request you to consider making Cytotoxicity and Biocompatibility as an "Optional" testing criteria in the baby diaper standard.

c. Further, unlike sanitary napkins which are covered under the simplified procedure, baby diapers are covered under standard procedure, which involves longer timelines and is an elaborate process. Therefore we would kindly request concerned authority to include Baby diapers under simplified certification procedure. Given the above, and also in view of the fact that accredited BIS labs for testing baby diapers will need some time for onboarding, it looks difficult that the registration can be sought prior to April 2024 by manufacturers of baby diapers.

d. Since it's a new requirement and a new registration process altogether, member companies would require detailed orientation on navigating through the BIS website, Product manual as well as detailed guidelines, instructions and/or SOP for making correct applications with the requisite data and supportings especially since the manual on BIS portal for making applications is quite different than the actual process. They would need time to familiarize themselves on the entirety of these requirements to ensure that the registration is duly obtained upon application, and that there are no queries and/ or rejections.

4. Steps and processes involved in inspection by Authorities for granting registration

a. As per the notified BIS registration requirements, the officers will need to conduct plant/ site inspections once the unique code request has been generated and samples are submitted for the testing. Therefore, as a next step, the site inspection would be expected, and the samples will be drawn by visiting inspectors for testing according to BIS standards and therefore the time required for these testing processes must be factored into the certification timeline, which we feel has not been taken into account, in the current timelines for implementation of QCO order for non-SMEs.

b. BIS officers shall be conducting plant/ site inspections, which would involve significant time and energy to be spent on audit, observations, and compliance checks in relation to the grant of a license. This entire process with multiple rounds of iterations and queries can lead to significant delays.

c. Further, post careful observations, deliberations and remarks in terms of compliance to all the relevant compliances mandated by BIS, the license number will be granted, which would involve significant time and consideration to be spent on each application and its contents as well as testing results. This entire process with multiple rounds of iterations and queries can lead to significant delays.

d. This is notwithstanding the fact that the Cytotoxicity and bio-compatibility tests which are mandatory for baby diapers, would require longer approval process, and additional timelines.

5. Packaging artwork readiness requires planning and management by Industry:

a. It may be noted that once BIS license is granted, following are the key mandatory requirements to appear on the product package:

- Standard (ISI) Mark
- License number;
- BIS Website details;
- Details of Manufacturing Party (currently where Manufacturer is the JobWorker, its name is not displayed on product pack);
- Additional text to be printed on pack with descriptors like 'refer batch coding area for license number etc.'

In relation to the aforementioned declarations, it is clarified that only the license number can be inkjet/online printed, all the rest of the declarations have to be pre-printed.

b. It may further be noted that new artwork for new packaging can only be sent for printing once the BIS license number has been granted. Generally, the lead time for manufacturers to get the new packaging materials is 4-12 weeks. Hence, this additional time from the date of registration needs to be factored for determining the date of implementation of the QCO Order.

<u>Our Prayer- Extension of QCO Order IN ADVANCE</u>

In view on the above submissions, it is very clear that QCO Order implementation effective 1st April 2024 is not possible for non-SME. The industry feels that it could very well be ready for implementation of the QCO Order effective 1st January 2025.

The industry also prays that it is equally important that the QCO Order extension be notified very much in advance (at least 3 months in advance, if not more). The reason for the same is as follows: Many FIHA members do not

meet the concerned IS Standards in its current (voluntary) form. If no certainty is provided in advance, over the extension of QCO Order for non-SMEs, the industry will have no option but to stop manufacturing, (given the lead time involved in ordering of raw materials which is very bulky and packaging materials that would be compliant with the concerned BIS Standards) much in advance of the existing QCO Order implementation date of 1st April 2024. And if such a scenario arises whereunder the industry stops to manufacture in advance and QCO Order extension intimation comes last minute – it would mean non availability/ shortages of essential hygiene products in the market, which would cause disruption and would not be in the interest of public at large.

We therefore, humbly request your good self to grant the extension and the extension order may kindly be communicated to the industry preferably by the first week of January 2024.

We are always committed to supporting the esteemed Ministry of Textile to achieve their vision.

ANNEX 7
(Item 5.*1*)

PROPOSED DRAFT AMENDMENTS IN IS 5405 and IS 17514

Doc: TXD 36 (xxxxx)

Draft **AMENDMENT NO. 4**

TO

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

(Not to be reproduced without the prior permission of BIS or used as amendment to the standard)

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

The pH of sanitary napkin (top and absorbent core) shall meet the following requirement when tested by the method given in IS 1390 :-

a) Thick sanitary napkin with 100 percent fluffy pulp in absorbent core – 4.0 to 8.0
b) Other sanitary napkins – 5.5 to 8.0

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

(*Page* 4, *clause* **9.1**) **—** Insert the following at the end:

'g) The manufacturer shall declare the material of top sheet, middle layer and bottom sheet of the product along with chemical ingredient on the label if agreed between the buyer and seller.'

(*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

(*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 meet the following requirement when tested by the method given in IS 1390 :-

a) Reusable sanitary pad/sanitary napkin/period panties with 100 percent fluffy pulp in absorbent core – 4.0 to 8.0
b) Other reusable sanitary pad/sanitary napkin/period panties – 5.5 to 8.0

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

(*Page* 4, *clause* **12.1**) **—** Insert the following at the end:

'g) The manufacturer shall declare the material of top sheet, middle layer and bottom sheet of the product along with chemical ingredient on the label if agreed between the buyer and seller.'

(*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 8
(Item 5.*2*)

COMMENTS ON PUBLISHED STANDARDS

Comments on IS 17509 (Disposable Baby Diaper - Specifications)

P&G, Mumbai

Sr. No.	Item Clause/Reference	P&G Proposal	Justification
1	**7.4 Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization** (IS 17509: 2021) - The manufacture shall ensure that raw material used for manufacturing the final product are safe for user based on its known toxicological characteristics at intended use. The biocompatibility of the material shall be detected by evaluating cytotoxicity, irritation, and skin sensitization test as per IS/ISO 10993 (Part 5) and IS/ISO 10993 (Part 10) respectively. For cytotoxicity, the material shall show reactivity as "None" when tested as per IS/ISO 10995 (Part 5). Similarly, the material shall be "Non-irritant and Non-sensitizer" when tested as per IS/ISO 10993 (Part 10). For preparation of samples for these tests, ISO 10993 (Part 12) shall be referred.	**Insert "OPTIONAL" in clause 7.4 title** **7.4 Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization (OPTIONAL)** **OR** **REPLACE EXISTING CLAUS with the following** **7.4 Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization** - The manufacturer shall ensure that raw materials used for manufacturing the final product are safe for user based on its known toxicological characteristics at intended use.	**a.** ISO 10993 provided general framework for biological evaluation of medical devices and never mandate to perform certain tests. Thus current wording is misleading and contradicts the framework principles laid down in ISO 10993. It is worthy to mention that such tests are not mandated in any part of the world. **b.** ISO 10993 is a series of standards specifically developed for medical devices and not for the general hygiene products. Also, diapers are not classified as "Medical Devices in India" **c.** Not practical in the current wording **d.** Involves animal testing which is banned in India and worldwide. **e.** Capability to **fully** test as per current clause is not available in the country and expensive (costs, long testing duration) **f.** False positive results **g.** This test alone is not a final guarantee of biocompatibility unless bridged by other scientific information

2	**Table 2** Requirement of Disposable Baby Diaper (Clause 7.2); IS 17509:2021	**To remove** "rate of absorption per gush (s) max **OR Change** from 60 to 300	a. This is an **editorial error** and in disagreement with the absorption capacity and rate of absorption method (Clause **B-4.6 & B-4.7**) b. As per the methodology waiting time is 5 minutes and all the liquid is expected to be absorbed within 5 minutes. Therefore, changing from 60 to 300 seconds will bring consistency with test
3	**B.2.2 Rigid Cover Plate (IS 17509:2021, Disposable Baby Diaper – Specifications)** Total weight: 6300 g (plate 605.3 g, weight 5694.7 g)	**Allow weight range tolerance ± 0.1% from target weight.** Plate: 605.3g ± 0.1% Weight: 5694.7 ± 0.1%	a. Slight variations in the weight manufacturing are inevitable due to factors like raw material variations, machine tolerances. B. The proposed ± 0.1% tolerance is based on P&G
4	**B-3 Conditioning of Test Specimen** (IS 17509:2021, Disposable Baby Diaper - Specification) + **5 Requirements** **(IS 6359:2023**, Method for Conditioning of Textiles) 5.1 The atmosphere in which physical tests on textile materials are performed. It has a relative humidity of 65 percent and a temperature of 27C. 5.2.1 Specific standard atmosphere shall have a temperature of 23 C and relative humidity of 50 percent. 5.2.3 Tolerance limits for	**1. To follow** Clause 5.2.1 standard atmosphere of 23C and 50% humidity. **2. Allow** higher tolerance limits for temperature and relative humidity in Clause 5.2.4 to ±2C and ±5%RH.	a. 23ºC and 55% RH are the general conditions in a lab b. A wider range is needed due to equipment variability, typically ±2C and ±5%RH.

5	**4 Fastening and Securing Mechanism** **5 Manufacture, workmanship and finish** **6 Types and Sizes** (IS 17509:2021, Disposable Baby Diaper – Specifications)	**Remove** this from Baby Diaper Product Manual. In fact, Raw material related testing too should not be part of manual.	These are subjective/visual tests/general expectations and in absence of clear test methods creates confusion. Nonetheless manufacturer already specifies product types, sizes etc. on label & being conveyed to the
6	**8 Sampling and Criteria for Conformity** (IS 17509:2021, Disposable Baby Diaper – Specifications) 8.1.2 Unless otherwise agreed, the number of baby diaper to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, 3 and 5 of Table 3.	**REMOVE** this clause from the IS 17509:2021	a. Presence of this clause is in disagreement with sampling & test frequency plan in Baby Diaper product manual. **Manual clearly states that** - "Table 1 where Levels of Controls for No. of Sample and Frequency for Requirement 4, 5, 6 states "Manufacturer shall put in place adequate in process controls/inspections to ensure conformity to the standard". b. In fact, sampling plan and testing frequency to be completely removed from standard and manual should be the only final reference. This will facilitate compliance implementation for the

7	**8 Sampling and Criteria for Conformity** (IS 17509:2021, Disposable Baby Diaper – Specifications) **Table 3 Number of Baby Diaper** **to be Selected** for nondestructive testing is between 13 to 125 and destructive testing is	**Reduce sampling and standardize** to n=3 for pH requirement. Standardize n=8 for absorption and rewet requirement. Standardize Phthalate sampling to n=3	a. In Product Manual (PM/17509/2) Table 1 Levels of Controls, no. of sample listed is one across requirement 3 and 7, while other requirements states that manufacturer to put in place inspections. b. Global practice for Phthalate testing is n=3
8	**Table 1 Levels of Control** (Product Manual (**PM/17509/2**)) 7.3 Hygiene Testing Requirement: The manufacturer shall perform the hygiene testing for the final product every quarter for monitoring purpose and whenever there is any change in the raw material, manufacturing premises 7.3.2 and the raw material supplier	**To amend** the existing statement in the manual as given below: **7.3 Hygiene Testing Requirement:** The manufacturer shall perform the hygiene testing for the final product every quarter for monitoring purpose.	a. The quarterly monitoring of hygiene is already factoring changes in the raw material, vendor occurred. b. This will facilitate manufactures without defeating core purpose of Hygiene Testing. c. If Finished product conformity is established then additional testing burden should not be added onto the manufacturers. d. Adherence to general GMP principle in the standard are key for
9	**7.1 pH Value** The pH of the diaper shall be from 5.5 to 8.0 when tested by the method given in IS 1390.	**To amend existing pH Limits** The pH of the diaper shall be from **3.5 to 8.0** when tested by the method given in IS 1390.	a. to broaden the choice of materials and future innovations b. Some arguments provided for Sanitary pads are applicable here as well (discussed during last meeting)

10	**8.2 Number of Tests and Criteria for Conformity**	**Insert the following -** 8.2.8 Each type of baby diaper shall be tested at least monthly for the pH value and Rate of Absorption, Rewet under Load and Minimum Absorption Capacity	a. This is an precision engineered product and higher testing frequency is not required. b. A monthly frequency is good enough for the purpose of BIS compliance. Nonetheless enforcement officials can check product conformity as per their will. C. To reduce unnecessary sample wastage, resources for no obvious benefit in terms of compliance and quality. d. Parametric release over time should be allowed and reflected in the
11	**6. Scope of License (PM/17509/2 May 2023)** Material - As declared	**To remove** this from Baby diaper product manual.	a. This to be in-line with Sanitary Napkins Manual b. A manufacturer may have many hundreds of raw materials. Having this under License scope change will be heavy burden on the industry c. As long finished product meets the conformity criteria such expectations are unnecessary. d. e.g. Unlike Steel Industry where material counts are 2-3, this is

12	**ANNEX A Grouping Guidelines (PM/17509/2 May 2023)** The following grouping guidelines shall apply for Grant of Licence (GoL)/Change in Scope of Licence (CSoL):	**To amend** the existing clause ANNEX-A GROUPING GUIDELINES The following grouping guidelines shall apply for Grant of Licence (GoL)/Change in Scope of Licence (CSoL) and **Routine tests post GoL:**	a. To include grouping guidelines for post approval testing (routine testing) and remove any ambiguity over testing scheme
13	**pt. i & ii (ANNEX A Grouping Guidelines (PM/17509/2 May 2023))** i. The manufacturer shall declare the types of materials being used to manufacture baby diapers as well as the types and sizes of the diapers being manufactured. ii. Samples of baby diapers of each type of material and of any of the types/sizes of baby	**To amend this clause** i. The manufacturer shall declare the types of materials being used to manufacture baby diapers as well as the types and sizes of the diapers being manufactured. ii. Samples of baby diapers of each type/size of baby diapers being manufactured and intended to be covered in the scope of licence, shall be tested.	a. This to be in-line with Sanitary Napkins Manual b. A manufacturer may have many hundreds of raw materials. Having this under License scope change will be heavy burden on the industry c. As long finished product meets the conformity criteria such expectations are unnecessary. d. e.g. Unlike Steel Industry where material counts are 2-3, this is

14	**pt. 5 CONTROL UNIT ANNEX C Scheme of Inspection and Testing (PM/17509/2 May 2023)** For the purpose of this scheme, entire quantity of disposable baby diapers manufactured from the same consignment of raw material, of the same type and size, manufactured under similar conditions in a day shall be taken as one control unit.	**To Remove** this clause from the baby diaper manual.	**This is in contradiction of Note 2** which states "*As manual – Note- 2* *Note–2: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.*" **As of today, all manufacturers are defining their own batch/lot/control unit in line with best practices**

ANNEX 9
(Item 5.*2*)

COMMENTS ON PUBLISHED STANDARDS

PROPOSED AMENDMENT IN IS 17509

Draft **AMENDMENT NO. 1**

TO

IS 17509 : 2021 DISPOSABLE BABY DIAPER — SPECIFICATION

'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).'

'h) The manufacturer shall declare the material of top sheet, middle layer and bottom sheet of the product along with chemical ingredient on the label if agreed between the buyer and seller.'

(*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 10
(Item 5.*3*)

COMMENTS ON PUBLISHED STANDARDS

PROPOSED AMENDMENT IN IS 17508

Draft **AMENDMENT NO. 1**

TO

IS 17508 : 2020 DISPOSABLE ADULT INCONTINENCE DIAPER — SPECIFICATION

(*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).'

‘h) The manufacturer shall declare the material of top sheet, middle layer and bottom sheet of the product along with chemical ingredient on the label if agreed between the buyer and seller.’

ANNEX 11

(Item 5.4)

COMMENTS ON PUBLISHED STANDARDS

CMD-II, BIS
Comments on IS 17354 : 2020, Medical Textiles — Dental Bib / Napkins — Specification

Clause	Comments	Justification
1 SCOPE	Requirements for disposable and reusable dental bib/napkins may be defined along with methods of test to distinguish them	This standard specifies the requirements for dental bib/ napkins (disposable and reusable) but does not provide any test/requirements to distinguish them
4 MANUFACTURE	For effective implementation, an indicative list of recommended and/or prohibited materials may be provided	clause states that the dental bib/napkins shall be made from suitable material that is not prohibited for use but does not specify any prohibited or recommended materials for use
5.2 Table 1 S No (iv) Absorption	The parameters under Absorption may be renamed as Liquid Absorbency Time and liquid absorptive capacity In accordance with IS 15891 (Part 6) Further, the test liquid to be used may be specified for the test	The parameters are termed as Sinking time and Water holding capacity whereas in the method of test standard IS 15891 (Part 6) they are referred as Liquid Absorbency Time and liquid absorptive capacity Further, the test method requires use of Specified liquid, agreed-upon and specified and also identified in the test report. It is felt that a suitable test liquid may be specified for the test in order to have uniformity in testing.
6 PACKAGING	Either shelf life may be specified or declaration of shelf life may be specified in the marking clause (we are specifying this in the marking clause of SIT presently)	The clause states that Packaging of the product should be, such as to maintain the integrity of the product throughout its shelf life. However, neither has shelf life been specified nor has declaration of shelf life been prescribed under the marking clause.

ANNEX 12
(Item 5.*4*)

COMMENTS ON PUBLISHED STANDARDS

PROPOSED AMENDMENT IN IS 17354

Doc: TXD 36 (xxxxx)

Draft **AMENDMENT NO. 1**

TO

IS 17354 : 2020 MEDICAL TEXTILES — DENTAL BIB / NAPKINS — SPECIFICATION

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(*Page* 1, *Table* 1, *Sl no. (iv),* a)] — Substitute 'Liquid absorbency time' for 'Sinking time'.

(*Page* 1, *Table* 1, *Sl no*. *(iv),* b)] — Substitute 'Liquid absorptive capacity' for 'water holding capacity'.

(*Page* 1, *Table* 1) — Add the following new note at the end:-

'Artificial saliva (*see* ISO 20701) shall be used as test liquid if agreed between the buyer and seller.'

(*Page* 2, *Clause* 7.1) — Insert the following information at the end:-

'f) Declared shelf-life of the product.'

ANNEX 13
(Item 6.*1*)
INTERNATIONAL ACTIVITIES

BRIEFING MEETING OF INDIAN DELEGATES AND RESOLUTION AND REPORT OF ISO/TC 338 PLENARY MEETING

For BIS Use Only

BUREAU OF INDIAN STANDARDS

Briefing meeting of Indian Delegation for plenary meeting of ISO/TC 338

Date	Time	Venue
01 December 2023 (Friday)	1100 h	Video Conference through CISCO Webex

ATTENDEES:

i) Shri S. Sivakumar, SITRA, Coimbatore
ii) Dr. E. Santhini, SITRA, Coimbatore
iii) Dr. Sadhana Srivastava, Indian Council of Medical Research, New Delhi
iv) Dr. Manisha Mathur, The Synthetics & Art Silk Mills Research Association, Mumbai
v) Shri Nirav Mehta, M/s Dima Products (ITTA), Mumbai
vi) Ms. Roocha Khedkar, Johnson and Johnson, Mumbai
vii) Ms. Shivani Swamy, Livinguard Technology Pvt. Ltd., Mumbai
viii) Smt. Tanya Mahajan, The Pad Project (NGO), India
ix) Shri Dharmbeer, Scientist D and Member Secretary, TXD 36
x) Ms. Shalini Shree, Executive assistant, BIS

Item 0 WELCOME AND INTRODUCTORY REMARKS

Shri Dharmbeer, Scientist D and Member Secretary, TXD 36 extended a hearty welcome to the experts and members nominated in ISO/TC 338. He emphasized for active participation from the members and requested for the precise inputs so as to decide the India's point of view during the plenary meeting.

Item 1 SALIENT OUTCOMES OF THE BRIEFING MEETING

1.1 The experts/member reviewed the agenda of ISO/TC 338 plenary meeting and discussed the progress report, India.s point of view and future action plan of Working Group (WG 1), Adhoc group, Task group. After discussion, the following was decided: -

ITEM 1.1.1 WG General Requirements

After the deliberation, the following was decided: -

i) Shri S. Sivakumar, SITRA shall share the latest working draft on the subject 'General and Safety Requirements of Menstrual Products' with experts/committee member of TXD 36.

ii) It was requested that the International Standards of other National Standards Body (NSBs) required for completion of work of WG 1 shall be informed to BIS by Shri S. Sivakumar.

iii) Shri S. Sivakumar, SITRA, Conveyor of WG 1 shall present the status report of WG 1 during plenary meeting highlighting – the work done / progress report by WG 1 since 2nd plenary meeting, provide the next meeting date of WG 1/completion of the document, challenges and support required from ISO/TC 338 secretariat/WG 1 experts, future action plan/roadmap for completion of the document. A presentation of 10-12 minutes shall be prepared by Convenor.

iv) Shri S. Sivakumar, SITRA, Conveyor and experts of WG 1 shall protect India's point view for change of title of WG 1 from 'General requirements' to 'Safety, Performance and General requirements of menstrual products'.

v) Shri S. Sivakumar, SITRA, Conveyor shall clarify the comments received from experts of other National Standards Body on working document and title of WG 1 (if required/raised during meeting).

vi) Indian expert may take leadership role as convenor/project leader or as an expert if separate subgroup is/are created for performance requirement dealing with disposable sanitary pad, reusable sanitary pad, tampon, menstrual cup etc.

vii) The other experts shall support Convenor on above matter.

ITEM 1.1.2 Ad hoc group Terminology

After the deliberation, the following was decided: -

i) Smt. Tanya Mahajan, Conveyor of Adhoc group shall present the status report of Adhoc group during plenary meeting highlighting – the work done/progress report by Adhoc group since 2nd plenary meeting, support required from adhoc group member/ISO TC 338 secretariat, future action plan for completion of the document, propose terminology as a New Work Item Proposal (NWIP). A presentation of 10-12 minutes shall be prepared by Convenor.

ii) Smt. Tanya Mahajan, Conveyor shall clarify the comments received from experts of other National Standards Body on CIB Ballot 'Preliminary work item, Menstrual Product- Terminology (if required/raised during meeting).

iii) The menstrual pad may be included under the scope of ISO/TC 338 and the definition may be included in terminology document.

iv) The definition like Maternity Pad, Synthetic material; Vaginal/vulval microbiota may be included in terminology document during NWIP stage.

v) The term related to light, medium, heavy menstruation may be in included in generic or as basic information in terminology document. If volume of flow is to be defined, then it may be included later in the specific document which covers the performance requirement.
vi) The terminology finalized by adhoc group shall be proposed as new item proposal for recognition of efforts done by convenor and experts from India.
vii) Smt. Tanya Mahajan agreed to continue as a Convenor if a working group/separate working group is required to be established for NWIP on Menstrual Product- Terminology. It was proposed that the existing adhoc group shall be converted to full-fledged working group if agreed by ISO/TC 338.
viii) It was also suggested that India may be flexible if terminology document prepared by adhoc is referred to existing WG 1 for NWIP but not as supporting document.
ix) The other experts shall support Convenor on above matter.

ITEM 1.1.3 Task Group Strategic Business Plan

After the deliberation, the following was decided:-

i) Dr. E. Santhani, Conveyor of Task Group shall present the status report of task group during plenary meeting highlighting – the work done / progress report by task group since 2nd plenary meeting, date of next meeting, future action plan for completion of the document. A presentation of 10-12 minutes shall be prepared by Convenor.
ii) Dr. E. Santhani, Conveyor of Task Group shall clarify the comments received from experts of other National Standards Body on strategic business plan (if required/raised during meeting).
iii) Dr. E. Santhani, Conveyor of Task Group may co-ordinate with Smt. Tanya Mahajan in case of any assistance for data/information required for strategic business plan before plenary meeting.
iv) The other experts shall support Convenor on above matter.

1.2 There being no other business, the meeting ended with a hearty vote of thanks to the *experts and members.*

Resolutions taken at the 3rd plenary meeting of ISO/TC 338, 8 December 2023

Resolution 15 -2023

ISO/TC 338 agreed to adopt the draft agenda (N 67) with minor modifications.

Resolution 16 -2023

ISO/TC 338 agrees that the secretariat of ISO/TC 338 together with Dharmbeer (India), Laurent Houillon (France), Kemi Allston (USA) to be appointed to the resolutions drafting committee.

Resolution 17 -2023

ISO/TC 338 agrees that all reports included in the agenda presented at the meeting, to be accepted. That includes the reports of AHG 1 Terminology, WG 1 General Requirements, TG 1 Strategic Business Plan, and organizations in liaison.

Resolution 18 - 2023

ISO/TC 338 agrees to accept to change the WG 1 title to "Safety, performance and general requirements of menstrual products", according to the voting results (N 61).

Resolution 19 – 2023

ISO/TC 338 requests the committee manager to launch a NWIP ballot for "General and safety requirements of menstrual products" as soon as BIS has submitted the proposal expected by the end of February 2024.

Resolution 20 - 2023

ISO/TC 338 requests AHG 1 to further investigate if maternity pads/post-partum pads should be included in the terminology document.

Resolution 21 – 2023

ISO/TC 338 agrees to register the terminology document as a Preliminary Work Item, and to appoint Tanya Mahajan (India) as project leader, as a consequence to maintain AHG 1 and to revise the terms of references accordingly.

Resolution 22 – 2023

ISO/TC 338 expresses their thanks to Veronica Viscovich, resigned as a liaison officer to ISO/TC 157 and ISO/TC 210 and requests the committee manager to launch a CIB for her replacement.

Resolution 23 – 2023

ISO/TC 338 expresses their thanks to all participants for their valuable contribution and for attending the meeting.

REPORT OF 3RD PLENARY MEETING OF ISO/TC 338 HELD ON 8 DECEMBER 2023

• USEFULNESS OF THE FOREIGN DEPUTATION WITH A BRIEF DESCRIPTION OF THE WORK CARRIED OUT

Hygiene-related practices of women during menstruation are of considerable importance, as it has a health impact in terms of increased vulnerability to reproductive tract infections (RTI). Menstrual Hygiene is vital for the empowerment and well-being of women and girls worldwide and gender equality.
ISO TC 338 on Menstrual product is newly established committee. There are 3 working groups (adhoc, working group, task group) in ISO TC/338 and in all the groups **BIS (India) has leadership role and nominated experts from India.**

1) Smt. Tanya Mahajan, The Pad Project (NGO), India (Convenor) - Adhoc group to define terminology
2) Shri S. Sivakumar, (Head, Medical Textiles), SITRA, Coimbatore (Convenor) - Working Group for General requirements
3) Dr. E. Santhini, SITRA, Coimbatore, (Convenor), Task group for the development of ISO/TC 338 Strategic Business Plan

The third plenary meeting of ISO/TC 338 'Menstrual Product' was held on 08th December 2023 in in virtual mode. Since the subject matter being dealt by ISO/TC 338 are important from India's perspective, critical and sensitive in nature so a strong representation at the plenary meeting was proposed to represent India during the meeting.

The following delegation of experts participated in the 3rd plenary meeting in virtual mode to represent India's point of view :-

8) **Shri J.K. Gupta, Sc-E & Head, Textiles (Head of Delegation)**
9) Shri Dharmbeer, Sc-D, Textiles, Member Secretary TXD 36
10) Shri S. Sivakumar, (Head, Medical Textiles), SITRA, Coimbatore
11) Dr. E. Santhini, SITRA, Coimbatore
12) Smt. Tanya Mahajan, The Pad Project (NGO), India
13) Shri Nirav Mehta, Dima Products, Mumbai
14) Ms. Roocha Khedkar, Kenvue, Mumbai

Presentations on the progress report of the task group for Strategic Business Plan, working group for general requirements and adhoc group for terminology were made by Dr. E. Santhini, Shri S. Sivakumar, SITRA and Ms. Tanya Mahajan respectively.

Dr. E. Santhini, SITRA during his presentation informed that ISO/TC 338/TG 1 was entrusted with the task of preparing the Strategic Business Plan for ISO/TC 338. This task group deals with the preparation of the strategic business document covering the following major points:

- Business environment for menstrual products.
- Benefits expected from the work of ISO/TC 338.
- Objectives of ISO/TC 338 and strategies for their achievements.
- Factors affecting the completion and implementation of ISO/TC work programme.
- Structure, current projects and publications of ISO/TC 338

The task group meetings were held on 01st June and 20th June 2023 and the draft ISO TC 338 strategic business plan was prepared. The draft document was circulated for 2 months through committee internal balloting and the comments received will be resolved in next meeting of task group scheduled on 18th December, 2023.

Shri S. Sivakumar, SITRA during his presentation informed that working Group 1 (WG 1) dealt with the preparation of working document for standard on menstrual products. This working group intended to address the general, performance and safety requirements of menstrual products (single use/Multiple use) for different applications for example internally and externally used products.

The second and third meeting of WG 1 were convened on 29-30 May 2023 and 06-07 September 2023 through virtual mode. The draft outline of the document for general and safety requirements for menstrual products was finalized during these meeting. It was decided to collect inputs from the members offline on clauses such as 6.3 Chemical assessment and safety, 6.4 Biological safety, 6.5 Exposure assessment.

Ms. Tanya Mahajan during his presentation informed that AHG1 dealt with the identification, selection and preparation of terminology and definition towards the standardization in the field of menstrual products (absorbing and collecting), covering all products intended for both single and multiple uses, regardless of material.

The comments received on committee internal balloting (CIB) were discussed and resolved during 2 meeting of adhoc group on 27th September and 30th October 2023. No clear definitions were available for terms related to light, medium and heavy menstruation. It was also informed that if maternity pads are to be included in the scope of ISO/TC 338, definitions related to maternity pads, lochia etc. will need to be included in the terminology document.

BENEFITS ACCRUED TO BIS

The important outcomes of the ISO/TC 338 Plenary meeting are as follows: -

a) The progress reports presented by India on the above 3 groups were accepted by the committee and leadership roles (Convenorship) of India have been continued in all the 3 WG1/TG1/AHG1.
b) The committee agreed to accept to change the WG 1 title to "Safety, performance and general requirements of menstrual products" under the Convenorship of India.
c) The committee agreed to launch a NWIP ballot for "General and safety requirements of menstrual products" under the Convenorship of India.

d) ISO/TC 338 agrees to register the terminology document as a Preliminary Work Item, and to appoint Tanya Mahajan (India) as project leader.
e) The proposal of Australia for the constitution of a new working group for 'Tampons' was not agreed upon due to objection by India.

• Conclusion and recommendations

1) ISO/TC 338 agreed to launch a NWIP ballot for "General and safety requirements of menstrual products" proposed by India.
2) The meeting of task group (TG1) of strategic business plan shall be convened to resolve the comments received from member countries on Committee Internal Ballot (CIB) on business plan.
3) The meeting of adhoc group (AHG1) shall be planned to further investigate if maternity pads/post-partum pads should be included in the terminology document and to include the remaining terminology document.
4) The terminology once finalized by adhoc group shall be proposed as new work item proposal.
5) The meeting of working group on general requirement shall be planned during 3rd week of January 2024 to discuss and prepare the working document and NWIP on 'General and safety requirements of menstrual products'.

A BRIEF SUMMARY OF THE REPORT

Sl. No.	**Purpose of foreign visit**	**Officer(s) deputed from the department along with justification (for visit and nomination of deputed officer), PAN and Aadhar No.**	**Countries visited with duration**	**Specific deliverables from the proposed visit**	**Expected outcome (as envisaged before the visit)**	**Final outcome (to be submitted after the visit)**
1	To participate in the plenary meeting of ISO/TC 338 held on 8th December 2023	Delegation participate through virtual mode	Through Virtual Mode	To continue the leadership roles (Convenorship) of India in in all the 3 groups- WG1/TG1/AHG1.	To continue the leadership roles (Convenorship) of India in in all the 3 groups- WG1/TG1/AHG1.	The progress reports presented by India on the above 3 groups were accepted by the committee and leadership roles (Convenorship) of India have been continued in all

	through virtual mode					the 3 WG1/TG1/AHG1.
				To propose preliminary work item on terminology as Committee Internal Ballot (CIB)	To propose preliminary work item on terminology as Committee Internal Ballot (CIB)	ISO/TC 338 agrees to register the terminology document as a Preliminary Work Item, and to appoint Tanya Mahajan (India) as project leader.
				The proposal to modify the title and scope of WG 1	To discuss and define the Scope and Title of Working Group 1	The committee agreed to accept to change the WG 1 title to "Safety, performance and general requirements of menstrual products" under the Convenorship of India.
				To propose NWIP on general and safety requirement of menstrual product	To discuss and propose NWIP on general and safety requirement of menstrual product under WG1	The committee agreed to launch a NWIP ballot for "General and safety requirements of menstrual products" under the Convenorship of India

					Opportunity to interact with like-minded countries/International Experts and soliciting their support on important items of Indian interest.	The proposal of Australia for the constitution of a new working group for 'Tampons' was not agreed upon due to objection by India.