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BUREAU OF INDIAN STANDARDS

AGENDA

Technical Textiles for Medtech Applications Sectional Committee, TXD 36 **28th Meeting**

Date	Time	Venue
13 September 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 27th meeting of the TXD 36 committee held on 16 July 2024 through CISCO webex videoconferencing was circulated vide our reference TXD 36/A 2.27 email dated 27 July 2024. No comments were received on the minutes.

1.1.1. The committee may **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 1 (Pages 5-7).**

2.1.1 The Committee may **REVIEW**.

2.2 Shri Kulveen Singh Bali, M/s Solventum India, Bangalore has requested for membership in TXD 36. He has more than 25 years of experience in quality & regulatory affairs in field of medical devices, manufacturing, distribution including pre and post marketing activities. He has done master in microbiology and SME for sterilization, clean room & aseptic processes, design, development and launch of new devices.

2.2.1 The Committee may **DECIDE.**

2.3 Shri Gopal Amrut Suryawanshi, M/s Avgol India Pvt. Ltd., Madhya Pradesh has requested for membership in TXD 36. He has done B.Sc in microbiology and diploma in Textiles. He has more than 14 years of experience in the field of testing, quality assurance and quality

control of non-woven fabric manufacturing such as spun melt, spun lace, needle punch and surgical cotton.

2.3.1 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 27th meeting is given at **Annex 2 (Pages 8-11).**

3.1.1 The Committee may **NOTE**.

Item 4 DRAFT AMENDMENT FOR FINALIZATION

4.1 As decided by the committee in last meeting, the following draft amendment was issued in wide circulation vide our letter reference no. TXD 36/25703 dated 07 August 2024 for eliciting comments from stake holders for 30 days : -

i) Amendment No. 1 to IS 18266 :2023, Textiles — Medical Respirator — Specification [Doc: TXD 36 (25703)]

The last date for comment was **06 September, 2024**.

The draft amendment as issued under wide circulation are given at **Annex 3 (Pages 12-13).**

The comments received from Shri Kulveen Bali - Solventum India, Shri Arnab Das -DGQA, Dr Manish Sabharwal -Dr. Sabharwal Wound Care and Shri Yogesh Gohel – Global Non-woven on amendment No. 1 to IS 17509 : 2021 are given as follows :-

Shri Kulveen Bali - I agree with the draft.
Shri Arnab Das - I agree with the draft.
Shri Manish Sabharwal - I agree with the draft.
Shri Yogesh Gohel, For Medical Respirator mask, particulate efficiency must be classified with micron size. As users and sellers are misinterpret the requirements.

4.1.1 The Committee may **DECIDE.**

Item 5 DRAFT STANDARD/AMENDMENT FOR APPROVAL FOR WIDE CIRCULATION

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

In the last meeting of TXD 36, the committee decided to constitute a panel of the following experts to discuss the comments received on IS 5405 and provide its recommendation for amendment and/or revision of standard: -

1) Ms. Shradha Dongre, SASMIRA, Mumbai (**Convenor**)
2) Dr. Sadhana Srivastava, ICMR New Delhi
3) Dr. E. Santhini, SITRA, Coimbatore

4) Shri Nirav Mehta/Smt. Roocha Khedkar, Representing Indian Technical Textile Association/ Feminine and Infant Hygiene Association, Mumbai
5) Smt. Tanya Mahajan, The Pad Products (NGO), India
6) Shri Mithun Shah, Anabia Technologies, Bengaluru
7) 2-3 expert's subject experts/Doctors
8) Member Secretary, TXD 36

The panel meetings were convened on 09 August 2024 and 05 September 2024. The agenda and minutes of the panel meeting are given at **Annex 4 (Pages 14-116).**

The proposed draft revision of IS 5405 is given at **Annex 5 (Pages 117-131).**

5.1.1 The Committee may **DECIDE.**

5.2 IS 17334 : 2019, Medical Textiles — Surgical Gowns and Surgical Drapes — Specification

In the 23rd meeting of TXD 36, it was requested that following stakeholders shall send samples to SITRA for testing of dry and wet bacterial penetration test: -

a) Dr. Sanjiiv Rehlan, FICCI/PWMAI (Shalex Overseas), New Delhi
b) Shri Sumit Marwah, Dispoline India Private Limited, Bengaluru
c) Shri Khalil Khan, Surya Textech, Chandigarh
d) Shri Apurva Ranka, Alpha Foam Private Limited, Pune

The information on latest test results and test report after TXD 36 meeting are yet to be received from stakeholders.

SITRA was also requested to provide additional information and applicable values for resistance to dry and wet bacterial penetration test for revision of IS 17334.

The extract of minutes of 23rd meeting of TXD 36 and the summary of test results received from SITRA (vide email dated 05 September 2024) are given at **Annex 6 (Pages 132-137).**

The proposed amendment 1 to IS 17334 : 2019 is given at **Annex 7 (Page 138).**

The proposed draft revision of IS 17334 : 2024 is given at **Annex 8 (Pages 139-155).**

5.2.1 The Committee may **DECIDE.**

Item 6 COMMENTS ON PUBLISHED STANDARDS

6.1 IS 17509 : 2021 Disposable Baby Diaper — Specification

The comments received from Shri Alok Birla, Swara Baby Products, Madhya Pradesh and BIS Rajkot Branch office through BIS Standards portal are given at **Annex 9 (Pages 156-157).**

The proposed draft amendment no. 3 to IS 17509 is given at **Annex 10 (Page 158).**

6.1.1 The Committee may **DECIDE.**

6.2 IS 17514 : 2021, Reusable Sanitary Pad/Sanitary Napkin/Period Panties — Specification

The comments received from Smt Tanya Mahajan, Menstrual Health Action for Impact (MHAI), New Delhi are given at **Annex 11 (Pages 159-162).**

6.2.1 The committee may **DECIDE.**

6.3 IS 17630 : 2021, Medical Textiles — Bedsheet and Pillow Cover — Specification

The comments received from Shri Dhanaanjay D Joshi, Alok Industries Limited are given at **Annex 12 (Page 163).**

6.3.1 The Committee may **DECIDE.**

Item 7 DATE AND PLACE OF NEXT MEETING

Item 8 ANY OTHER BUSINESS

ANNEX 1

(Item 2.1)

SCOPE AND COMPOSITION

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 **(including medical devices made of textile material)** such as healthcare and hygiene textile products, implantable and non-implantable and extra corporeal textile products.'

Meeting(s) held	**Date & Place**
26th Meeting	15th April, 2024 (Through VC)
27th Meeting	16th July, 2024 (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	Smt. Prabha Hegde (Smt. Kavitha Kulkarni)	2/2
3.	All Indian Institute of Medical Sciences, New Delhi	Dr. Vijaydeep Siddharth (Dr. Sidhartha Satpathy)	2/2
4.	Alpha Foam Ltd., Pune	Shri Rajiv Ranka (Shri Apurva Ranka)	2/2
5.	Association of Healthcare Providers, New Delhi	Capt. Baban Rai (Dr. Sunil Khetarpal)	1/1
6.	Association of Indian Medical Device Industry (AiMeD), New Delhi	Shri Amit Kumar (Smt. Rama Venugopal)	1/2
7.	Central Drugs Standard Control Organization, New Delhi	Mr. Aseem Sahu (Ms. Shyamni Sasidharan)	1/2
8.	Cologenesis Healthcare Pvt. Ltd, Salem	Shri R Krishana Kumar Shri K. Ramprasad	1/2
9.	DMSRDE, Kanpur	Dr. Mukesh Kumar Sinha	0/2

10.	Defence Research & Development Establishment (DRDE), Gwalior	Dr. Vikas B. Thakre (Shri Suraj Bharati)	0/2
11.	DGAFMS, Ministry of Defence, New Delhi	Surg Capt S.S Dalawayi (Surg Lt Cdr Kotian V. Gopal)	0/2
12.	DGQA (Ministry of Defence), New Delhi	Shri S.S Kashyap (Shri Arnab Das)	2/2
13.	Dima Products, Mumbai	Shri Nirav Mehta (Shri Raghavan Adiyodi)	2/2
14.	Director General of Health Services, New Delhi	DGC (I) (Dr. Umesh Devappa Surangi)	2/2
15.	Dispoline India Private Limited, Bangalore	Shri Sumit Marwah	2/2
16.	Dr. Sabharwals Manufacturing Labs Pvt Ltd Panchkula	Shri Manish Sabharwal (Shri Dhruv Sabharwal)	2/2
17.	Federation of Indian Chambers of Commerce & Industry, New Delhi	Dr. Sanjiiv Rehlan (Ms Tulsi)	2/2
18.	Ginni Filaments Limited NOIDA	Shri Arun Nag (Shri Ayan Chakraborty)	2/2
19.	Indian Council of Medical Research, New Delhi	Dr. Sadhana Srivastav	2/2
20.	Indian Institute of Technology, New Delhi	Prof Ashwini Agarwal (Prof Bipin Kumar)	2/2
21.	Indian Technical Textile Association, Mumbai	Dr. Anup Rakshit (Shri Mahesh Kudav)	1/2
22.	Johnson and Johnson Private Limited, Mumbai	Smt. Monika Sathe (Ms. Roocha Khedkar)	2/2
23.	KOB Medical Textiles Pvt Ltd, Palladam	Shri Arun Buchade (Shri T. Balaji)	2/2
24.	Livinguard Technologies Pvt. Ltd., Mumbai	Ms. Shivani Swamy (Shri Shashank Morje)	2/2

25.	Maulana Azad Medical College, New Delhi	Dr. Pawanindra Lal (Dr. KirtiNath Saxena)	2/2
26.	Medline Healthcare Industries Pvt. Ltd, Pune	Mr. Anothony D' Costa (Shri Dhaval Ghuge)	1/2
27.	Ministry of Textiles (NTTM), New Delhi	Shri Ajay Pandit	2/2
28.	National Accreditation Board for Hospitals and Healthcare Providers, New Delhi	Dr. Kashipa	1/1
29.	Nobel Hygiene, Mumbai	Shri Joy Devassy (Smt. Sneha Gupta)	2/2
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.	Surya Textech, Chandigarh	Shri Khalil Khan (Shri Yogesh Yadav)	1/2
33.	Textiles Committee Mumbai	Shri Kartikeyan Dhanda (Dr. P. Ravichandran)	2/2
34.	The Pad Project (NGO), India	Smt. Tanya Mahajan	2/2
35.	The South India Textile Research Association, Coimbatore — 641014	Shri S. Sivakumar (Dr. E. Santhini)	2/2
36.	The Synthetics & Art Silk Mills Research Association, Mumbai	Dr Manisha Mathur (Smt. Shradha Dongre)	2/2
37.	Tynor Orthotics Private Limited, Panjab	Shri Neeraj Mehra (Dr Chetan Mittal)	1/1

ANNEX 2
(Item 3.1)

SUMMARY OF ACTIONS TAKEN ON THE MINUTES OF 27th 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** The committee finalized the following amendments for publication :- i) Amendment No. 2 to IS 17509 : 2021 Disposable Baby Diaper — Specification [Doc: TXD 36 (25701)] ii) Amendment No. 1 to IS 758 : 2023 Medical Textiles — Absorbent Cotton Gauze — Specification (Fifth Revision) [Doc: TXD 36 (25704)] iii) Amendment No. 1 to IS 863 : 2023, Medical Textiles — Cotton Bandage Cloth — Specification (Third Revision) [Doc: TXD 36 (25705)]	The amendments were published.
5.1	**DRAFT AMENDMENT FOR APPROVAL FOR WIDE CIRCULATION** 1) Amendment No. 1 to IS 18266, Textiles — Medical Respirator — Specification [Doc: TXD 36 (25703)] The committee decided that the above draft amendment shall be issued in **wide circulation** for **30 days** for eliciting technical comments from stakeholders.	Coming up under discussion in agenda item **4.1.**
6.1	**NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD** New Subjects (Knee Cap, Lumbo Sacral Belt, Wrist and Forearm Splint, Ankle Binder, Wrist and Forearm Splint, Chest Binder)	The working draft under preparation.

	The committee requested Shri Neeraj Mehra, M/s Tynor Orthotics Pvt. Ltd., Mohali and Dr. Manish Sabharwal, Dr. Sabharwals Wound Care, Baddi (on Knee Cap) to share the working draft on the above subjects based on inhouse technical data, scientific data and International Practice.	
7.1	**INTERNATIONAL ACTIVITIES** BIS to prepare a New Proposal Form 4 for ISO/PWI 25130 General and safety requirements of menstrual products latest by September 30, 2024	New Proposal Form 4 is under preparation.
7.2	**INTERNATIONAL ACTIVITIES** New Work Item Proposal, ISO/NP 25199, Guidelines for Processing of Multiple-Use Healthcare Textiles	The ballot for ISO/AWI 25199 successfully concluded on 12 July 2024. Further committee internal ballot (CIB) was issued by ISO TC 304 for creation on new working on healthcare textiles. The balloting results are yet to be received.
8.1	**COMMENTS ON PUBLISHED STANDARDS** The committee decided that an amendment incorporating following minor editorial changes shall be issued in IS 5405 : 2019 :- 1) IS 5405: 2019, Amendment No. 5 to IS 5409 : 2019, Sanitary napkins - Specification (second revision) [Doc No.: TXD 36 (26214)] The committee also decided to constitute a panel of to discuss the comments received on IS 5405 and provide its recommendation for amendment and/or revision of standard.	Amendment 5 to IS 5405 : 2019 has been published. The discussion on proposed revision of IS 5405 is coming under discussion in agenda item **5.1.**
8.2	**COMMENTS ON PUBLISHED STANDARDS** 1) IS 17787 : 2021, Medical Textiles — Nonwoven Wipes — Specification 2) IS 17788 : 2021, Medical Textiles — Nonwoven Fabric for Wipes — Specification	

	The committee decided as follows:- i) The following stakeholder will share the inhouse data and test report of NABL Approved lab for atleast 5 samples of non-woven wipes each for parameters like dimension, ph test, fiber composition, breaking strength:- a) Shri Ayan Chakraborty, Ginni Filament, Haridwar b) Smt. Roocha Khedkar, Kenvue Mumbai c) Shri Basudev Basu, Welspun India Limited, Gujarat d) Shri Rohit Srivatav, Unicharm Gurgaon ii) Shri Ayan Chakraborty, Ginni Filament will share the inhouse data and test report of NABL approved lab of atleast 5 samples each for tensile strength and breaking strength as per IS 15891 (Part 3) : 2011 and IS 15891 (Part 18) : 2017. iii) Shri Basudev Basu, Welspun India Limited, Gujarat will share the inhouse data and test report of NABL Approved Lab for atleast 5 samples each for needle punched non-woven wipes for all parameters as per IS 17787 : 2021 and IS 17788 : 2021.	The technical inputs/data are yet to be received.
9.1	**REVIEW OF PRE-2000 STANDARDS/DUE FOR REVIEW** The committee decided the following: - i) The committee requested experts/committee member to send their comments and suggestion for standards due for review/pre-2000 standards within 15 days. ii) BIS should approach other stakeholder who are not represented in TXD 36 committee/working groups/panel for their feedback and suggestion for changes required in these standards. iii) BIS shall prepare the review performa and circulate the same to committee members for 15 days through BIS Standards Portal. If no comments received after 15 days, the standards shall be reaffirmed for a further period of 5 years. iv) If the pre-2000 standards are not is use/limited use, they shall be archived for the time being.	The review performas have been circulated to TXD 36 members for their comments. The comments on standards due for review/pre-2000 are yet to be received from TXD 36 members/stakeholders

	v) Based on the suggestion/comments of experts where amendment and revision are required in the published standard, BIS shall fill the Performa for review and prepare the draft amendment/draft revision. The draft amendment/draft revision standard so prepared shall be issued in wide circulation for 30 days for eliciting technical comments from stakeholders. BIS may carry out the editorial changes in the draft if required.	

ANNEX 3
(Item 4.*1*)

DRAFT AMENDMENT FOR FINALIZATION

Doc: TXD 36 (25703)

DRAFT AMENDMENT NO. 1 JUNE 2024

TO

IS 18266 : 2023 TEXTILES — MEDICAL RESPIRATOR — SPECIFICATION

(*Foreword*, *Fourth Paragraph*) — Insert the following paragraph:

'For clinical tasks that do not involve exposure to potentially infectious bodily fluids and aerosols; and do not require inward leakage test and fit test, a surgical mask as per IS 16289 may be used rather than a medical respirator. Additionally, in industrial applications, medical respirators should not be used because they lack an exhalation valve and do not meet the requirement of clogging test for coal and dolomite loading.'

(*Page* 2, *clause* **4.3**) — Insert the following figure after the clause:

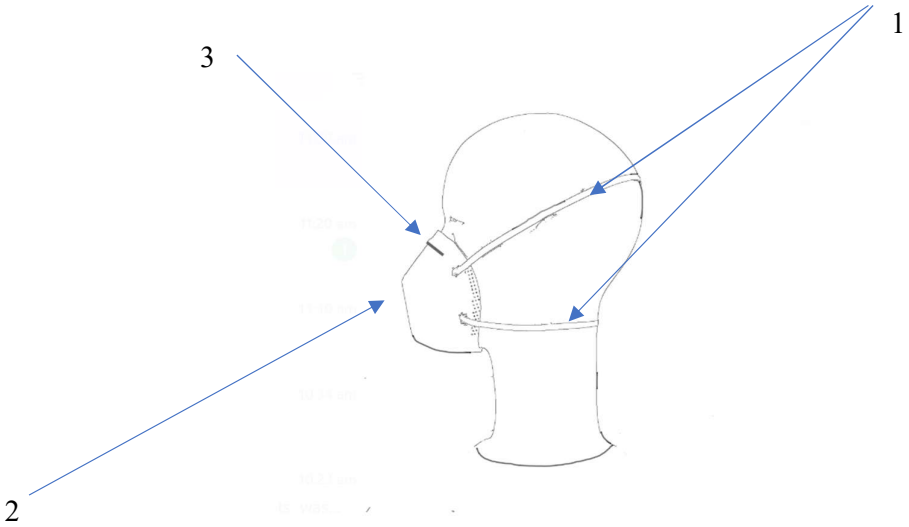


FIG. 1 MEDICAL RESPIRATOR COMPONENTS (FOR GUIDANCE ONLY)

1. Head Harness
2. Filter (Fabric layers)
3. Nose clip

Note - Nose pad and head harness adjuster are optional.

(*Page* 2, *clause* **5.1,** *Second Sentence*) **—** Substitute the following for the existing**:** -

'The medical respirators are classified into two classes based on performance: -

a) IN95 **—** Filtering out at least 95 % particles should be use by healthcare personnel (HCP) during all health care setting
b) IN99 **—** Filtering out at least 99% particles should be use by healthcare personnel (HCP) during high-risk situation or for improved fit factor.'

(*Page* 2, *clause* **5.1,** *Table* 1*, Note* 2) **—** Substitute 'should' for 'shall.'

(*Page* 2, *clause* **5.1,** *Table* 1*, Note* 2) **—** Substitute 'design' for 'designed.'

(*Page* 4, *clause* **6.1**) **—** Insert the following Note after the clause:

'NOTE — 'Information given from sl no. (e) to (k) shall be legibly marked on each pack of medical respirator.'

ANNEX 4
(Item 5.1)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

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

For BIS Use Only

BUREAU OF INDIAN STANDARDS

AGENDA

Panel meeting – Revision/Amendment of IS 5405 Sanitary Napkin

Date	Time	Venue
09 August 2024 (Friday)	1100 h	Video Conference through CISCO Webex

CONVENOR: Smt. Shradha Dongre, SASMIRA, Mumbai

MEMBER SECRETARY, TXD 36 : Shri Dharmbeer, Scientist D, Textiles, BIS New Delhi

Item 0 WELCOME AND INTRODUCTORY REMARKS

Item 1 COMMENTS ON PUBLISHED STANDARDS

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

In the last meeting of TXD 36, the committee decided to constitute a panel of the following members to discuss the comments received on IS 5405 and provide its recommendation for amendment and/or revision of standard within 30 days: -

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

The panel members were requested to provide the inputs on the following aspects :-

i) Ambiguity in the existing clause of IS 5405 : 2019 for better understanding and/or implementation of the standard.
ii) Technical inputs on size/dimension, variety, performance requirement and test method for disposable pantyliner and maternity pad for inclusion in IS 5405.
iii) Requirement/value and test method for 100 % flushable sanitary napkin and/or 100 % biodegradable sanitary napkin.
iv) Requirement/value and test method for dioxin and furan chemical substances traces are found/relevant in disposable sanitary pad.
v) Requirement for volatile organic compounds for disposable sanitary pad.
vi) Any other comments/queries on implementation of the standard.

The inputs/comments received from SITRA, Dima Products, Kenvue, P &G, ICMR, Soothe Healthcare, Unicharm India and Anabio Technologies are given at **Annex 1 (Pages 3-49).**

1.1.1 The Panel may **DELIBERATE** and **DECIDE.**

ANNEX 1
(Item *1.1*)

COMMENTS ON PUBLISHED STANDARDS

a) Dr. E. Santhini, SITRA

Subject: clarification on queries on IS 5405 received from stack holder - Reg

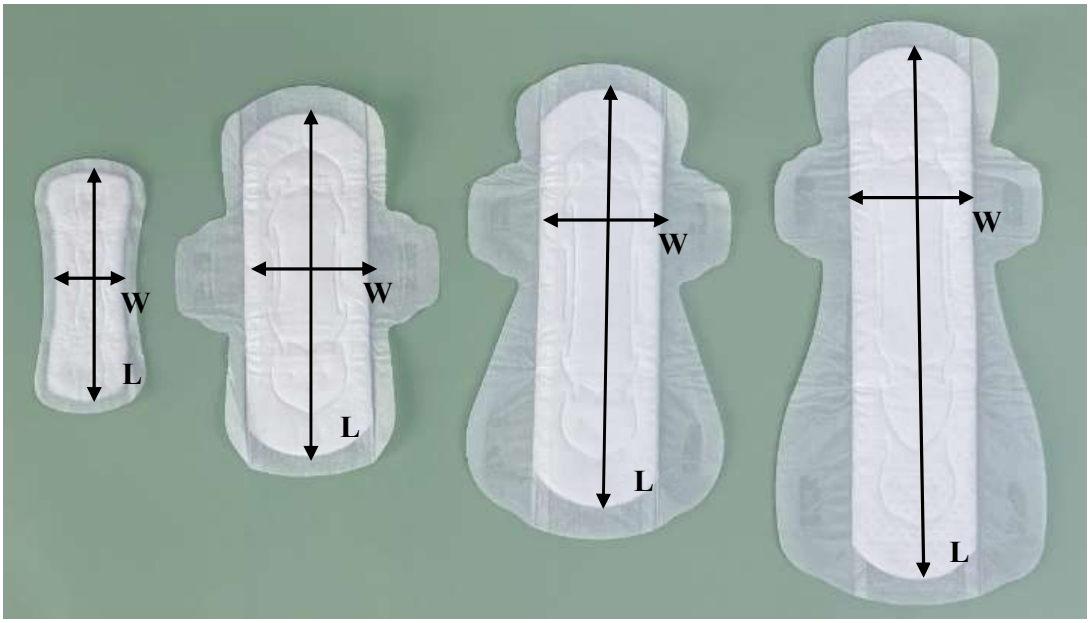
Dear sir,

With reference to the above subject, the clarification on queries received for IS 5405 from stakeholders are as follows :-

1) How to measure length and width in case of different design absorbent core like rectangular, round.

SITRA Response:

For any shape and size of sanitary napkin, the length of the sanitary napkin should be measured from top center portion to bottom center portion. The width of the sanitary napkin should be measured center portion of left side wing core part to center portion of right-side wing core part. The illustration for the measurement core dimension for difference shape and size of sanitary napkins are given in figure – 1.



L – Length; W – Width

Figure – 1 Measurement of core dimension for different size of sanitary napkins

2) Is there need to define the method for measurement of dimension.

SITRA Response:

The method given in SITRA Response – 1 may be used as the method for measurement of dimension

3) How many samples you are testing for dimension/size and ability to withstand pressure after absorption

SITRA Response:

10 samples are used for dimension / size test. One sample is used for ability to withstand pressure after absorption test.

4) Clause 6.2, when worn shall not chafe or give any uncomfortable feeling, how to assess this, may vary from person to person.

SITRA Response:
Currently it is assessed manually through hand feel testing. However, fabric touch tester can be adopted to provide numerical value for softness of top sheet of napkin.

5) Disposable panty liner and maternity pad are covered in IS 5405 or not. If not, what are the different requirements other than given in IS 5405:2019.

SITRA Response:
Currently they are not covered under IS 5405. Absorbency is the key requirement where the volume of the liquid should be kept different for these products. In our experience, we have carried out water absorption time, water absorption capacity as per ISO 20158 for few of customers. These tests were carried out in addition to the requirements specified in IS 5405 and also as per the direction from the customer.

6) Whether dioxin and furan chemical traces are found in sanitary pad. What could be the requirement and test methods.

SITRA Response:
Based on our literature review "Binay Kumar, Jandeep Singh, Sunil Mittal & Harminder Singh, 2023, "The Indian perspective on the harmful substances found in sanitary napkins and their effects on the environment and human health", Web link : https://link.springer.com/article/10.1007/s11356-023-26739-2", The presence of dioxin and furan chemical traces are found in Indian sanitary pad. The details of analysis report are as follows:

Name of the Chemicals	Observed value
Dioxin	0.244 pg/g to 21.419 pg/g
Furan	0.07 pg/g to 0.563 pg/g

The above test was performed using GCMS (Gas Chromatography Mass Spectroscopy).

7) Is it possible in practical to manufacturer flushable and 100 % biodegradable sanitary napkin? What could be the procedure, requirement and test method. Any international standard/reference.

Yes, it is possible to manufacture Flushable sanitary napkin or 100% biodegradable sanitary napkin. Flushability of the napkin can be tested as per NWSP 511.02 and biodegradability as per IS 17088 (it is for compostable) / AATCC 30, part 3.

b) Shri Nirav Mehta, Dima Products, Mumbai

- Whether disposable pantyliner and maternity pad are covered in IS 5405 or not. If not, what are the different requirements/variety other than given in IS 5405 :2019. Please share inputs on additional size/dimension, variety, performance requirement and test method.

Currently Panty liners and maternity napkins are not covered under IS 5045 and can be included with different size and performance requirements.
For panty Liners the general sizes vary from 145mm to 200mm. The main difference will be in the width and absorption capacity.

For maternity napkins, the absorption capacity should be higher as compared to the current napkins
This topic should be referred to the separate committee to come up with size and performance parameters.

- Is it possible in practical to manufacturer 100 % flushable sanitary napkin and/or 100 % biodegradable sanitary napkin. Whether we need to include these additional requirements in the existing standard. What could be the procedure, requirement, and test method.

There are many raw material suppliers and manufacturers of Sanitary Napkins working on the project of 100% biodegradable Sanitary Napkins. Also research and development is going on to make flushable Sanitary Napkins, however I am not aware of any napkins available commercially in India.

- Whether dioxin and furan chemical substances traces are found/relevant in disposable sanitary pad. What could be the possible requirement and test method.

Long time back, the woodpulp manufactures were using chlorine based chemicals to bleach the pulp, however as per my knowledge, the woodpulp manufacturers have adapted Elemental chlorie free chemicals to bleach the pulp since past 15 years. This eliminates the possibility of dioxins.
However we can take up the study of presence of dioxin and furan in the Sanitary Napkins in the market by testing it in BIS approved labs.

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)**
6. Manufacture, Workmanship and Finish The wood Pulp or other absorbent filler shall be arranged and neatly cut to the required size and shape of the napkin without any wrinkles and distortion. The absorbent material is deposited onto a pre-glued cover in such a way that it does not cause lump formation with the effect of	To incorporate the manufacturing process of manufacturing tab and tab-less napkins. Also to include scope for innovation to eliminate glue in the future.	**6. Manufacture, Workmanship and Finish** The wood Pulp or other absorbent filler shall be arranged and neatly cut to the required size and shape of the napkin without any wrinkles and distortion. The absorbent material is deposited onto a pre-glued /	The manufacturing process of Sanitary Napkins is undergoing changes and new technologies are being adapted. We may add a note at the end of the paragraph to mention that the "Manufacturing process (mentioned above) may vary among different structure, types and	1) **Sanitary Napkin tab-less**  2) **Sanitary Napkin with tab**

sudden pressure. The covering fabric should cover the filler completely and shall extend beyond the width for wing formation or beyond the length of the filler to form tabs or loops at each end. The absorbent along with the cover is then fed to the embossing unit, if any pattern is required to be embossed. Finally, a pre-glued barrier is applied on the other side of absorbent filler, forming a complete napkin structure. A napkin is then sealed using heat and pressure along the periphery or alternatively, it can be stitched or glued, depending upon the type of material used. In case of tab-less napkins, an adhesive system or other suitable methods may be introduced for holding the napkins securely in position. The barrier is applied with adhesive with release paper to fix the napkin to the undergarment, for the tab-less napkins.		***without glue*** cover in such a way that it does not cause lump formation with the effect of sudden pressure. The covering fabric should cover the filler completely and shall extend beyond the width ***for wing formation of the filler*** or beyond the length of the filler to form tabs or loops at each end. The absorbent along with the cover is then fed to the embossing unit, if any pattern is required to be embossed. Finally, a pre-glued barrier is applied on the other side of absorbent filler, forming a complete napkin structure. A napkin is then sealed using heat and pressure ***or other methods*** along the periphery or alternatively, it can be stitched or glued, depending upon the type of material used. In case of tab-less napkins, an adhesive system or other suitable	shape of the napkins." This way we keep future scope for innovation.	 **3) Napkin without wings** 

		methods may be introduced for holding the napkins securely in position. The barrier ***or cover*** is applied with adhesive with release paper to fix the napkin to the undergarment, for the tab-less napkins.		
1 – Scope		Need to include the word Panty Liner		
5 - Sizes Size of Panty liners		Total length of panty liner Regular - Upto 165mm in length Large – 166mm and above		
7.2 – Ability to withstand pressure after absorption		Panty liner shall absorb 3 ml of colored distilled water		

Notes :

Maternity pads also can be included, however some of the current Sanitary Napkins available for normal use are also being used for maternity purpose. The absorption capacity should be increased to 50ml instead of 30ml for Sanitary Napkins. However a study is required before recommending the fluid quantity.

c) Smt. Monika Sathe, Kenvue, Mumbai

IS 5405 : 2019, Sanitary Napkins — Specification (Second Revision) covers the requirements for disposable (non-reusable) sanitary napkins for external use and has been brought under mandatory BIS certification through Quality Control Order issued by Ministry of Textiles, Govt of India.
Based on the below feedback in trailing mail and through further review of comments from the panel, if the current standard is revised to include panty liners, the timeline for implementation of the requirements and certification for this new product i.e., panty liners would take longer time due to :

1. Addition of a new product type-Panty liners needs detailed evaluation of requirements, testing needs and lab infrastructure for meeting BIS expectations.
2. Assessment of raw materials : Raw materials used in panty liner products need to be evaluated through suppliers and their awareness, technical discussions and implementation would take time.

3. BIS compliance at manufacturing sites : These products are manufactured within India and also imported, hence review of current controls and changes required in processes/documentation to meet BIS compliance.
4. Awareness and training : Since such products are also imported, the understanding of BIS requirements and inspection readiness for certification of these sites outside India needs various preparedness activities-e.g., training, testing capabilities, resources, etc.

Thus, with the above rationale and the time and effort for the BIS compliance, we recommend that the standard requirements for the panty liner products shall not be made effective earlier than Dec 2025.

Kindly let us know for additional information or further technical discussion on the comments and we will be glad to share the same.

Ms. Monika Sathe and Ms. Roocha Khedkar, R&D, JNTL Consumer Health (India) Pvt. Ltd.

DOCUMENT NO: IS 5405:2019 Sanitary Napkins – Specification, Second revision.

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)**
Specification title Sanitary Napkins	Include Panty Liners	Sanitary Napkins including Panty Liners	**N/A**	**N/A**
Foreword Sanitary napkin is an absorbent material used to absorb fluid discharged during menstruation. As compared to cloth and other materials (husks, ashes, etc.) used during menstruation, it provides better hygiene and protection against leakage	Add use of Panty liner	Panty Liner is an absorbent material used to absorb small quantity of fluid discharged from vagina, like daily vaginal discharge, menstrual fluid, or urinary incontinence.	**N/A**	**N/A**

Section I SCOPE This standard covers the requirements for disposable (non-reusable) sanitary napkins for external use	Include panty liner in scope	This standard covers the requirements for disposable (non-reusable) absorbent hygiene products like sanitary napkins, Panty Liners for external use.	**N/A**	**N/A**
Section 3 **Materials** All types of sanitary napkins basically consist of three major components:	**N/A**	All kinds of Sanitary pad and Panty Liner consist of three major components**.**	**N/A**	**N/A**
Section 3.2 Absorbent Core An absorbent core forming the middle layer(s) shall consist of filler materials, such as cellulose pulp, cellulose wadding, tissue, cotton, wood pulp, other absorbent and super absorbent materials or combination of these materials, etc. It shall be free from lumps, oil spots, dirt or foreign material	The standards allow to use of cotton as absorbent core. Considering that material from natural source is permissible to use the clarification of foreign matter is practical.	Section 3.2 Absorbent Core An absorbent core forming the middle layer(s) shall consist of filler materials, such as cellulose pulp, cellulose wadding, tissue, cotton, wood pulp, other absorbent and super absorbent materials or combination of these materials, etc. It shall be free from lumps, oil spots, dirt or foreign material **(un-intended foreign matter that can cause injury or discomfort)**		

Section 3.3 Barrier or Bottom Sheet The barrier shall be made of suitable leak proof material so that it meets the requirement specified in 7.2	**N/A**	The barrier shall be made of suitable leak proof material of films or non-woven material so that it meets the requirement of ability to withstand pressure.	**N/A**	**N/A**
Section 4.1 The sanitary napkin shall be of following types: a) thick napkins; and b) thin napkins	**N/A**	Include c) Panty Liners	**N/A**	**N/A**
Section 5 **SIZES** Size of sanitary napkins shall be as agreed to between the purchaser and the supplier. Sizes of sanitary napkins shall be variable depending on the absorbent capacity, purchaser's needs and wing features	Include information related to Panty Liner	Size of Panty Liner should be as agreed to between the purchaser and the supplier. Sizes of Panty Liner should be variable depending on the absorbent capacity and purchaser's needs.	N/A	N/A
Section 6 MANUFACTURE, WORKMANSHIP AND FINISH	N/A	Refer attachment 3 for manufacturing process	**N/A**	**N/A**
Section 6.2 of MANUFACTURE, WORKMANSHIP AND FINISH The sanitary napkins shall have a soft feel and when worn shall not chafe or give any uncomfortable	The standards allow to use of cotton as absorbent core. Considering that material from natural source is	The sanitary napkins shall have a soft feel and when worn shall not chafe or give any uncomfortable feeling. They shall be free from all sorts of foreign		

feeling. They shall be free from all sorts of foreign matter	permissible to use the clarification of foreign matter is practical.	matter **(un-intended foreign matter that can cause injury or discomfort)**		
Section 7.1 pH Value Amendment 4 '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: 2022/ISO 3071: 2020	Applicable for Panty liner	'The pH of product shall be from 3.5 to 7.5 when tested by the method given in IS 1390: 2022/ISO 3071: 2020	**N/A**	**N/A**
Section 7.2 Ability to Withstand Pressure after Absorption	Include same method with modification to suit Panty liner	The Panty Liner shall absorb **5 ml of coloured distilled water** and it shall not show leakage at the bottom or sides of the Panty liner when tested according to method given in Annex (B) **Include in Annexure B** Lay the Panty Liner on a flat level transparent surface, so that underside of panty liner can be observed. Drip at the rate of 1 ml per minute, 5 ml of coloured distilled water maintained at temperature of 27°C ± 2°C on to the centre of the liner from a height of 1-2 mm.	Suitable to absorb a sudden gush or low menstrual flow	Patient education: Vaginal discharge in adult women (Beyond the Basics) - UpToDate Estimation of menstrual blood loss volume based on menstrual diary and laboratory data Ulrike Schumacher1,2*, Jens Schumacher3 , Uwe Mellinger4 , Christoph Gerlinger4 , Andreas Wienke5 and Jan Endrikat

		After the liner has absorbed full amount of coloured distilled water, keep a standard weight of 1 kg for 1 min on the portion where coloured distilled water was absorbed. Observe the bottom and sides of sanitary napkin for any leak through. Test sample passes if liquid does not leak through and fails if liquid leak through.		
Section 7.3 Hygiene Testing Requirement **7.3.1.1**Test method	N/A	Refer attachment 4	N/A	**N/A**
Section 8.2 Number of Tests and Criteria for Conformity **8.2.4**		8.2.1 and 8.2.1.1 Refer attachment 2 The manufacturer shall perform the hygiene testing for the final product every six months for monitoring purpose and whenever there is a change in the raw material, manufacturing premises, and the supplier of the raw material.		
Section 7.4 Biocompatibility Evaluation Cytotoxicity, Irritation and Skin Sensitization	No change	N/A	N/A	**N/A**

Amendment 1 & 2				
Section 7.5 Biodegradability (Optional)	No change	N/A	N/A	**N/A**

Section 8.1 **8.1 Lot** All the sanitary napkin of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot. **8.1.1** Each lot shall be tested separately for ascertaining the conformity of the lot. **8.1.2** The number of sanitary napkin to be selected from the 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.	N/A	Refer Attachment 2 for suggestions for sampling plan	N/A	**N/A**
Section 8.2 Number of Tests and Criteria for Conformity 8.2.1, 8.2.2, 8.2.3,	N/A	Refer Attachment 2	N/A	**N/A**

IS 5405: 2019, Sanitary Napkins — Specification (Second Revision) covers the requirements for disposable (non-reusable) sanitary napkins for external use and has been brought under mandatory BIS certification through Quality Control Order issued by Ministry of Textiles, Govt of India.
If the current standard is revised to include panty liners, the timeline for implementation of the requirements and certification for this new product i.e., panty liners would take longer time due to:

1. **Addition of a new product type-Panty liners needs detailed evaluation of requirements; testing needs and lab infrastructure for meeting BIS expectations.**
2. **Assessment of raw materials: Raw materials used in panty liner products need to be evaluated through suppliers and their awareness, technical discussions and implementation would take time.**

3. **BIS compliance at manufacturing sites: These products are manufactured within India and imported, hence review of current controls and changes required in processes/documentation to meet BIS compliance.**
4. **Awareness and training: Since such products are also imported, the understanding of BIS requirements and inspection readiness for certification of these sites outside India needs various preparedness activities-e.g., training, testing capabilities, resources, etc.**

Thus, with the above rationale and the time and effort for the BIS compliance, we recommend that the standard requirements for the panty liner products shall not be made effective earlier than Dec 2025.

Attachment 1

EVALUATION OF MARKETED SAMPLES

Proposed Method for Ability to Withstand Pressure

Lay the Panty Liner on a flat level transparent surface, so that underside of panty liner can be observed. Drip at the rate of 1 ml per minute, 5 ml of coloured distilled water maintained at temperature of 27°C ± 2°C on to the centre of the liner from a height of 1-2 mm. After the liner has absorbed full amount of coloured distilled water, keep a standard weight of 1 kg for 1 min on the portion where coloured distilled water was absorbed. Observe the bottom and sides of sanitary napkin for any leak through. Test sample passes if liquid does not leak through and fails if liquid leak through.

Observation: Marketed samples tested complied with the proposed method.

Carefree Super Dry (mfg:09/2023)	**Whisper daily Liners (mfg:09/2023)**	**Sofy Antibacterial Panty liner (mfg:27/08/2023)**	**Sofy panty liner cool (mfg:11/08/2021)**	**Sofy daily fresh panty liner (mfg:09/11/2023)**	**Sirona daily wear panty liner (mfg:12/2023)**	**Pee safe Panty liners (mfg:Oct 2023)**	**Plush Panty liner (mfg: 17/12/2023)**	**Carefree 20 gsm SMMS barrier**	**Sirona 100% OC panty liners(S) (01/12/2022)**
Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies

pH tested as per IS 1390: 2022/ISO 3071: 2020

Carefree Super Dry (mfg:09/2023)	**Whisper daily Liners (mfg:09/2023)**	**Sofy Antibacteria Panty liner (mfg:27/08/2023)**	**Sofy panty liner cool (mfg:11/08/2021)**	**Sofy daily fresh panty liner (mfg:09/11/2023)**	**Sirona daily wear panty liner (mfg:12/2023)**	**Pee safe Panty liners (mfg:Oct 2023)**	**Plush Panty liner (mfg: 17/12/2023)**	**Sirona 100% OC panty liners(S) (01/12/2022)**

5.3	6.0	4.8	4.9	5.0	5.4	5.5	6.4	6.3

Dimensions

Whisper daily liners						
	Product Dimension		Absorbent core Dimension		Transfer Layer Dimension	
Sr. No.	length (mm)	Width (mm)	length (mm)	Width (mm)	length (mm)	Width (mm)
Average	150.4	48.8	120	30	138.8	35

Sofy Daily Fresh Panty Liner				
	Product Dimension		Absorbent core Dimension	
Sr. No.	length (mm)	Width (mm)	length (mm)	Width (mm)
Average	155	55	138	45

Sofy Antibacteria Panty liner				
	Product Dimension		Absorbent core Dimension	
Sr. No.	length (mm)	Width (mm)	length (mm)	Width (mm)
Average	155	55	139	45

Sofy pantyliner cool freshness				
	Product Dimension		Absorbent core Dimension	
Sr. No.	length (mm)	Width (mm)	length (mm)	Width (mm)
Average	155.2	55.4	140	45

Sirona Daily wear Panty Liners				
	Product Dimension		Absorbent core Dimension	
Sr. No.	length (mm)	Width (mm)	length (mm)	Width (mm)
Average	185	50	184	50

Pee safe Panty Liners(infused with aloe vera)				
	Product Dimension		Absorbent core Dimension	
Sr. No.	length (mm)	Width (mm)	length (mm)	Width (mm)
Average	184.2	51.2	184.2	51

Plush Panty liners				
	Product Dimension		Absorbent core Dimension	
Sr. No.	length (mm)	Width (mm)	length (mm)	Width (mm)
Average	150	51	150	53

Carefree Super Dry

	Product Dimension		Absorbent core Dimension	
Sr. No.	length (mm)	Width (mm)	length (mm)	Width (mm)
Average	157	55	141	40

Conclusion on Sizes:

Recommended Size	**Recommended Absorbent core length**	**Recommended Absorbent core width**
Small	**≤ 135 mm**	**min 30 mm**
Regular	**136-179**	
Large	**≥ 180 mm**	

Note : The sizes serve as recommendations, Sizes of Panty Liner can be variable depending on the absorbent capacity and purchaser's needs

Attachment 2

- For any new product or any change in existing product, first lot can be tested
- The recommended Quality Assurance plan in Product manual can be referred.
- Any product failing in one or more of the requirements defined in Quality Assurance plan shall be termed as defective. The lot shall be considered as conforming to the Quality Assurance plan, if the total number of defectives found in the sample is less than or equal to the acceptance number given in Quality Assurance plan. Otherwise, the lot shall be rejected

Recommended No of samples to be selected

Lot size	Non-destructive testing		Destructive testing	
	No of napkins to be selected	Acceptance number	No of napkins to be selected	Acceptance number
Upto 280	13	1	3	0
281-500	13	1	3	0
501- 1200	20	1	3	0
1201-3200	32	2	3	0
3201-10000	32	2	3	0
10001-35000	50	3	3	0
35001-150000	80	5	3	0
150001-500000	80	5	3	0
500000 and above	125	7	3	0

- For production at steady rate (Regular production), the testing shall be performed once in six months.

Attachment 3

6.1

Recommended manufacturing process is as below -

The absorbent core shall be arranged and neatly cut to the required size and shape of the product without any wrinkles and distortion. The absorbent core is deposited on a cover in such a way that it does not form lump during usage.

Depending on the product design, the absorbent core shall be over wrapped neatly in the covering fabric then cut / crimped to the required size and shape of the product.

The covering fabric should cover the filler completely and shall extend beyond the length of the absorbent core to form tabs or loops at each end, in case of product with tabs. The absorbent core along with the cover is then fed to the embossing unit, if any pattern is required to be embossed. Finally, a pre-glued / non glued (if other advanced process is used) barrier is applied on to other side of absorbent core, forming a complete product structure. The product is then sealed using, heat/ pressure/glue /stitched or other advanced process, along the periphery, depending upon the type of material used. In case of tab-less product, an adhesive system or other suitable method may be introduced for holding the product securely in position during usage. The barrier may carry the adhesive to fix the product to the undergarment, for the tab-less product.

Attachment 4
7.3.1.1 *Test method*

A sample of 5 gm from the centre portion of the product shall be checked for its absorbency in eluent such as 0.85 percent sodium chloride or equivalent medium till it reaches saturation limit. Add eluent either ten times the absorbent quantity of the product or the quantity in which the product completely immerse. The product shall be shaken vigorously in the eluent and the liquid shall be extracted from it. Report the quantity of the eluent used for extraction, time and frequency of shaking in the test report. The extract shall be serially diluted and plated out on respective mediums, that is, plate count agar (PCA) or equivalent for bacterial bioburden and Sabouraud Chloramphenicol agar (SCA) or equivalent for fungal bioburden. Incubate PCA plates at 30-35°C for 72 h, and report the results.. Similarly incubate SCA plates at 20-25°C for 7 days. Report the results. The typical colony characteristics are shown in Fig. 1. in section 7.3.2.1 Test method of IS:5405:2019 (second revision)

Whether dioxin and furan chemical substances traces are found/relevant in disposable sanitary pad? What could be the possible requirement and test method?

Dioxins are highly toxic and can cause reproductive and developmental problems, damage the immune system, interfere with hormones, and cause cancer.

As per WHO, more than 90% of human exposure is through food, mainly meat and dairy products, fish and shellfish. Many national authorities have programmes in place to monitor the food supply.

All people have background exposure to dioxins, which is not expected to affect human health. However, due to the highly toxic potential, efforts are needed to reduce current background exposure. Prevention or reduction of human exposure is best done via source-directed measures, i.e. strict control of industrial processes to reduce formation of dioxins. (https://www.who.int/news-room/fact-sheets/detail/dioxins-and-their-effects-on-human-health

Dioxins and furans are not made for any specific purpose; however, they are created when products like herbicides are made. They are also created in the pulp and paper industry, from a process that bleaches the wood pulp. In addition, they can be produced when products are burned.

Sanitary napkins consist mainly of following components –

- Top layer
- Absorbent core
- Bottom layer
- Adhesives
- Release paper.
- Pouch
- Fragrance

These components are obtained from either petrochemical, Synthetic or natural origin.
The components like Topsheet, Bottom layer, Adhesive, Pouch and Fragrance majorly come from petrochemical and Synthetic source do not involve any bleaching process.

The absorbent core and Release paper come from pulp and paper Industry.

The Absorbent core majorly consist of wood pulp obtained from softwood tree indigenous to northern and southern America. All the wood based cellulose pulp, except the dissolving grades, manufactured by pulp supplier is bleached using an elemental chlorine free (ECF) process.

There are three main types of bleaching techniques used by the paper industry.
Elemental Chlorine Free (ECF) is a technique that uses chlorine dioxide for bleaching wood fibre, replacin g elemental chlorine gas.
Totally Chlorine Free (TCF) is a technique that uses oxygenbased bleaching chemicals, such as oxygen and hydrogen peroxide, replacing all chlorine containing bleaching chemicals.

Process Chlorine Free (PCF) is a technique used for the brightening and bleaching of recycled fibre, replacing all chlorine containing compounds with oxygenbased bleaching chemicals.
In the 1980's, an association was made between the use of elemental chlorinebased bleaching and the presence of dioxins, most notably 2,3,7,8tetrachlorodibenzop-dioxin (TCDD). As a result, the paper industry eliminated the use of elemental chlorine bleaching and began using ECF, and to a much lesser extent TCF, technologies. The replac ementof elemental chlorine with ECF or TCF reduced the formation of environmentally significant chlorinated or ganic compounds, including 2,3,7,8TCDD and 2,3,7,8TCDF, to nondetectable levels.
Both ECFandTCF technologies comply with US effluent discharge guidelines and have similar low environmental impacts ascompared to the use of elemental chlorine bleaching (water quality, chlorinated dio xins, chlorinated furans, AOX; andthe ability to run partially closed water systems and recycle alkaline filtrates). Additionally, ECF has higher wood yields than TCF.
TCF would raise the cost of products that are supplied to manufacturers of sanitary napkins at an equivalent pulp brightness, while not providing additional environmental or wood yield benefits.
The wood pulp supplier who manufactures and supply cellulose wood pulp as absorbent core for manufacturing of Sanitary pad ensure have controls to monitor and ensure the compliance to US effluent discharge guidelines. The Dioxin and Furans if tested in Sanitary pad shall be found within safe exposure limits and therefore not relevant to be tested. This is supported basis a risk assessment study of dioxins in sanitary napkins produced in Japan was performed. The daily estimated exposure volume to dioxins was compared with the tolerable daily intake (TDI). The concentrations of dioxins such as polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and dioxin-like polychlorinated biphenyls (DL-PCBs) in seven sanitary napkins were measured using gas chromatography and mass spectroscopy analytical methods. Among the seven napkins, a range of 0.0044–0.076 pg TEQ/g dioxins was measured. Daily estimated exposure volume from sanitary napkins was calculated and estimated to be 0.000024–0.00042 pg TEQ/kg/d. For hazard assessment, 0.7 pg TEQ/kg/d was used which was the lowest level of TDI among TDI values reported by international agencies.

Tolerable daily intake (TDI) of dioxins reported by various assessment agencies.

Agency (): evaluation year	Endpoints	Body burden (ng/kg/d)	Equivalent human intake (pg TEQ/kg/d)	Uncertainty factor	TDI (pg TEQ/kg/d)
WHO (1988)	Decreased sperms in rats	28–73	14	10	1–4
	Immune suppression in rats		25		
	Increased genital information in female rats		37		
	Neurobehavioral effects in monkey		21		
JECFA (2001)	Decreased sperm production in rats	28–42	426–620	9.6	2.3[a]
	Decreased ano-genital distance in male rats	16–22	237–330	3.2	
EC SCF (2001)	Decreased sperm production in rats	20	20	9.6	2[b]
U.K. COT (2001)	Decreased sperm production in rats	33	43	9.6	2
JMHLW/JMOE (1999)	Decreased sperms in rats	86	43.6	10	4
	Immune suppression in rats				
	Increased genital information in rats				
U.S. EPA (2012)	Decreased sperm count and motility in men exposed to TCDD as boys epidemiologic cohort study	–	20	30	0.7[c]
	Increased TSH in neonates, epidemiologic cohort study				

EC SCF = European Commission Scientific Committee on Food.
JECFA = The Joint FAO–WHO Expert Committee on Food Additives.
JMHLW/JMOE = Japan Ministry of Health, Labour and Welfare/Japan Ministry of the Environment.
U.K. COT = United Kingdom Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment.
WHO = WHO European Centre for Environment and Health International Programme on Chemical Safety.
U.S. EPA = United States Environmental Protection Agency.
[a] 70 pg TEQ/kg/month.
[b] 14 pg TEQ/kg/week.
[c] Reference dose (RfD).

When the daily exposure volume was compared with the TDI, the former was approximately 1666–29,166 times less than the latter. This fact indicated that the risk of exposure to dioxins from sanitary napkins produced in Japan was negligible.

Ref: Risk assessment study of dioxins in sanitary napkins produced in Japan; Satoko Ishii, Ritsuko Katagiri, Toshiyuki Kataoka, Mitsuhiro Wada, Shigeo Imai, Kanji Yamasaki; Regulatory Toxicology and Pharmacology 70 (2014) 357–362.

Test Method and requirements –
The test requirement of Dioxins and Furans can be included for materials that are bleached using process other than ECF and TCF bleaching process**.** The product need not be tested if sanitary napkin is manufactured in hygienic condition as mentioned in ANNEXC (Clause 7.3.3) of IS:5405:2019 and if no bleaching is happening during manufacturing of the product.
As per Codex, they have referenced Dioxins and furans to Reference value adapted from Regulation EC 1259/2011 on contaminants in foodstuff. Aside to that, we have German regulation on chemicals.
https://www.gesetze-im-internet.de/chemverbotsv_2017/BJNR009410017.html

d) **Dr. Sadhana Srivastava, Scientist G, ICMR, New Delhi**

Referring to the mail below, my comments on the stakeholder aspect is as follows:

1. IS 5405:2019 primarily focuses on sanitary napkins. As per my knowledge, it does not cover disposable pantyliners and maternity pads. For pantyliners and maternity pads, additional specifications need to be defined like different sizes/dimensions, absorbency levels, and performance requirements.
2. The practical feasibility of manufacturing of completely flushable sanitary napkins is currently limited due to material constraints and environmental considerations. However we have made some patent search to understand the technical intervention for 100 % flushable sanitary napkins and observed that the scaling up of this technology is required to it more confusable for marketeable product. However some market products like "Cresa - Hot water soluble sanitary napkins" are available in market.
3. It is possible that the traces of Dioxins and Furans are present due to the bleaching process during the manufacturing practices. It is established fact that dioxin and furan exposures are linked to cancer, reproductive harm, and hormone disruption therefore their relevance, permissible limits and method of detection must be clearly defined.

e) Shri Prashant Jadhav, Procter & Gamble, India

We are glad to share our comments in the table below –

Sr. No.	**BIS Enquiry**	**P&G Response**
i	Technical inputs on size/dimension, variety, performance requirement and test method for disposable pantyliner and maternity pad for inclusion in IS 5405	Procter & Gamble is happy to provide inputs, comments on standards however we consider the need to create new standard for the Panty Liners & Maternity Pads due to different design, usage scenarios & performance aspects. If BIS still considers to include these products in the IS 5405 we request more time to study, accommodate with respect to the existing standard. **1. Period Panty/Maternity Pants**

		Design aspects are different to the conventional sanitary napkin. P&G is of opinion NOT TO include Period Panty in the existing Sanitary napkin standard. In case the BIS feels the need to standardize period panty P&G is ok to collaborate with BIS & Industry to develop new standard for the period panty. P&G would like to have more clarity on terminology (Period Panty Vs Maternity pad as intended use is different). Pls note that Maternity Pads are Period Panty are different products as maternity pads are used for the post-partum conditions. **2. Panty Liners** Panty Liners are not the menstrual product. They are intended for the daily usage (to manage non-menstrual vaginal discharge). Due to the different usage scenario, liners are smaller than menstrual pads and typically have less fluid absorption capacity (starting from 1 ml). Thereby we suggest separate new standards to be developed for Period Panties/Maternity Pads and Panty Liners.
ii	Requirement/value and test method for 100 % flushable sanitary napkin and/or 100 % biodegradable sanitary napkin. Please share the specific test method in the separate annexure.	No comments from P&G
iii	Requirement/value and test method for dioxin and furan chemical substances traces are found/relevant in disposable sanitary pad. Please share the specific test method in the separate annexure	a. We do not consider Dioxins and Furans to be of relevance to include them in IS 5405: b. In the manufacturing of AHPs, certain raw materials like cotton, cellulose pulp, and viscose undergo a bleaching process. In the past, elemental chlorine gas was used, but it has been phased out in favor of more environmentally friendly practices. The industry standards now adopts the Elemental Chlorine-Free (ECF) bleaching method, which significantly reduces the presence of Dioxin/Furan. It's also important to note that the bleaching process is not carried out on the finished products themselves. c. Trace amounts of Dioxin/Furan that may be present in AHPs are typically due to the ubiquitous nature of these compounds in the environment. Therefore, we suggest not to include this test parameter in the standard.

iv	Requirement for volatile organic compounds for disposable sanitary pad.	a. We don't see the need to include VOCs in the standard because this does not bring additional safety benefit for menstrual pads. We consider harmful levels of VOCs are already forbidden in the standard by the comprehensive safety requirement that 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. In P&G, we ensure this requirement is met through the Exposure Based Risk assessment. b. VOCs can be added intentionally to the product as part of the perfume RM. For this case, IFRA standard guides on acceptable values. (If BIS has specific VOCs that they are concerned about, we can do a deeper analysis and provide specific feedback). Therefore, we suggest not to include this test parameter in the standard.
v	Any other comments/queries on implementation of the standard	**IS 5405 Amendment 3:** Remove "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". **Justification:** The current wording is not clear, because the Phthalate limit in IS 5405 is defined for the final product but the testing requirements is on raw material stage as well. a. The Phthalate limit in IS 5405 is defined for the final product, thus the testing needs to be done on the final product. It is not possible to test at raw material stage because there is no limit given per raw material. b. Scope of IS 5405 is the final product. Thus, for consistency of the target group of this standard, it makes sense to test the final product c. Harmonization with IS 17509 for Disposable Baby Diapers is suggested.

Sr. No.	**Topic (Inputs requested by BIS)**	**P&G Position**
1	Whether disposable pantyliner and maternity pad are covered in IS 5405 or not. If not, what are the different requirements/variety other than given in IS 5405 :2019. Please share inputs on additional size/dimension, variety, performance requirement and test method.	**1. Period Panty/Maternity Pants** Design aspects are different to the conventional sanitary napkin. P&G is of opinion NOT TO include Period Panty in the existing Sanitary napkin standard. In case the BIS feels the need to standardize period panty P&G is ok to collaborate with BIS & Industry to develop new standard for the period panty. P&G would like to have more clarity on terminology (Period Panty Vs Maternity pad as intended use is different).

		2. Panty Liners Panty Liners are not the menstrual product. They are intended for the daily usage (to manage non-menstrual vaginal discharge). Due to the different usage scenario, liners are smaller than menstrual pads and typically have less fluid absorption capacity (starting from 1 ml).
2	Is it possible in practical to manufacturer 100 % flushable sanitary napkin and/or 100 % biodegradable sanitary napkin. Whether we need to include these additional requirements in the existing standard. What could be the procedure, requirement, and test method.	P&G is of opinion to deliberate this topic in the committee & move forward accordingly.
3	Whether dioxin and furan chemical substances traces are found/relevant in disposable sanitary pad. What could be the possible requirement and test method.	• Dioxins and Furan chemical substances are not found (or below detection limits) and not relevant in disposable sanitary napkins • The identification of Chemical impurities should be based on the type of raw materials & their origin. • Random inclusion of such impurities is unscientific. In the manufacturing of AHPs, certain raw materials like cotton, cellulose pulp, and viscose undergo a bleaching process. In the past, elemental chlorine gas was used, but it has been phased out in favour of more environmentally friendly practices. The industry standards now adopts the Elemental Chlorine-Free (ECF) bleaching method, which significantly reduces the presence of Dioxin/Furan. It's also important to note that the bleaching process is not carried out on the finished products themselves. *Trace amounts of Dioxin/Furan that may be present in AHPs are typically due to the ubiquitous nature of these compounds in the environment.*

f) Ms Paridhi, Soothe Healthcare,

Technical inputs on size/dimension, variety, performance requirement and test method for disposable pantyliner and maternity pad for inclusion in IS 5405.

Disposable Panty liners dimension are as follows:

- Small: 150mm longer, 60mm wider (Front) 50mm wider(Center) 60mm wider(Back)
- Large: 185mm longer, 65mm wider (Front) 50mm wider(Center) 65mm wider(Back)

Tolerance - (+/-2mm)

ii) Requirement/value and test method for 100 % flushable sanitary napkin and/or 100 % biodegradable sanitary napkin. Please share the specific test method in the separate annexure.

100 % biodegradable sanitary napkin manufacturing is possible if we use plant-based glue and replace silicon coating with wax coating. (Subjected to trial and development)

As of now there is no specific method available for internal lab tests, therefore we can follow the same sanitary napkin test method IS 5405:2021 for biodegradable sanitary napkins

iii) Requirement/value and test method for dioxin and furan chemical substances traces are found/relevant in disposable sanitary pad. Please share the specific test method in the separate annexure.

Need to send product for testing for verification of dioxin and furan.

Widely Used method for verification: GC-MS – gas chromatography-mass spectrometry.

iv) Requirement for volatile organic compounds for disposable sanitary pad.

iv) Any other comments/queries on implementation of the standard.

Whether disposable pantyliner and maternity pad are covered in IS 5405 or not. If not, what are the different requirements/variety other than given in IS 5405 :2019. Please share inputs on additional size/dimension, variety, performance requirement and test method.

ANS: Pantyliner and maternity pad are not covered in IS 5405.

Is it possible in practical to manufacturer 100 % flushable sanitary napkin and/or 100 % biodegradable sanitary napkin. Whether we need to include these additional requirements in the existing standard. What could be the procedure, requirement, and test method.

ANS: Yes 100 % biodegradable sanitary napkin manufacturing is possible if we use plant-based glue and replace silicon coating with wax coating. (Subjected to trial and development)

Whether dioxin and furan chemical substances traces are found/relevant in disposable sanitary pad. What could be the possible requirement and test method.

ANS: Need to send product for testing for verification of dioxin and furan.

Widely Used method for verification: GC-MS – gas chromatography-mass spectrometry

g) Shri Rohit Srivastava, Unicharm India Comments

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)

4.1 Thickness type: Thin type **4.2 Wing/No wing, Tab/No Tab: No wing, No Tab** **5.Size Length 155±10 ㎜** **7.1 pH(6-8)** **7.2 Coloured water amount: 30ml⇒7.5ml**	**The absorbent size of panty liners is smaller than that of napkins, so if you apply the same amount of BIS method, there is a concern that all of it will leak out.**	**7.2 We conducted a leakage test of the Panty Liner using our own products. There is a concern that all products will definitely leak if the product is 30ml, so we would like you to change it to around 7.5ml.**		

h) Shri Mithun A. Shah, Anabio Technologies

1) Whether disposable pantyliner and maternity pad are covered in IS 5405 or not. If not, what are the different requirements/variety other than given in IS 5405 :2019. Please share inputs on additional size/dimension, variety, performance requirement and test method.

Response:
Pantyliners, primarily used for daily discharge and light spotting, and maternity pads, designed for postnatal use to manage heavier bleeding after childbirth, can sometimes fall under the broader category of sanitary napkins due to their similar usage in maintaining hygiene.
In the IS 5405:2019 standard, which specifies requirements for disposable (non-reusable) sanitary napkins, the scope and materials sections clearly state that the standard covers products consisting of three major components:
Cover or top sheet: The layer in contact with the skin.
Absorbent core: The middle layer responsible for absorbing and retaining fluid.
Barrier or bottom sheet: The layer that prevents fluid from leaking out of the napkin.
Given this definition, any sanitary product incorporating these three components would be covered within the scope of IS 5405:2019. The size/dimension, performance requirement and test method for pantyliner (primarily used for daily discharge and light spotting) and maternity pads (designed for postnatal use to manage heavier bleeding after childbirth) has to be specified separately.

2) Is it possible in practical to manufacturer 100 % flushable sanitary napkin and/or 100 % biodegradable sanitary napkin. Whether we need to include these additional requirements in the existing standard. What could be the procedure, requirement, and test method.

Response:
Flushable Sanitary Napkins:
Yes, it is possible and practical to manufacture flushable sanitary napkins.
Biodegradable Sanitary Napkins:
Yes, it is possible and practical to manufacture flushable sanitary napkins.
It is more feasible to produce 90% biodegradable sanitary napkins using materials such as organic cotton, bamboo, or other plant-based fibers for the absorbent core, and biodegradable films for the barrier layers.

To include requirements for flushable and biodegradable sanitary napkins in existing standards, an amendment or new section in the standard (IS 5405) would be necessary. This would involve defining criteria for biodegradability and flushability, as well as specifying appropriate test methods (reference methods listed below).

Requirements:
Biodegradability: The product must decompose naturally into non-toxic components within a specified period under standard composting conditions.
Flushability: Flushability refers to the ability of an item or substance to be safely and effectively disposed of by flushing it down a toilet. The product must disintegrate completely in water and not cause blockages in sewage systems.

Test Methods:
For Biodegradability:
ISO 14855-1:2012: Determination of the ultimate aerobic biodegradability of plastic materials under controlled composting conditions.
ASTM D6400: Standard specification for labeling of plastics designed to be aerobically composted in municipal or industrial facilities.
ISO 17088:2008: Specifications for compostable plastics, which can be adapted for other biodegradable materials.
For Flushability:
INDA/EDANA Flushability Guidelines (followed in US & Europe): Testing for toilet and drainline clearance, disintegration, and biodegradation.
UK Water Industry (followed in UK): Testing for toilet and drainline clearance, disintegration, snagging, settling and biodegradation by chemical & biological methods.

These methods have been designed for flushable wipes and need to be reviewed and modified to suit sanitary napkins.
Flushability Standard Specifications
CONTENTS

Introduction and Background

Sewer systems are designed to handle "lavatory contents," "water used for cooking or washing," and surface runoff. However, a common issue in these systems is the blockage of pipelines and pumps, which can lead to service disruptions, sewer flooding, and environmental pollution. Addressing these blockages is often costly and complex.

A primary cause of these blockages is the flushing of non-flushable items, such as conventional sanitary pads, and other non-flushable products into the sewer system. Although these items may seem to flush easily from the toilet bowl, they can create significant problems once inside the wastewater infrastructure.

To determine whether a product is truly flushable, it must undergo evaluation according to criteria that consider the entire journey through the toilet system, the subsequent sewer system, and the wastewater treatment process. The criteria outlined in this standard have been developed to assess the flushability of sanitary napkins and pantiliners. Products that meet these criteria are expected to avoid causing blockages or other issues within the sewer system.

The disposal of harmful substances into public sewers or drains is prohibited. This includes materials that could damage sewer infrastructure, obstruct the flow of sewage, or negatively impact wastewater treatment processes.

Additionally, hazardous substances, and materials that create nuisances, or pose risks to public health are not permitted.

The purpose of this standard is to establish criteria for the safe disposal of flushable sanitary napkins, ensuring that these items do not contribute to blockages or environmental harm. The criteria mentioned in this document are explained from a conceptual angle, as the quantifiable pass/fail criteria are still under development and require extensive data generation. These criteria will be updated in the next revision.

1. SCOPE

This specification outlines the test methods to determine whether a product is suitable for disposal through a toilet into a drain or sewer system. It is developed for flushable sanitary napkins and pantiliners, whether the product is capable of flushing.

2. DEFINITIONS

For this specification, the following definitions apply:

2.1 **Flushable Product** – Any product designed and manufactured for disposal via the sewer system.

2.2 **Drainline** – A small diameter pipe (100mm) connecting a domestic property to the public sewer system.

2.3 **Snag** – Engagement of a product on a protrusion or rough pipe joint.

2.4 **'Stranded'** – Temporary settlement of material on the pipe invert.

2.5 **Wastewater Treatment Plants (WTP)** – Domestic sewage treatment plant in the apartment, for the town and city.

3. REQUIREMENTS

3.1 **General**

The product is evaluated against seven requirements, including one general criterion (Safety in the Environment) and six physical tests. These tests ensure the product does not negatively impact sewer or treatment systems. The tests include:

a) Toilet bowl clearance.

b) Drainline clearance.

c) Disintegration in the drainline.

d) Continued disintegration in the sewer.

e) Settlement in treatment processes.

f) Determination of synthetic and non-synthetic organic components.

3.2 **Safety in the Environment**

Manufacturers must ensure that their products comply with legislation regarding disposal through the sewer system, avoiding substances restricted due to environmental regulations.

3.3 **Toilet Bowl Clearance**

Toilet bowl clearance is the first stage of evaluation where test specimens are flushed into the toilet to observe whether they clear the bowl and to determine how many flushes are required for them to do so. The test specimens must pass through the toilet's water trap (U-bend) without causing any surcharging or overflow. Additionally, they should not require any maintenance to clear potential blockages.

3.4 **Drainline Clearance**

Following the toilet bowl clearance test, the drainline test is conducted to determine whether the test specimens can pass through the drainline without causing any issues. The specimens must travel through the drainline without settling, snagging, or causing blockages. They should not require additional maintenance to clear any potential obstructions caused by the specimens.

3.5 **Disintegration in the Drainline**
This test is crucial for assessing the performance in the drainline, where the test specimens must disintegrate adequately to prevent blockages. The specimens should break down sufficiently to minimize the risk of clogging the drain pipes.
3.6 **Disintegration in the Sewer System**
In the sewer line, further disintegration of the test specimens is necessary to ensure they break down into smaller pieces, preventing issues or blockages at any points in the sewer system, such as bends or joints. The specimens should continue to disintegrate effectively, avoiding obstruction of screens, plumbing valves, or any part of the sewer line.
3.7 **Settlement**
Upon entering the wastewater treatment plant, the material passes through screening and primary clarifiers, where most large suspended particles are removed. The majority of the disintegration by-products from the test specimens must settle during the primary treatment stage, ensuring they do not interfere with the secondary treatment process.
3.8 **Determination of Synthetic and Non-Synthetic Organic Components**
The content disposed of in the sewer system should contain a minimal amount of synthetic materials. The test specimens must have a minimal percentage of synthetic organic components to ensure the treatment system can handle them effectively. The majority of the test specimens should consist of organic or biodegradable materials.
4. **REFERENCES:**
INDA/EDANA Guidelines for Assessing the Flushability of Disposable Nonwoven Products (GD4)
Guidelines outlining tests and criteria for determining the flushability of nonwoven disposable products.
Water Industry Specification (WIS) 4-02-06: Fine to Flush
Specification detailing criteria and tests for products to be labeled as safe to flush by the UK Water Industry.
International Water Services Flushability Group (IWSFG) Specifications for Flushable Products
Global standards define tests and requirements for products to ensure they are safe for flushing and wastewater systems.
UK Building Regulations
Building Regulations Approved Document H: Drainage and Waste Disposal (2015 edition)
European Standards
EN 752: Drain and sewer systems outside buildings.
French Standard
NF U44-164: Organic Soil Improvers and Growing Media - Analytical Method for Inert Components - Bleach Washing Method
5. **APPENDICES:**

- Appendix A: Toilet Bowl Clearance Test Procedure
- Appendix B: Drainline Clearance Test Procedure
- Appendix C: Disintegration in the Drainline Test Procedure
- Appendix D: Disintegration in the Sewer System Test Procedure
- Appendix E: Settling Test Procedure
- Appendix F: Determination of Synthetic and Non-Synthetic Organic Components

Appendix A - Toilet Bowl Clearance Test

The purpose of this test is to confirm that flushable products, including flushable sanitary napkins and pantiliners, can pass through the toilet's water trap (U-bend) without causing the water level to rise to the rim or result in an overflow.

A.1 Apparatus

A 4.5-liter flush toilet connected to a water supply and discharge pipe. The 4.5-liter flush volume is representative of commonly used units.

This test may be conducted in conjunction with the Drainline Clearance Test, with the toilet connected to a drainline as specified in Appendix B.

A.2 Safe Practices

The procedure shall use tap water. Each testing laboratory is responsible for establishing and following its safety practices, including the use of appropriate personal protective equipment.

A.3 Test Procedure

1. Confirm that the flush volume is 4.5 liters (±0.2 liters).
2. Flush the toilet to clear any debris.
3. Place the sample(s), including flushable sanitary napkins, in the toilet bowl, flush once, and record whether:
    a) The entire sample(s) cleared the toilet bowl and entered the drain downstream of the water trap (U-bend).
    b) The water level in the toilet reached the rim at any time.
4. If the product does not clear the bowl and U-bend (i.e., the product is not visible in the drainline), wait for the cistern to refill and repeat step 3.
5. Once the entire sample has entered the drain, record the total number of flushes used.

Appendix B - Drainline Clearance Test

The Drainline Clearance Test ensures that flushable sanitary napkins and pantiliners can pass through household drainlines without causing blockages. This test may be conducted in conjunction with the Toilet Bowl Clearance Test (see Appendix A).

B.1 Apparatus

1) A 4.5-litre flush toilet connected to a water supply, discharging into the drainline of the test rig.
2) The test rig features clear plastic pipes with a 100 mm nominal internal diameter, connected with sleeve joints, set at a gradient of 1:80, with a minimum length of 10m from the point of toilet discharge to the end of the drainline.

B.2 Safe Practices:

The procedure uses tap water. Each testing laboratory must establish and follow safe practices, including the use of appropriate personal protection equipment.

B.3 Test Procedure

1. Confirm the toilet flush volume is 4.5 litres.
2. Flush the toilet to clear the drainline and bowl of any debris.
3. For the initial flush:
    a) Place the sample(s) in the toilet bowl and flush once. Record whether the sample(s) enter the drainline and the distance traveled.
    b) If the sample(s) do not enter the drainline, wait for the cistern to refill and repeat the flush.
4. After the sample has entered the drainline, record the distance traveled from the toilet connection.
5. Wait a few minutes to allow water to drain behind the product. Subsequent flushes, using only water (4.5 litres per flush), are conducted at few-minute intervals.
6. Record the distance traveled by test specimens for each flush.

Appendix C - Disintegration in the Drainline Test:

The purpose of this test is to verify that flushable sanitary napkins and pantiliners disintegrate sufficiently to avoid clogging the drainline. Products must start disintegrating to prevent forming blockages when they encounter obstacles or imperfections in the drainline.

C.1 Apparatus

- An orbital shake table with a 25 mm horizontal orbital diameter, adjustable up to 150 rpm, and relevant clamps for securing conical flasks.
- Baffled shake flasks with a 2-litre/3-litre nominal capacity.
- A dark-colored shallow tray.
- A drying oven set to 105°C.
- Crucibles.
- A desiccator.
- An analytical balance.

C.2 Safe Practices:

Use tap water for the test. Laboratories must establish and adhere to their safety practices, including personal protection equipment.

C.3 Test Procedure

Disintegration Test:

1. Weigh the test samples with an analytical balance to the nearest 0.01 g.
2. Add 1 litre of tap water to a baffled shake flask.
3. Secure the flask on the orbital shaker with clamps.
4. Add a single test specimen to the flask, scrunching it to simulate use.
5. Repeat for five flasks.
6. Set the shaker to 100 rpm.
7. After 3 hours, stop the shaker.
8. Pour the contents of each flask into a dark-colored shallow tray, ensuring a water depth of 15-20 mm. Gently disentangle the broken-up product without further breaking it.
9. Transfer the contents onto a sieve submerged in water with the sieve's sides at least 10 mm out of the water. Avoid overfilling the sieve.
10. Spread the contents across the sieve without further breaking them.
11. Agitate the sieve submerged in the water to remove the disintegrated pieces attached to the other disintegrated pieces or with the surface of the sieve.
12. Observe the disintegration, measure the largest fragments, and photograph them.
13. Collect the retained material, dry it in an oven at 105°C for 12 hours, and cool it in a desiccator.
14. Weigh the dried material to the nearest 0.01 g.
15. Determine the proportion of product mass that passed through the sieve using the following formula:

Percentage Disintegrated=(Mass Passed through Sieve / Initial Mass of Sample)×100

Appendix D – Disintegration in the Sewer System Test

This test ensures that a product continues to disintegrate adequately in the sewer system, beyond the requirements of the Drainline Disintegration Test, to prevent blockages at sewer systems.

D.1 Apparatus:

Use apparatus as described in Appendix C: C.1, except the sieve, which should be a 5.6 mm perforated plate sieve.

D.2 Safe Practices:

Conduct the test using tap water. Laboratories must develop and implement appropriate safety protocols, including personal protective equipment.

D.3 Test Procedure:

Disintegration Test:

1. Weigh the test samples with an analytical balance to the nearest 0.01 g.
2. Add 1 litre of tap water to a baffled shake flask.
3. Secure the flask on the orbital shaker with clamps.
4. Add a single sample to the flask, scrunching it to simulate use.
5. Repeat for five flasks.
6. Set the orbital shaker to 120 rpm for 6 hours.
7. After 6 hours, stop the shaker.
8. Pour the contents of each flask into a dark-colored shallow tray, ensuring a water depth of 15-20 mm. Gently disentangle the broken-up product without further breaking it.
9. Transfer the content onto the sieve, which should be submerged in water with the sieve's sides at least 10 mm out of the water.
10. Agitate the sieve submerged in the water to remove the disintegrated pieces attached to the other disintegrated pieces or with the surface of the sieve.
11. Document the extent of disintegration with photographs at the end of shaking.
12. Determine the proportion of product mass passing through the sieve using the following formula.

Percentage Disintegrated=(Mass Passed through Sieve / Initial Mass of Sample)×100

Appendix E – SETTLING TEST

The purpose of the test is to confirm that the disintegration by-products of the test specimens settle out during the primary settlement stage of the sewage treatment process and ensure only minimal percentages are passed on to the secondary treatment, thereby avoiding disruption to the overall sewage treatment process. This is critical for both large and small wastewater treatment works, including domestic treatment facilities such as packaged sewage treatment facilities. The test ensures that any larger semi-intact fragments of the product are removed during the primary settlement stage if there is no inlet screening process.

E.1 Apparatus

1) Settling column: A 2.0 m length of transparent plastic pipe with a 200 mm nominal internal diameter, mounted vertically on a test stand. The column should be equipped with:
    a. A pipe cap (to seal the base) with a drain valve.
    b. A drain valve is fitted halfway up the column.
    c. Markings for the upper timing line (1.60 m above the column base), lower timing line (1.20 m below the upper timing line), and flotation line (300 mm above the column base).
2) Stopwatch or other suitable timing device.

E.2 Safe Practices

Conduct the procedure using tap water. Each testing laboratory must develop and implement its safe practices, including appropriate personal protective equipment.

E.3 Test Procedure

1. Close all column valves and ensure the column is connected to a suitable drain or collection vessel.
2. Fill the column with tap water to at least 100 mm above the upper timing line.
3. Fill the column to minimize aeration of the water and maximize the release of entrained air.
4. Allow time for bubbles to dissipate.
5. Pour a single 1-liter sample into the center of the column.
6. Start timing when the first fragment or fiber reaches the upper timing line.
7. Stop timing when the last fragment or fiber passes the bottom timing line.
8. Record the travel time between the timing lines.
9. Repeat steps 5-8 for all ten samples.
10. After testing all samples, leave the column undisturbed for 24 hours.
11. Inspect the column to record if any samples have risen above the flotation line.
12. Check the samples whether they refloat within 24 hours, if yes, then tap the column to release trapped air, and wait 1 hour.
13. Record if there are any changes in the specimen's behavior.

Appendix F – DETERMINATION OF SYNTHETIC AND NON-SYNTHETIC ORGANIC COMPONENTS

The purpose of this test is to evaluate the percentage of synthetic organic materials in the product, which is primarily composed of non-synthetic organic matter. This is essential for ensuring that disposable products are not introducing significant amounts of synthetic polymers into the waste stream.

F.1 Apparatus and Reagents

1) **Apparatus:**
   a) 2-liter beaker
   b) 0.5 mm stainless steel sieve
2) **Reagents:**
   a) 14/15% solution of bleach (NaClO)
   b) Tap water

F.2 Safe Practices

The method involves the use of a 15% active bleach solution (NaClO), which is corrosive. The dissolution process may produce low levels of chlorine gas. Therefore, the test must be conducted in a fume cupboard. Laboratories should develop and implement their safety procedures, including the use of appropriate personal protective equipment.

F.3 Test Procedure

1. Place the product in a 2-liter beaker.
2. In a fume cupboard, cover the sample with 1000 ml of 14/15% bleach solution. Ensure all of the samples are soaked.

Note: *The reaction may be exothermic and produce chlorine fumes.*

3. Allow the sample to react for 48 hours, stirring at the beginning and end of the test period.
4. After 48 hours, pour the contents of the beaker onto a sieve.
5. Rinse the sample by carefully pouring 2 liters of tap water over the sieve.
6. Collect the retained particles in the sieve, dry them in an oven, and measure the weight.

For BIS Use Only

BUREAU OF INDIAN STANDARDS

MINUTES

Panel meeting – Revision/Amendment of IS 5405 Sanitary Napkin

Date	**Time**	**Venue**
09 August 2024 (Friday)	**1100 h**	**Video Conference through CISCO Webex**

CONVENOR: Smt. Shradha Dongre, SASMIRA, Mumbai

Member Secretary, TXD 36: Shri Dharmbeer, Scientist D, Textiles, BIS New Delhi

ATTENDEES:

1) Smt. Shradha Dongre, SASMIRA, Mumbai (**Convenor**)
2) Shri D. Veerasubramaniam, SITRA, Coimbatore
3) Shri Nirav Mehta, M/s Dima Products Mumbai (Representing Indian Technical Textile Association/ Feminine and Infant Hygiene Association, Mumbai)
4) Ms. Roocha Khedkar/Smt. Monika Sathe, Kenvue Mumbai
5) Ms. Shivani Swamy, Livinguard Technology Pvt. Ltd., Mumbai
6) Smt. Tanya Mahajan, The Pad Products (NGO), India
7) Shri Sashank Singh, Soothe Healthcare, Noida
8) Ms. Dipti Sharma, Unicharm India, Gurugram
9) Shri Mithun Shah, Anabia Technologies, Bengaluru
10) Shri Dharmbeer, Member Secretary, TXD 36

Item 0 WELCOME AND INTRODUCTORY REMARKS

Smt. Shradha Dongre, SASMIRA, Mumbai (Convenor) extended a hearty welcome to the members of panel. She emphasized for active participation from the members and requested for the precise inputs so as to arrive at consensus.

Member secretary has also welcomed the Convenor and all other members.

Item 1 COMMENTS ON PUBLISHED STANDARDS

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

The panel members were requested to provide the inputs on the following aspects: -

i) Ambiguity in the existing clause of IS 5405 : 2019 for better understanding and/or implementation of the standard.
ii) Technical inputs on size/dimension, variety, performance requirement and test method for disposable pantyliner and maternity pad for inclusion in IS 5405.
iii) Requirement/value and test method for 100 % flushable sanitary napkin and/or 100 % biodegradable sanitary napkin.
iv) Requirement/value and test method for dioxin and furan chemical substances traces are found/relevant in disposable sanitary pad.
v) Requirement for volatile organic compounds for disposable sanitary pad.
vi) Any other comments/queries on implementation of the standard.

The panel considered the technical inputs/comments received from SITRA, Dima Products, Kenvue, P &G, ICMR, Soothe Healthcare, Unicharm India and Anabio Technologies as given in **Annex 1** of the agenda and thereon.

After deliberations, the panel recommended the following changes may be incorporated during amendment/revision in IS 5405: -

i) The panel suggested that disposable panty liners and maternity napkins are not covered in IS 5405 and should be included in the existing standard. The requirement for disposable panty line and maternity pad are similar as given in IS 5405 except difference in design, size and absorbency level.
ii) The title of the standard shall be updated as 'IS 5405 : 2019 Disposable Pantyliner/Sanitary Napkins/Maternity Pad/Period Panty.'
iii) The scope of the standard shall be modified as 'This standard covers the requirements for disposable (non-reusable) pantyliner/sanitary napkins/maternity pad/period panty for external use.
iv) The term 'sanitary napkin' shall be updated as 'pantyliner/sanitary napkins/maternity pad/period panty' in the existing standard.
v) The term 'napkin' shall be updated as 'pantyliner/sanitary napkins/maternity pad/period panty' in the existing standard.
vi) The following note shall be included under clause 3 :-

(*Page* 1, *clause* **3**) **—** Insert the following note at the end:

'NOTE — The requirements given in **3.1** to **3.3** are for guidance of the manufacturer. The material and design may vary between different types and sizes of the pantyliner/sanitary napkins/maternity pad/period panty or as per the agreement between buyer and seller.

vii) The following information shall be included after clause 4.1 :-

c) Pantyliner

d) Maternity pad

e) Period panty

viii) The following note shall be included under clause 4 :-

(*Page* 1, *clause* **4**) **—** Insert the following new note at the end:

'NOTE — The requirements given in **4.1** to **4.2** are for guidance of the manufacturer. The type and shape may vary between different design of the pantyliner/sanitary napkins/maternity pad/period panty or as per the agreement between buyer and seller.

ix) Clause 5 Sizes, (*Page* 1, *clause* **5**) **—** Substitute the following for the existing:

Size of pantyliner/sanitary napkins/maternity pad/period panty shall be as agreed to between the purchaser and the supplier. Sizes of pantyliner/sanitary napkins/maternity pad/period panty shall be variable depending on the absorbent capacity, purchaser's needs and wing features. The recommended sizes are classified as follows in table 1:

Table 1 Size of Pantyliner/Sanitary Napkin/Maternity Pad/Period Panty
(for reference and guidance only)

(*Clause* 5)

Sl No	**Name of product**	**Size**	**Pad length (mm) (absorbent core only)**	**Pad width (mm) (Absorbent core only)**
i)	Pantyliner	Small	≤ 135	*Min* 30
		Regular	136 to 179	
		Large	≥ 180	
ii)	Sanitary napkin	Regular	≤ 210	*Min* 55
		Large	211 to 240	
		Extra - large	241 to 280	
		XXL	≥ 281	
iii)	Maternity pad	-	≥ 281	*Min* 80
iv)	Period panty	-	230 to 300	80 to 140

x) The following note shall be included under clause 6 manufacture, workmanship and finish:-

(*Page* 2, *clause* **6**) **—** Insert the following note at the end:

'NOTE — The requirements given in **6.1** are for guidance of the manufacturer. The manufacture, workmanship and finish may vary between different design, types and sizes of the pantyliner/sanitary napkins/maternity pad/period panty or as per the agreement between buyer and seller. The manufacture should use chlorine free wood pulp in the absorbent core.

xi) Clause 6.2 (*Page* 2, *clause* **5**) **—** Substitute the following for the existing:-

The pantyliner/sanitary napkins/maternity pad/period panty shall have a soft feel and when worn shall not chafe or give any uncomfortable feeling when observed visually. They shall be free from all sorts of foreign matter (unintended foreign matter that can cause injury or discomfort).'

xii) The following note shall be included under clause 7.1 :-

(*Page* 2, *clause* **7.1**) **—** Insert the following new note at the end:

'NOTE — If the required weight of the test specimen in not sufficient in one sample, then more no. of samples of the same lot may be taken for testing of the product .

xiii) Clause 7.2 (*Page* 2, *clause* **7.2**) **—** Substitute the following for the existing:-

'7.2 Ability to Withstand Pressure after Absorption

The pantyliner/sanitary napkins/maternity pad/period panty shall absorb coloured distilled water as given in table 2 and it shall not show leakage at the bottom or sides of the sanitary napkin, when tested according to method given in Annex B.'

Table 2 Ability to Withstand Pressure after Absorption for Pantyliner/Sanitary Napkins/Maternity Pad/Period Panty

(*Clause* 7.2, Annex B)

Sl No	Name of product	Liquid Absorption (ml), Min
i)	Pantyliner	1
ii)	Sanitary napkin	30
iii)	Maternity pad	50
iv)	Period panty	30

xiv) The following note shall be included under clause 7.3 :-

(*Page* 2, *clause* **7.3.2.1**) **—** Insert the following new note at the end:

'NOTE — If the required weight of the test specimen under clause 7.3.1.1 and 7.3.2.1 is not sufficient in one sample, then more no. of samples of the same lot may be taken for preparation of test specimen.'

xv) (Page 2, *clause* **7.3.1,** *fourth line*) **—** Substitute 'IS/ISO 11737-1' for 'ISO 11737 (Part 1).'

xvi) (Page 5, Annex A) **—** Substitute 'IS/ISO 11737-1 : 2018' for 'ISO 11737-1 : 2018.'

xvii) (Page 3, Clause 8) **—** Substitute 'Table 3' for 'Table 1.'

xviii) The following note shall be included under clause 7.3 :-

(*Page* 2, *clause* **7.3.2.1**) **—** Insert the following new note at the end:

'NOTE — If the required weight of the test specimen under clause 7.3.1.1 and 7.3.2.1 is not sufficient in one sample, then more no. of samples of the same lot may be taken for preparation of test specimen.'

xix) The following note shall be included under clause 8, Table 1 :-

(*Page* 3, *clause* **8.1.2**) **—** Insert the following new note at the end:

'NOTE — The sampling plan given in table is for guidance of manufacturer/user. The other sampling plan may also be followed if agreed between buyer and seller.

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

'g) The absorption capacity after pressure (ml)

xxi) (*Page* 5, Annex B, *clause* **B-1,** *second sentence*) **—** Substitute the following for the existing:-

'Drip at the rate of 1 ml (pantyliner)/5 ml (other product) per min, coloured distilled water as given in table 2 maintained at temperature of 27°C ± 2°C on to the centre of the product from a height of 1-2 mm.'

xxii) The panel requested Smt. Roocha Khedkar/Smt. Monika Sathe to share the requirement (limit) for volatile organic compound test and Dixon/furan based on their inhouse data/International practice.

xxiii) The panel requested **Shri D. Veerasubramanian** and **Smt. Sharadha Dongre, SASMIRA** to share the information based on sample tested in last 3-6 months for ability to withstand pressure after absorption for pantyliner, maternity pad and period panty.

xxiv) The panel requested Smt. Tanya Mahajan to co-ordinate with stakeholders for inputs on test based on blood coagulation which may be considered as an alternative method for absorbency test within 30 days.

xxv) The panel requested Shri Shri Mithun Shah, Anabia Technologies, Bengaluru to share the requirement and test method for 100 % biodegradable sanitary napkin within 30 days and 100 % flushable sanitary napkin within 3 months.

xxvi) The panel requested member secretary to co-ordinate with other manufacturers for their inputs on size, design, absorbency level for of pantyliner, maternity pad, period panty.

xxvii) The panel requested member secretary to prepare the draft amendment/revision of IS 5405 : 2019 based on above changes within 07 days. BIS may carry out editorial changes in the draft amendment/standard.

xxviii) The panel recommended that the draft amendment/revision may be circulated to concerned stakeholders for their comments/feedback.

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

For BIS Use Only

BUREAU OF INDIAN STANDARDS

AGENDA

Panel meeting – Revision/Amendment of IS 5405 Sanitary Napkin

Date	Time	Venue
05 September 2024 (Thursday)	1100 h	Video Conference through CISCO Webex

CONVENOR: Smt. Shradha Dongre, SASMIRA, Mumbai

MEMBER SECRETARY, TXD 36 : Shri Dharmbeer, Scientist D, Textiles, BIS New Delhi

Item 0 WELCOME AND INTRODUCTORY REMARKS

Item 1 COMMENTS ON PUBLISHED STANDARDS

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

In the last meeting of TXD 36, the committee decided to constitute a panel of the following members to discuss the comments received on IS 5405 and provide its recommendation for amendment and/or revision of standard within 30 days: -

9) Ms. Shradha Dongre, SASMIRA, Mumbai (**Convenor**)
10) Dr. Sadhana Srivastava, ICMR New Delhi
11) Dr. E. Santhini, SITRA, Coimbatore
12) Shri Nirav Mehta/Smt. Roocha Khedkar, Representing Indian Technical Textile Association/ Feminine and Infant Hygiene Association, Mumbai
13) Smt. Tanya Mahajan, The Pad Products (NGO), India
14) Shri Mithun Shah, Anabia Technologies, Bengaluru
15) 2-3 expert's subject experts/Doctors
16) Member Secretary, TXD 36

The first panel meeting was convened on 09 August 2024 through virtual mode. The recommendation/minutes of the first panel meeting is given at **Annex 1 (Pages 3-8).**

Based on the recommendation of the panel, the draft revision of IS 5405 was prepared and circulated vide our email dated 26 August 2024 for the comments of the members/stakeholders for 07 days. The last date of comments was 02 September 2024.
The draft revision of IS 5405 is given at **Annex 2 (Pages 9-21).**
The comments received from ICMR, BIS Chennai Branch Office, TZMO Group, Dima Products, P &G, MHAI, Kenvue, FIHA, Nine Hygiene and Shekhani Industries on Draft revision of IS 5405 and request for extension of QCO are given at **Annex 3 (Pages 22-66).**
1.1.1 The Panel may **DELIBERATE** and **DECIDE.**

ANNEX 1
(Item *1.1*)
THE RECOMMENDATION/MINUTES OF THE FIRST PANEL MEETING held on 09 AUGUST 2024
For BIS Use Only

BUREAU OF INDIAN STANDARDS

MINUTES
Panel meeting – Revision/Amendment of IS 5405 Sanitary Napkin

Date	Time	Venue
09 August 2024 (Friday)	1100 h	Video Conference through CISCO Webex

CONVENOR: Smt. Shradha Dongre, SASMIRA, Mumbai
Member Secretary, TXD 36: Shri Dharmbeer, Scientist D, Textiles, BIS New Delhi
ATTENDEES:

11) Smt. Shradha Dongre, SASMIRA, Mumbai (Convenor)
12) Shri D. Veerasubramaniam, SITRA, Coimbatore
13) Shri Nirav Mehta, M/s Dima Products Mumbai (Representing Indian Technical Textile Association/ Feminine and Infant Hygiene Association, Mumbai)
14) Ms. Roocha Khedkar/Smt. Monika Sathe, Kenvue Mumbai
15) Ms. Shivani Swamy, Livinguard Technology Pvt. Ltd., Mumbai
16) Smt. Tanya Mahajan, The Pad Products (NGO), India
17) Shri Sashank Singh, Soothe Healthcare, Noida
18) Ms. Dipti Sharma, Unicharm India, Gurugram
19) Shri Mithun Shah, Anabia Technologies, Bengaluru
20) Shri Dharmbeer, Member Secretary, TXD 36

Item 0 WELCOME AND INTRODUCTORY REMARKS

Smt. Shradha Dongre, SASMIRA, Mumbai (Convenor) extended a hearty welcome to the members of panel. She emphasized for active participation from the members and requested for the precise inputs so as to arrive at consensus.

Member secretary has also welcomed the Convenor and all other members.

Item 1 COMMENTS ON PUBLISHED STANDARDS

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

The panel members were requested to provide the inputs on the following aspects: -

vii) Ambiguity in the existing clause of IS 5405 : 2019 for better understanding and/or implementation of the standard.

viii) Technical inputs on size/dimension, variety, performance requirement and test method for disposable pantyliner and maternity pad for inclusion in IS 5405.

ix) Requirement/value and test method for 100 % flushable sanitary napkin and/or 100 % biodegradable sanitary napkin.

x) Requirement/value and test method for dioxin and furan chemical substances traces are found/relevant in disposable sanitary pad.

xi) Requirement for volatile organic compounds for disposable sanitary pad.

xii) Any other comments/queries on implementation of the standard.

The panel considered the technical inputs/comments received from SITRA, Dima Products, Kenvue, P &G, ICMR, Soothe Healthcare, Unicharm India and Anabio Technologies as given in Annex 1 of the agenda and thereon.

After deliberations, the panel recommended the following changes may be incorporated during amendment/revision in IS 5405: -

xxix) The panel suggested that disposable panty liners and maternity napkins are not covered in IS 5405 and should be included in the existing standard. The requirement for disposable panty line and maternity pad are similar as given in IS 5405 except difference in design, size and absorbency level.

xxx) The title of the standard shall be updated as 'IS 5405 : 2019 Disposable Pantyliner/Sanitary Napkins/Maternity Pad/Period Panty.'

xxxi) The scope of the standard shall be modified as 'This standard covers the requirements for disposable (non-reusable) pantyliner/sanitary napkins/maternity pad/period panty for external use.

xxxii) The term 'sanitary napkin' shall be updated as 'pantyliner/sanitary napkins/maternity pad/period panty' in the existing standard.

xxxiii) The term 'napkin' shall be updated as 'pantyliner/sanitary napkins/maternity pad/period panty' in the existing standard.

xxxiv) The following note shall be included under clause 3 :-

(*Page* 1, *clause* 3) — Insert the following note at the end:

'NOTE — The requirements given in 3.1 to 3.3 are for guidance of the manufacturer. The material and design may vary between different types and sizes of the pantyliner/sanitary napkins/maternity pad/period panty or as per the agreement between buyer and seller.

xxxv) The following information shall be included after clause 4.1 :-

c) Pantyliner

d) Maternity pad

e) Period panty

xxxvi) The following note shall be included under clause 4 :-
(*Page* 1, *clause* 4) — Insert the following new note at the end:
'NOTE — The requirements given in 4.1 to 4.2 are for guidance of the manufacturer. The type and shape may vary between different design of the pantyliner/sanitary napkins/maternity pad/period panty or as per the agreement between buyer and seller.

xxxvii) Clause 5 Sizes, (*Page* 1, *clause* 5) — Substitute the following for the existing:

Size of pantyliner/sanitary napkins/maternity pad/period panty shall be as agreed to between the purchaser and the supplier. Sizes of pantyliner/sanitary napkins/maternity pad/period panty shall be variable depending on the absorbent capacity, purchaser's needs and wing features. The recommended sizes are classified as follows in table 1:

Table 1 Size of Pantyliner/Sanitary Napkin/Maternity Pad/Period Panty
(for reference and guidance only)

(*Clause* 5)

Sl No	Name of product	Size	Pad length (mm) (absorbent core only)	Pad width (mm) (Absorbent core only)
i)	Pantyliner	Small	≤ 135	*Min* 30
		Regular	136 to 179	
		Large	≥ 180	
ii)	Sanitary napkin	Regular	≤ 210	*Min* 55
		Large	211 to 240	
		Extra - large	241 to 280	
		XXL	≥ 281	
iii)	Maternity pad	-	≥ 281	*Min* 80
iv)	Period panty	-	230 to 300	80 to 140

xxxviii) The following note shall be included under clause 6 manufacture, workmanship and finish:-
(*Page* 2, *clause* 6) — Insert the following note at the end:
'NOTE — The requirements given in 6.1 are for guidance of the manufacturer. The manufacture, workmanship and finish may vary between different design, types and sizes of the pantyliner/sanitary napkins/maternity pad/period panty or as per the agreement between buyer and seller. The manufacture should use chlorine free wood pulp in the absorbent core.

xxxix) Clause 6.2 (*Page* 2, *clause* 5) — Substitute the following for the existing:-
The pantyliner/sanitary napkins/maternity pad/period panty shall have a soft feel and when worn shall not chafe or give any uncomfortable feeling when observed visually. They shall be free from all sorts of foreign matter (unintended foreign matter that can cause injury or discomfort).'

xl) The following note shall be included under clause 7.1 :-

(*Page* 2, *clause* 7.1) — Insert the following new note at the end:

'NOTE — If the required weight of the test specimen in not sufficient in one sample, then more no. of samples of the same lot may be taken for testing of the product .

xli) Clause 7.2 (*Page* 2, *clause* 7.2) — Substitute the following for the existing:-

'7.2 Ability to Withstand Pressure after Absorption

The pantyliner/sanitary napkins/maternity pad/period panty shall absorb coloured distilled water as given in table 2 and it shall not show leakage at the bottom or sides of the sanitary napkin, when tested according to method given in Annex B.'

Table 2 Ability to Withstand Pressure after Absorption for Pantyliner/Sanitary Napkins/Maternity Pad/Period Panty

(*Clause* 7.2, Annex B)

Sl No	Name of product	Liquid Absorption (ml), Min
i)	Pantyliner	1
ii)	Sanitary napkin	30
iii)	Maternity pad	50
iv)	Period panty	30

xlii) The following note shall be included under clause 7.3 :-

(*Page* 2, *clause* 7.3.2.1) — Insert the following new note at the end:

'NOTE — If the required weight of the test specimen under clause 7.3.1.1 and 7.3.2.1 is not sufficient in one sample, then more no. of samples of the same lot may be taken for preparation of test specimen.'

xliii) (Page 2, *clause* 7.3.1, *fourth line*) — Substitute 'IS/ISO 11737-1' for 'ISO 11737 (Part 1).'

xliv) (Page 5, Annex A) — Substitute 'IS/ISO 11737-1 : 2018' for 'ISO 11737-1 : 2018.'

xlv) (Page 3, Clause 8) — Substitute 'Table 3' for 'Table 1.'

xlvi) The following note shall be included under clause 7.3 :-

(*Page* 2, *clause* 7.3.2.1) — Insert the following new note at the end:

'NOTE — If the required weight of the test specimen under clause 7.3.1.1 and 7.3.2.1 is not sufficient in one sample, then more no. of samples of the same lot may be taken for preparation of test specimen.'

xlvii) The following note shall be included under clause 8, Table 1 :-

(*Page* 3, *clause* 8.1.2) — Insert the following new note at the end:

'NOTE — The sampling plan given in table is for guidance of manufacturer/user. The other sampling plan may also be followed if agreed between buyer and seller.

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

'g) The absorption capacity after pressure (ml)

xlix) (*Page* 5, Annex B, *clause* B-1, *second sentence*) — Substitute the following for the existing:-

'Drip at the rate of 1 ml (pantyliner)/5 ml (other product) per min, coloured distilled water as given in table 2 maintained at temperature of 27°C ± 2°C on to the centre of the product from a height of 1-2 mm.'

l) The panel requested Smt. Roocha Khedkar/Smt. Monika Sathe to share the requirement (limit) for volatile organic compound test and Dixon/furan based on their inhouse data/International practice.

li) The panel requested Shri D. Veerasubramanian and Smt. Sharadha Dongre, SASMIRA to share the information based on sample tested in last 3-6 months for ability to withstand pressure after absorption for pantyliner, maternity pad and period panty.

lii) The panel requested Smt. Tanya Mahajan to co-ordinate with stakeholders for inputs on test based on blood coagulation which may be considered as an alternative method for absorbency test within 30 days.

liii) The panel requested Shri Shri Mithun Shah, Anabia Technologies, Bengaluru to share the requirement and test method for 100 % biodegradable sanitary napkin within 30 days and 100 % flushable sanitary napkin within 3 months.

liv) The panel requested member secretary to co-ordinate with other manufacturers for their inputs on size, design, absorbency level for of pantyliner, maternity pad, period panty.

lv) The panel requested member secretary to prepare the draft amendment/revision of IS 5405 : 2019 based on above changes within 07 days. BIS may carry out editorial changes in the draft amendment/standard.

lvi) The panel recommended that the draft amendment/revision may be circulated to concerned stakeholders for their comments/feedback.

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

ANNEX 2

(Item *1.1*)

For Comments Only

Proposed Draft Revision

IS 5405 : 2024 Disposable Pantyliner/Sanitary Napkins/Maternity Pad/Period Panty

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FOREWORD

(Formal clause will be added later)

Disposable pantyliner/sanitary napkins/maternity pad/period panty is an absorbent hygiene material used to absorb fluid discharged during menstruation. As compared to cloth and other materials (husks, ashes, etc.) used during menstruation, it provides better hygiene and protection against leakage.

This standard was originally published in 1969; and subsequently revised in 1980 and 2019. The third revision has been made to incorporate the following major changes:-

a) All amendments have been incorporated.
b) Title and scope of the standard has been updated.
c) Material and sizes have been modified.
d) Requirement of pantyliner, maternity pad and period panty have been specified.
e) Manufacture, workmanship and finish have been modified.
f) The procedure and requirement of ability to withstand pressure after absorption have been modified.
g) pH and hygiene testing requirement have been updated.
h) Sampling and criteria for conformity has been modified.
i) Marking clause has been modified.
j) References to Indian Standard have been updated.

This standard contains clause **5.1** which calls for an agreement between the purchaser and the supplier regarding dimensions. However, recommended dimensions have been specified.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (second revision)’.The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Draft Indian Standard

DISPOSABLE PANTYLINER/SANITARY NAPKINS/MATERNITY PAD/PERIOD PANTY — SPECIFICATION

(*Third Revision*)

1 SCOPE

This standard covers the requirements for disposable (non-reusable) pantyliner/sanitary napkins/maternity pad/period panty for external use.

2 REFERENCES

The standards given in Annex A contain provisions which, through reference in this text, constitute provisions of this standard. 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.

3 MATERIALS

All types of pantyliner/sanitary napkins/maternity pad/period panty basically consist of three major components:

a) cover or the top sheet;
b) absorbent core, and
c) the barrier or bottom sheet.

3.1 Cover/Top sheet

The cover/top sheet is the material which comes under contact with skin during use. The cover of pantyliner/sanitary napkins/maternity pad/period panty shall be of good quality cotton, rayon knitted sleeve or gauze, non-woven fabric or any other materials with sufficient porosity to permit the assembled product to meet the absorbency requirements. If cotton gauze is used, it shall conform to IS 758.

3.2 Absorbent Core

An absorbent core forming the middle layer(s) shall consist of filler materials, such as cellulose pulp, cellulose wadding, tissue, cotton, wood pulp, other absorbent and super absorbent materials or combination of these materials, etc. It shall be free from lumps, oil spots, dirt or foreign material (unintended foreign matter that can cause injury or discomfort) when examined visually.

3.3 Barrier or Bottom Sheet

The barrier shall be made of suitable leak proof material so that it meets the requirement specified in **7.2**.

‘NOTE — The requirements given in **3.1** to **3.3** are for guidance of the manufacturer. The material and design may vary between different types and sizes of the pantyliner/sanitary napkins/maternity pad/period panty or as per the agreement between buyer and seller.’

4 TYPE AND SHAPES OF PANTYLINER/SANITARY NAPKINS/MATERNITY PAD/PERIOD PANTY

4.1 The pantyliner/sanitary napkins/maternity pad/period panty shall be of following types:

a) Thick napkins
b) Thin napkins
c) Pantyliner
d) Maternity pad; and
e) Period panty

NOTE — The thin napkins contain a compressed sheet of absorbent material in the core, whereas thick napkins are referred as fluff pulp napkins.

4.2 Pantyliner/sanitary napkins/maternity pad/period panty can be of various shapes and design such as wings/no wings, tab/tab-less etc. or as per purchaser's needs.

NOTES —

1) Pantyliner/sanitary napkins/maternity pad/period panty with wings provide better grip on the undergarments so that product remains in its position under dynamic conditions. Some products can also be folded to be carried in a small pouch.
2) The requirements given in **4.1** to **4.2** are for guidance of the manufacturer. The type and shape may vary between different design of the pantyliner/sanitary napkins/maternity pad/period panty or as per the agreement between buyer and seller.

5 SIZES

Size of pantyliner/sanitary napkins/maternity pad/period panty shall be as agreed to between the purchaser and the supplier. Sizes of pantyliner/sanitary napkins/maternity pad/period panty shall be variable depending on the absorbent capacity, purchaser's needs and wing features. The recommended sizes are classified as follows in table 1:

Table 1 Size of Pantyliner/Sanitary Napkin/Maternity Pad/Period Panty
(for reference and guidance only)

(*Clause* 5)

Sl No	**Name of product**	**Size class**	**Pad length (mm) (absorbent core only)**	**Pad width (mm) (absorbent core only)**
i)	Pantyliner	Small	≤ 135	*Min* 30
		Regular	136 to 179	

		Large	≥ 180	
ii)	Sanitary napkin	Regular	≤ 210	*Min* 55
		Large	211 to 240	
		Extra - large	241 to 280	
		XXL	≥ 281	
iii)	Maternity pad	-	≥ 281	*Min* 80
iv)	Period panty	-	230 to 300	80 to 140

6 MANUFACTURE, WORKMANSHIP AND FINISH

6.1 The wood pulp or other absorbent filler shall be arranged and neatly cut to the required size and shape of the pantyliner/sanitary napkins/maternity pad/period panty without any wrinkles and distortion. The absorbent material is deposited on to a pre-glued or without glue cover in such a way that it does not cause lump formation with the effect of sudden pressure. The covering fabric should cover the filler completely and shall extend beyond the width for wing formation or beyond the length of the filler to form tabs or loops at each end. The absorbent along with the cover is then fed to the embossing unit, if any pattern is required to be embossed. Finally, a pre-glued barrier is applied on to other side of absorbent filler, forming a complete pantyliner/sanitary napkins/maternity pad/period panty structure. A pantyliner/sanitary napkins/maternity pad/period panty is then sealed using heat and pressure along the periphery or alternatively, it can be stitched or glued, depending upon the type of material used. In case of tab-less pantyliner/sanitary napkins/maternity pad/period panty, an adhesive system or other suitable method may be introduced for holding the pantyliner/sanitary napkins/maternity pad/period panty securely in position. The barrier is applied with adhesives with release paper to fix the pantyliner/sanitary napkins/maternity pad/period panty to the undergarment, for the tab-less pantyliner/sanitary napkins/maternity pad/period panty.

'NOTE — The requirements given in **6.1** are for guidance of the manufacturer. The manufacture, workmanship and finish may vary between different design, types, and sizes of the pantyliner/sanitary napkins/maternity pad/period panty or as per the agreement between buyer and seller. The manufacture should use chlorine free wood pulp in the absorbent core of the product.'

6.2 The pantyliner/sanitary napkins/maternity pad/period panty shall have a soft feel and when worn shall not chafe or give any uncomfortable feeling when observed visually. They shall be free from all sorts of foreign matter (unintended foreign matter that can cause injury or discomfort).

7 REQUIREMENTS

7.1 *p*H Value

The *p*H of pantyliner/sanitary napkins/maternity pad/period panty (top and absorbent core) shall be from 3.5 to 7.5 when tested by the method given in IS 1390.

'NOTE — If the required weight of the test specimen in not sufficient in one sample, then more no. of samples of the same lot may be taken for testing of the product .

7.2 Ability to Withstand Pressure after Absorption

The pantyliner/sanitary napkins/maternity pad/period panty shall absorb coloured distilled water as given in table 2 and it shall not show leakage at the bottom or sides of the sanitary napkin, when tested according to method given in Annex B.

Table 2 Ability to Withstand Pressure after Absorption for Pantyliner/Sanitary Napkins/Maternity Pad/Period Panty

(*Clause* 7.2, Annex B)

Sl No	**Name of product**	**Liquid Absorption (ml),** *Min*
i)	Pantyliner	1
ii)	Sanitary napkin	30
iii)	Maternity pad	50
iv)	Period panty	30

7.3 Hygiene Testing Requirement

Total viable count (total number of bacteria and fungi) shall not be more than 1 000 cfu/gm and *Staphylococcus aureus* shall be absent.

7.3.1 *Bacterial and Fungal Bioburden*

The pantyliner/sanitary napkins/maternity pad/period panty shall be tested for bacterial and fungal bioburden in accordance with method given in **7.3.1.1**. For selecting sample item portion (SIP), appropriate eluent and methods of extraction; IS/ISO 11737 (Part 1) shall be referred.

7.3.1.1 *Test method*

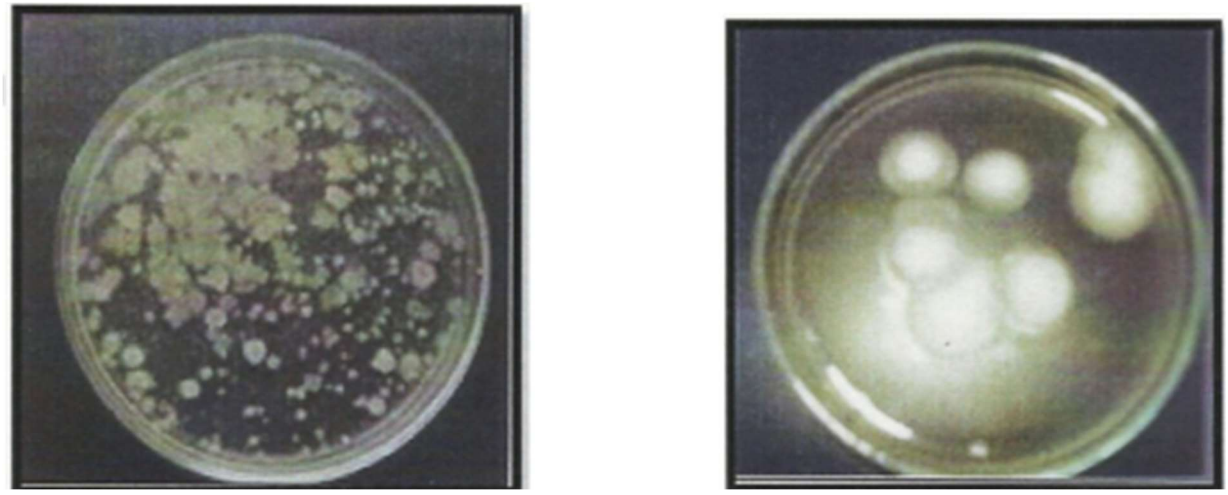
A sample of 5 gm cut from the centre portion of the pantyliner/sanitary napkins/maternity pad/period panty shall be checked for its absorbency in eluent such as 0.85 percent sodium chloride or equivalent medium till it reaches saturation limit. Add eluent either ten times the absorbent quantity of the pantyliner/sanitary napkins/maternity pad/period panty or the quantity in which the pantyliner/sanitary napkins/maternity pad/period panty completely immerse. The pantyliner/sanitary napkins/maternity pad/period panty shall be shaken vigorously in the eluent and the liquid shall be extracted from it. Report the quantity of the eluent used for extraction, time and frequency of shaking in the test report. The extract shall be serially diluted and plated out on respective mediums, that is, plate count agar (PCA) for bacterial bioburden and sabouraud chloramphenicol agar (SCA) for fungal bioburden. Incubate PCA plates at 30-35°C for 24 h and count colonies. Continue incubation upto 72 h, re-examine the plates after 48 h and 72 h, and report the results that have not resulted in overgrowth. Similarly incubate SCA plates at 20-25°C for 3 days and count the fungi. Re-examine after incubation for 5 and 7 days. Report the results from incubation time that does not result in over growth. The typical colony characteristics are shown in Fig. 1.

7.3.2 *Test for Common Skin Pathogen — Staphylococcus Aureus*

The pantyliner/sanitary napkins/maternity pad/period panty shall be tested for the presence of Staphylococcus aureus in accordance with method given in **7.3.2.1.** For the preparation of medium such as cooked salt medium, baird-parker medium and method for coagulase test; IS 5887 (Part 2) shall be referred.

7.3.2.1 *Test method*

A sample of 5 gm cut from the centre portion of the pantyliner/sanitary napkins/maternity pad/period panty shall be completely immersed in appropriate volume of enrichment medium like cooked salt medium or equivalent medium. Incubate for enrichment purpose at 37°C for 24 h. Report the quantity of the medium used for enrichment in the test report. The incubated sample shall be shaken vigorously in the medium and the liquid shall be extracted from the pantyliner/sanitary napkins/maternity pad/period panty. The extract shall be streaked onto a Staphylococcal isolation medium, such as Baird-Parker medium or equivalent and incubated at 37°C for 24-48 h and examine for growth. The result is considered positive if black colonies with a narrow white margin, surrounded by a zone of clearance are seen. Suspect colonies must show coagulase activity to confirm presence of Staphylococcus aureus. The typical colony characteristic is shown in Fig. 2.



(A) **(B)**

Fig. 1 Typical Colony Characteristics of Bacterial Bioburden (A) and Fungal Bioburden (B)

Fig. 2 Typical Colony Characteristics of *Staphylococcus Aureus*

'NOTE — If the required weight of the test specimen under clause 7.3.1.1 and 7.3.2.1 is not sufficient in one sample, then more no. of samples of the same lot may be taken for preparation of test specimen.'

7.3.3 Good Manufacturing Practice Guideline for Hygiene Requirement

The pantyliner/sanitary napkins/maternity pad/period panty shall be manufactured under good hygienic conditions. The general guidelines for good manufacturing practice to maintain hygiene requirement at manufacturing facility are given in Annex C.

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

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. The biocompatibility of the material shall be detected by evaluating cytotoxicity, irritation and skin sensitization test as per IS/ISO 10993 Part 5, IS 17932 (Part 7) and IS 17932 (Part 6) respectively.

For cytotoxicity, the material shall show reactivity as ‘non-cytotoxic’ when tested as per IS/ISO 10995 Part 5.

Similarly, the material shall be ‘Non-irritant and Non-sensitizer’ when tested as per IS 17932 (Part 7) and IS 17932 (Part 6) respectively. For preparation of samples for these tests, IS/ISO 10993 Part 12 shall be referred.

7.5 Compostability or Biodegradability during Composting (Optional)

The manufacturer who are claiming their product as compostable or biodegradable during composting shall pass the test on the final product as per IS/ISO 17088.

7.6 Phthalate Test

The amount of phthalate present in pantyliner/sanitary napkins/maternity pad/period panty 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.

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 Lot

All the pantyliner/sanitary napkins/maternity pad/period panty of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot.

8.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

8.1.2 The number of pantyliner/sanitary napkins/maternity pad/period panty to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, column 3 and column 5 of Table 3.

8.1.3 These pantyliner/sanitary napkins/maternity pad/period panty shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

Table 3 Number of Pantyliner/Sanitary Napkins/Maternity Pad/Period Panty to be Selected

(*Clause* 8.1.2)

Sl No.	Lot Size	Non-Destructive Testing		Destructive Testing	
		No. of Products to be Selected	Acceptance Number	No. of Products to be Selected	Acceptance Number
	N	*n*	*a*	n_1	a_1
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13	1	5	0
ii)	281 - 500	13	1	5	0
iii)	501 - 1 200	20	1	5	0
iv)	1 201 - 3 200	32	2	8	0
v)	3 201 - 10 000	32	2	8	0
vi)	10 001 - 35 000	50	3	8	0
vii)	35 001 - 150 000	80	5	13	0
viii)	150 001 - 500 000	80	5	13	0
ix)	500 001 and over	125	7	13	0

NOTES —

1) For hygiene testing, biocompatibility evaluation, biodegradability and compostability refer clause **8.2.4**, **8.2.5** and **8.2.6** respectively.
2) The sampling plan given in table is for guidance of manufacturer/user. The other sampling plan may also be followed if agreed between buyer and seller.

8.2 Number of Tests and Criteria for Conformity

8.2.1 All pantyliner/sanitary napkins/maternity pad/period panty to be selected as per column 3 of Table 3 shall be examined for workmanship and finish.

8.2.1.1 Any pantyliner/sanitary napkins/maternity pad/period panty 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 3. Otherwise, the lot shall be rejected.

8.2.2 Out of the sample already found satisfactory according to **8.2.1.1**, a sub-sample as per column 5 of Table 3 shall be taken. This sub-sample shall be further tested for the remaining requirements.

8.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective pantyliner/sanitary napkins/maternity pad/period panty found in the sample (*see* **8.2.2**) is less than or equal to the acceptance number as given in column 6 of Table 3.

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.

8.2.5 The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material for manufacturing the product.

8.2.6 The testing for compostability or biodegradability during composting shall be carried out once for existing products and whenever there is a change in the raw material for manufacturing the product.

9 MARKING

9.1 Each pack shall be legibly and indelibly marked with the manufacturer's name or trade mark, size, type and number of pantyliner/sanitary napkins/maternity pad/period panty contained in the pack in addition to the following:

a) Directions of use;
b) Disposability instructions. The manufacturer shall provide the instruction to users for safe disposal of the product as per *Solid Waste Management Rules*, 2016 or any other rules and regulation published from time to time;
c) Batch/Lot no. and date of manufacturing;
d) The absorption capacity after pressure (ml);
e) The information whether the product is compostable or biodegradable during composting (if applicable).
f) 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); and
g) Any other information required by law in force or agreed between the buyer and the seller.

9.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the Bureau of Indian Standards Act, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

10 PACKING

Pantyliner/sanitary napkins/maternity pad/period panty shall be packed in rigid or flexible packages that protect the product from contaminants during shipment and storage. This package could be constructed of materials, such as carton board, polyethylene, polypropylene, polyester or other safe materials that provide sufficient protection to the product. The package should be free of any torn or damaged areas.

ANNEX A

(*Clause* 2)

LIST OF REFERRED STANDRDS

IS No./Other Publication	*Title*
758 : 2023	Specification for cotton gauze, absorbent, non-sterilized (*fourth revision*)
1390 : 2022/ ISO 3071 : 2020	Textiles — Determination of *p*H of aqueous extract (*third revision*)
4905 : 2015	Random sampling and randomization procedures (*first revision*)
5887 (Part 2) : 1976	Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of Staphylococcus aureus and faecal Streptococci (*first revision*)
9873 (Part 6) : 2021/ ISO 8124-6 : 2018	Safety of toys Part 6 Determination of certain phthalate esters in toys and children's products (*first revision*)
17932 (Part 6) : 2023	Biological evaluation of medical devices Part 6 Tests for skin sensitization
17932 (Part 7) : 2024	Biological evaluation of medical devices Part 7 Tests for irritation
IS/ISO 10993-5 : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 10993-12 : 2021	Biological evaluation of medical devices Part 12 Sample preparation and reference materials
IS/ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
IS/ISO 17088 : 2021	Specification for compostable plastics (*second revision*)

ANNEX B

(*Clause* 7.2)

METHOD FOR DETERMINATION OF ABILITY TO WITHSTAND PRESSURE AFTER ABSORPTION

B-1 TEST PROCEDURE

Lay the pantyliner/sanitary napkins/maternity pad/period panty on a flat level transparent surface, so that underside of pantyliner/sanitary napkins/maternity pad/period panty can be observed. Drip at the rate of 1 ml (pantyliner)/5 ml (other product) per min, coloured distilled water as given in table 2 maintained at temperature of 27°C ± 2°C on to the centre of the pantyliner/sanitary napkins/maternity pad/period panty from a height of 1-2 mm. After the pantyliner/sanitary napkins/maternity pad/period panty has absorbed full amount of coloured distilled water, keep a standard weight of 1 kg for 1 min on the portion where coloured distilled water was absorbed. Observe the bottom and sides of pantyliner/sanitary napkins/maternity pad/period panty for any leak through. Test sample passes if liquid does not leak through and fails if liquid leak through.

B-2 Add 0.01 g colour of Bromocresol Purple (Grade – Chemical analytical grade or equivalent) in 1 000 ml of distilled water and stir evenly to get uniform coloured solution.

ANNEX C

(*Clause* 7.3.3)

GOOD MANUFACTURING PRACTICE FOR HYGIENE REQUIREMENT

Maintaining hygiene at production facility is essential for ensuring products are appropriate for consumers use. Following are recommended guidelines for ensuring hygiene at facilities:

a) Location should be free from objectionable odours, smoke, dust and other contaminants.
b) Separate areas shall be demarcated for storing raw materials, production and final product storage.
c) Separate area shall be demarcated for storing personal effects and personal protective equipment of unit workers to minimize risk of contamination.
d) Toilet and hand-washing station shall be positioned away from storage/production area.
e) Provision of 70 percent isopropyl alcohol (IPA) solution for hand sanitization inside the production facility.
f) Appropriate lighting and proper ventilation of the facility shall be ensured.
g) Flooring shall be either concrete, tiled or with chips to ensure ease of cleaning. Floors, walls, ceilings, doors and windows shall be easy to clean and without crevices or openings that shall not allow accumulation of dirt.
h) Regular pest control measures shall be put in place.

j) Adequate receptacles for disposing waste generated within the facility shall be made available and shall be frequently emptied and cleaned.
k) Poster/sign encouraging safety and hygiene practices like use of personal protective equipment, use of hand sanitizer etc. shall be displayed.
m) Pre-packaged finished product shall be checked thoroughly and ensured to be free from foreign particles, dirt, hair, and other visible contaminants.
n) Hand hygiene shall be practised during manufacturing.
p) A cleaning and maintenance schedule shall be drawn up for cleaning of the facility, toilets, washing areas, waste receptacles and for cleaning/disinfection of the equipment

ANNEX 3
(Item *1.1*)
Comments on proposed draft revision *Proposed Draft Revision*
IS 5405 : 2024 Disposable Pantyliner/Sanitary Napkins/Maternity Pad/Period Panty

a) **Dr. Sadhana Srivastava, ICMR New Delhi**

Thanks for sharing the draft for kind comments. The draft seems to be fine.
Thanks & Regards
Dr.Sadhana Srivastava

b) BIS Chennai Branch (Manak Manthan Comments)

i) It is suggested that antibiotic-impregnated, nanoparticle-incorporated sanitary pads be developed to enhance consumer safety. The appropriate requirements for these could be included in the relevant standards.
ii) It is proposed that a separate standard for sanitary napkins with an added herbal layer be developed, considering the growing consumer demand for herbal products.
iii) It is recommended that instead of increasing the number of absorbent layers in sanitary napkins, the standard may specify appropriate raw materials that ensure effective fluid absorbency.**

c) TMZO Group, India

NAME OF THE COMMENTATOR/ORGANIZATION: Tormiskie Zakiady Materialow Opatrunkowych SA
DOCUMENT NO:
Data for products: Bella Mamma Comfort, Bella Control Discreet Pants, Bella Control Pants.

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)**
Size of products (Table 1, Clause 5)	Maternity pads meet requirements	-	-	-
	Period pants don't meet requirements	core length (mm)	430 to 490	according Technical Data Sheets for that products
		core width (mm)	80 to 150	
pH	no data	test according suggest standard ISO 3071:2020 for product with SAP is impossible	-	-
Ability to Withstand Pressure after Absorption	accept	-	-	-
Absorption capacity/Absorption time	accept	ISO 11948-1/NAFC	-	-

Bacterial and Fungal Bioburden	accept	-	-	-
Staphylococcus Aureus	accept	-	-	-
Phthalate Test	products (maternity pads, period pants need to be tested in external laboratory	-	-	-

NAME OF THE COMMENTATOR/ORGANIZATION: Torwriskie Zaklady MaterialOw Opatrunkowych SA
DOCUMENT NO:
Data for products: sanitary pads and pantyliners under Bella brand

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)**
5 SIZES	we recommend changing ranges for sanitary pads and the absorbent core of pantyliners	Pantyliner sizes: small ≤ 134 Regular 135 to 157 Large ≥ 158Pad width (mm) (absorbent core only) min 20		Based on the global offer of TZMO SA for pantyliners
7.2 Ability to Withstand Pressure after Absorption	we propose to adjust the value of fluid volumes	from 30 ml to 25 ml - for sanitary pads, and from 1 ml to 0.5 ml for pads		Based on internal methodology that simulates filling the product at the indicated time, with a specified volume and then subjected to a test under load
7.3.1	We propose to add information	We propose a provision that		Based on the tests made in EU

Bacteria1 and Fungal Bioburden	about the specific methodology	microbiological tests microbiological tests are carried out in accordance with EU Pharmacopea X.		
7.6 Phthalate Test	Changing of the Regulation on the presence of phthalates in hygienic products	Regulation of the presence of phthalates in hygiene products includes, among others, the REACH Directive, while indicating on selected phthalates and their maximum permissible content. In view of needs of the Indian market, we recommend maintaining these provisions and at the same time ordering periodic testing of products and raw materials through the Indian company in laboratories indicated by IS.		the REACH Directive
8.1.3 selection	Changing of sampling	In view of the reference in the draft IS standard to the fact that these standards are created in accordance with ISO standards we recommend the		ISO 2859-1

		introduction of sampling according to other method		
9.1 a)	Removing the description requirement	We recommend not to provide the way of use as description, Alternatively - pictograms		Based on the experience of TZMO as the producer — there is no need of IFU
9.1 d)	change the note about the claimed absorbency under load	We recommend to change the note about A note on the package about the claimed absorbency under load in ml. We recommend removing this provision Alternatively – in form of drops		Based on the experience of TZMO as the producer
9.1 f)	We recommend to change the requirements	Such studies should be available at the separate request of the buyer not as written obligatorily		Based on the EU requirements
Annex B, B-2	Change of the colouring agent	We recommend a change That for the test included in para. **7.2** may be used with other staining agents in particular : Methyl orange CAS: 547-58-0; Acid fuchsin CAS: 3244-88-0		Accepted methodology according to the point **7.2**

(Clause 8.1.2)

Lot Site to be Selected	No. of Products	Acceptance Number

2 - 15	2	0
16 - 50	3	0
51 - 150	5	0
151 - 500	8	1
501 - 3 200	13	1
3 200 - 35 000	20	2
35 001 - 500 000	32	3
powyzej 500 000	50	5

Sub: TZMO Group representation on the decision of the panel constituted by the TXD 36 committee to include Panty liners, Maternity Pads and Period Panties to the existing IS 5405

Respected Sir,

We are writing on behalf of TZMO S.A., a company located in Poland, engaged in manufacture and trading of personal hygiene and medical products under the Brand name of "Bella" for feminine hygiene, "Seni" for incontinence care, "Bella Baby Happy" for babies and newborn's hygiene and "Matopat" for medical products like, surgical gowns, drapes, gauze medical devices.

TZMO Group has been operating in India since 2002 and it has since then been a major market player and manufacturer of sanitary pads, maternity pads, panty liners and period panties, for sale in the Indian market and globally. TZMO's daughter company, BellaPremier Happy HygieneCare Private Limited is the first company in India to obtain the BIS certification for sanitary pads under the Standard 5405 in the year 2015. We highly value the role of the Bureau of Indian Standards (BIS) in ensuring quality, safety, and performance in consumer products and appreciate the comprehensive work done on IS 5405:2019 for sanitary pads.

However, we would like to respectfully request that the Ministry of Textiles and the BIS reconsider including panty liners under the purview of the IS 5405_2019 standard for sanitary pads. Panty liners serve a different purpose than sanitary pads and therefore warrant a distinct classification and testing methodology. We would like to highlight the following points for your kind consideration:

1. Purpose and Usage: Unlike sanitary pads, panty liners are not dedicated to menstruation. Their primary function is to offer daily protection by absorbing minimal daily secretions and spotting, and they are often used as additional protection for underwear when using tampons or menstrual cups during menstruation. Panty liners are much smaller, thinner, and more lightweight as they are designed for daily wear and are discreet enough to go unnoticed under clothing. Panty liners are designed for all-day wear or short-term use in non-menstrual situations. However, sanitary pads are typically larger, thicker, and designed to offer more coverage and protection during menstruation, particularly during heavier flow days.

2. Comfort and flexibility: Panty liners are designed for maximum comfort and flexibility, allowing women to wear them on a daily basis without any noticeable bulk. They prioritize discretion over absorbency.

Sanitary pads, on the other hand, while they do aim for comfort, they prioritize absorbency and protection over discretion, making them typically bulkier than panty liners.

3. Product Diversity: Panty liners come in various lengths and absorbency levels, allowing customers to select the appropriate product based on their individual needs. However, the panty liners have minimal absorbency, as they are intended to handle only light discharge or spotting. They are not suitable for heavy menstrual bleeding. The absorption requirements vary depending on the product's purpose, and consumer preferences often guide the selection of these products.

4. Testing Standards: While IS 5405:2019 applies to sanitary pads, we believe that this standard is inadequate for testing panty liners due to their different structure and function. We test our panty liners using the ISO 11948-1 method, an internationally recognized standard that better suits the characteristics of these products.

5. Compliance: The raw materials used to produce our sanitary pads meet the IS 5405:2019 standard. However, we emphasize that the same classification should not apply to panty liners as they are different in design and usage. Panty liners, like sanitary pads, can be categorized into thick and thin varieties but are primarily differentiated by their purpose.

6. Product composition: Panty liners are made with materials that focus on light absorption and breathability to provide all-day comfort. Sanitary pads are often designed with more advanced absorbent layers, leak-proof barriers, and sometimes with wings for extra protection during menstruation.

Secondly, we would like to respectfully request that the Ministry of Textiles and the BIS reconsider including maternity pads under the purview of the IS 5405_2019 standard for sanitary pads. Maternity pads serve a different purpose than sanitary pads and therefore warrant a distinct classification and testing methodology. We would like to highlight the following points for your kind consideration:

1. Absorbency Capacity: Maternity Pads are much thicker, longer, and have a higher absorbency level to handle the significant flow that occurs after delivery. Sanitary Pads, on the other hand, come in different sizes and absorbencies, they are typically thinner and less absorbent than maternity pads because they are meant for lighter menstrual flow.

2. Size and Coverage: Maternity Pads tend to be larger in size, providing more coverage to ensure complete protection during heavy postpartum bleeding. The broader design also helps in protecting stitches or C-section scars from irritation. While sanitary pads also come in various sizes, they are generally more streamlined and designed for ease of wear during daily activities.

3. Composition and Design: Maternity Pads are often made from softer, more cushioned materials to provide comfort for women recovering from childbirth. Some may be hypoallergenic or extra-breathable to minimize the risk of infection or irritation in a sensitive area. Sanitary Pads are typically designed for

general comfort and discretion during normal activities. They focus on being thin, flexible, and absorbent for daily movement.

4. Medical and Clinical Consideration: Maternity Pads are often recommended by healthcare professionals due to their ability to manage lochia (postpartum bleeding) effectively and protect sensitive areas during recovery. Sanitary Pads are not typically recommended for postpartum use because they may not provide sufficient protection or comfort during this period.

However, Considering the Need to include the Panty Liner towards the Standards of Sanitary Napkin 5405:2019 then there will be some modifications as per below information.

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Specific Proposal (Draft clause to be add/amended)	Remarks	Technical Reference and justification on which (2), (3), (4) are based
(1)	(2)	(3)	(4)	(5)
Section 4.1 The sanitary napkin shall be of following types: a) thick napkins; and b) thin napkins	N/A	Panty Liner should be of following types: a) Thick pantyliner b) Thin pantyliner	N/A	N/A
Section 5 SIZES Size of sanitary napkins shall be as agreed to between the purchaser and the supplier. Sizes of sanitary napkins shall be variable depending on the absorbent capacity, purchaser's needs and wing features. The recommended sizes are classified as follows:	N/A	The recommended sizes mentioned below as Note (a Section)5	N/A	N/A
(ANNEX B) Section 7.2	If it will be implemented	The Panty liner should absorb 0,5	N/A	Patient education: Vaginal discharge in

Ability to Withstand Pressure after Absorption	then modification required as per product category	ml of colored distilled water and the test will be executed as per "B-1 TEST PROCEDURE"		adult women (Beyond the Basics): Estimated discharge one-half to one teaspoon (2 to 5 mL) of white or clear, thick, mucus-like, and mostly odorless vaginal discharge every day.

Note:
Section 5: Sizes of panty liner should be depending upon the length of the product for which the recommended size range mentioned below

All dimensions are in mm.	Minimum	Maximum	Size Recommendation
Total Product Length	≤ 130		XS
	130	145	S
	146	169	M
	170	199	L
	≥ 200		XL
Absorbent core width	Min 19		

Maternity Pad / Period Panty recommendation:
The design and purpose of period panties and maternity pants differ from conventional sanitary napkins. Therefore, it is recommended not to include them under the sanitary napkin standards. It would be more appropriate to establish separate regulations for these products.

In conclusion, we kindly request that the Ministry of Textiles and the BIS to consider the above points and assess the suitability of the current standards in regulating panty liners and maternity pads under separate Standard instead of Sanitary Napkin 5405:2019. We are more than willing to engage in further discussions or provide any additional information necessary to support our position.

We are always committed to supporting the esteemed Ministry of Textile and Bureau of Indian Standards to achieve their vision.

d) Shri Nirav Mehta, Dima Products, Mumbai

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)**
Foreword			It will be advisable to mention Napkin and Pad have the same meaning. This is because the words Sanitary Pads are commonly used in the Indian Market	
IS 5405 : 2024 Disposable Pantyliner/Sanitary Napkins/Maternity Pad/Period Panty	To be changed at all places in the specification	IS 5405 : 2024 Disposable Sanitary Napkins / Maternity Pad / Period Panty / Pantyliner	Since the original standard was for Sanitary Napkins, change of product order in the title	
3.2 Absorbent Core An absorbent core forming the middle layer(s) shall consist of filler materials, such as cellulose pulp, cellulose wadding, tissue, cotton, wood pulp, other absorbent and super absorbent materials or combination of these materials, etc. It shall be free from lumps, oil spots, dirt or foreign material (unintended foreign matter that can cause injury or		3.2 Absorbent Core An absorbent core forming the middle layer(s) shall consist of filler materials, such as cellulose pulp, cellulose wadding, tissue, cotton, wood pulp, other absorbent and super absorbent materials or combination of these materials, etc. It shall be free from lumps ***(unintended)***, oil spots, dirt or foreign material (unintended foreign	Added the word unintended as the modern napkins are designed to have extra absorbent core at the center of the napkin. This results in the lump formation in the napkin but works better for the end consumer.	

discomfort) when examined visually.		matter that can cause injury or discomfort) when examined visually.		
4.1 The pantyliner / sanitary napkins / maternity pad / period panty shall be of following types: f) Thick napkins g) Thin napkins h) Pantyliner i) Maternity pad; and j) Period panty		**4.1** The pantyliner / sanitary napkins / maternity pad / period panty shall be of following types: a) Thick napkins b) Thin napkins ***a) Sanitary Napkins*** b) Maternity pad c) Period panty d) Pantyliner	As per some of the latest products available in the market there are combinations of absorbent core where either a) compressed fluff OR b) compressed fluff + compressed sheet are used used to manufacture thin napkins. There is no difference in the test parameters between Thin and Thick Sanitary Napkins This will also keep innovation space open.	
4.2 Under notes 2) The requirements given in **4.1** to **4.2** are for guidance of the manufacturer. The type and shape may vary between different design of the pantyliner /		**2)** The requirements given in **4.1** to **4.2** are for guidance of the manufacturer. The type and shape may vary between different design of the pantyliner / sanitary napkins /	The products are FMCG and are used by the consumers. The end consumers are not in direct touch with the manufacturers. A note can be added that in case	

sanitary napkins / maternity pad/ period panty or as per the agreement between buyer and seller.		maternity pad / period panty or as per the agreement between buyer and seller or ***manufacturers product design***.	of institutional buyer, the buyer and seller can have their own agreement and arrangement.	
5 Sizes		Under Sanitary Napkins XXL 281 to 320 XXXL >= 321	Based on the market requirements, recently several pads are introduced in the Indian market, which has total pad length over 320 to 420 mm. This calls for an additional size so that consumers will have clarity	
5 Sizes		Panty liner (total length) Small <= 139mm Regular 140mm - 170mm Large >= 171mm	In many Panty liners, the absorbent core is the same length as the total length of the liner and hence clarity is required.	
5 Sizes		'NOTE — If the required weight of the test specimen in not sufficient in one sample, then more no. of samples of the same lot may be taken for testing of the product .	The recommended sizes are classified as follows in table 1	
6. Manufacture, Workmanship and Finish The wood Pulp or other absorbent filler shall be	To incorporate the manufacturing process of	6. Manufacture, Workmanship and Finish The wood Pulp or other absorbent filler	The manufacturing process of Sanitary Napkins is undergoing	Sanitary Napkin tab-less

arranged and neatly cut to the required size and shape of the napkin without any wrinkles and distortion. The absorbent material is deposited onto a pre-glued cover in such a way that it does not cause lump formation with the effect of sudden pressure. The covering fabric should cover the filler completely and shall extend beyond the width for wing formation or beyond the length of the filler to form tabs or loops at each end. The absorbent along with the cover is then fed to the embossing unit, if any pattern is required to be embossed. Finally, a pre-glued barrier is applied on the other side of absorbent filler, forming a complete napkin structure. A napkin is then sealed using heat and pressure along the periphery or alternatively, it can be stitched or glued, depending upon the type of material used. In case of tab-less napkins, an adhesive system or other suitable methods may be introduced for	manufacturing tab and tab-less napkins. Also to include scope for innovation to eliminate glue in the future.	shall be arranged and neatly cut to the required size and shape of the napkin without any wrinkles and distortion. The absorbent material is deposited onto a pre-glued / ***without glue*** cover in such a way that it does not cause lump formation with the effect of sudden pressure. The covering fabric should cover the filler completely and shall extend beyond the width ***for wing formation of the filler*** or beyond the length of the filler to form tabs or loops at each end. The absorbent along with the cover is then fed to the embossing unit, if any pattern is required to be embossed. Finally, a pre-glued barrier is applied on the other side of absorbent filler, forming a complete napkin structure. A napkin is then sealed using heat and pressure ***or other methods*** along the periphery or alternatively, it can be stitched or glued, depending upon the type of material used. In case of tab-less	changes and new technologies are being adapted. We may add a note at the end of the paragraph to mention that the "Manufacturing process (mentioned above) may vary among different structure, types and shape of the napkins." This way we keep future scope for innovation.	 Sanitary Napkin with tab  Napkin without wings 

holding the napkins securely in position. The barrier is applied with adhesive with release paper to fix the napkin to the undergarment, for the tab-less napkins.		napkins, an adhesive system or other suitable methods may be introduced for holding the napkins securely in position. The barrier *or cover* is applied with adhesive with release paper to fix the napkin to the undergarment, for the tab-less napkins.		
6 Manufacture, Workmanship and Finish			Since we are adding Maternity Pads, Period Panty and Panty liners, Do we want to have a small description of the manufacturing process. description of the manufacturing process. This is because the manufacturing process of period panty is completely different as compared to Sanitary Napkins or Panty Liner	
7.3.1 Test Method	To add	'NOTE — If the required weight of the test specimen in not sufficient in one sample, then more no. of samples of the same		

		lot may be taken for testing of the product .		
7.3.2.1 Test Method	To add	'NOTE — If the required weight of the test specimen in not sufficient in one sample, then more no. of samples of the same lot may be taken for testing of the product .		
8.1.3 Table 3		Note – 3) The sampling plan given in table is for guidance of manufacturer / user. The other sampling plan may also be followed ***as per manufacturers quality assurance plans*** if agreed between buyer and seller.	The products are FMCG and are used by the consumers. The end consumers are not in direct touch with the manufacturers.	
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.		The manufacturer shall perform the hygiene testing for the final product every ***half year*** quarter for monitoring purpose and whenever there is a change in the raw material, manufacturing premises, and the supplier of the raw material.		
9 Marking d) The absorption capacity after pressure (ml);		Remove d) The absorption capacity after pressure (ml);	The absorption capacity is fixed in the standards, irrespective of the	

			size of respective products. In the future BIS can carry out a study / project where by product wise, size wise absorption capacity can be determined and the same can be represented through 5 droplets on the packaging. This exercise will required detailed study and time.	

C) Shri Prashant Jadhav, Procter and Gamble, Mumbai

NAME OF THE COMMENTATOR/ORGANIZATION: Procter & Gamble, India

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh) revision draft IS 5405	**Comments**	**Specific Proposal (Draft clause to be added/amended)**	**Remarks**	**Technical References and justification on which (2), (3), (4) are based**
(1)	**(2)**	**(3)**	**(4)**	**(5)**
5 SIZES Table 1 Size of Pantyliner/Sanitary Napkin/Maternity Pad/Period Panty *(for reference and guidance only)*		**PROPOSAL 1 Remove Table 1 & use the following statement: Size of pantyliner/sanitary napkins/maternity pad/period panty shall be as agreed to between the purchaser and the**		**Considering that the table is intended for reference and guidance purposes only, it is suggested to remove the table. Despite being labeled as reference values;**

		supplier. Sizes of pantyliner/sanitary napkins/maternity pad/period panty shall be variable depending on the absorbent capacity, purchaser's needs and wing features. Size As declared in the label with a tolerance of ± 10 mm. **PROPOSAL 2** **Make this as an OPTIONAL requirement by adding word "OPTIONAL" in the header:** **5 SIZES (OPTIONAL)**		**recent experiences have shown that laboratories have failed product samples on the ground of not meeting the dimensions as per the table. Removing the table eliminates interpretational differences that may arise due to its presence.**
9. Marking **9.1 Each pack shall be legibly and indelibly marked with the manufacturer's name** **or trademark, size, type and number of pantyliner/sanitary napkins/maternity pad/period panty contained in the pack** **in addition to the following:**	**"Type of Pads" here would refer to "Thin" or "Thick" sanitary napkins according to draft proposal**	**9.1 Each pack shall be legibly and indelibly marked with the manufacturer's name or** **trademark, size, type and number of pantyliner/sanitary napkins/maternity pad/period panty contained in the pack in** **addition to the following:** **a) product identifier (e.g.**	**Editorial comment**	**"Thick" and "thin" is technical language that is not used by the consumer in relation to sanitary pads. We agree it's relevant to label the product identifier, but we consider it not consumer meaningful to label "thin" or "thick".** **Any additional labelling obligation would not increase the**

		pantyliner, sanitary napkin, maternity pad/period panty)		**consumer knowledge.**
9. Marking **9.1 (d) The absorption capacity after pressure (ml)**	**It is not required to display all technical parameters on the product label.**	**Remove this element from the labelling requirements.**	**Technical comment**	**All certified products have to comply with minimum absorbency capacity which is already guaranteed by the standard.** **Overall absorbency is not a meaningful parameter for a consumer.** **The consumer chooses the product according to the fitment/size.**
9. Marking **9.1 Each pack shall be legibly and indelibly marked with the manufacturer's name or trademark, size, type and number of pantyliner/sanitary napkins/maternity pad/period panty contained in the pack in addition to the following:**	**Current version of the standards states "Each consumer pack" whereas the draft standard mentions "Each pack". *Does this mean that all packaging, including customer and secondary packaging will have to include these marking requirements?***	**Keep the current labelling requirements to "each consumer pack" as given below:** **9.1 Each consumer pack shall be legibly and indelibly marked with the manufacturer's name or trademark, number of sanitary napkins contained in it, and size designation in addition to the following:**		**"Each pack" can also include shippers and secondary packaging. It is not meaningful to keep all labelling requirements in secondary packaging that are not consumer-facing SKUs.**

7.6 Phthalate Test **The amount of phthalate present in pantyliner/sanitary napkins/maternity pad/period panty 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.**	**Suggest removing testing at raw material stage for various reasons (see column 5)**	**Adopt the clause from IS 17509 (Disposable Baby Diaper)** **The amount of phthalate present in pantyliner/sanitary napkins/maternity pad/period panty shall be < 0.1 percent (individual or in combination) when tested as per the method given in IS 9873 (Part 6).**	**Technical**	**1. Harmonization with IS 17509 (Disposable Baby Diapers) is suggested. In IS 17509, Phthalate testing is mandated on Finished Product only.** **2. Scope of IS 5405 is the final product. Thus, for consistency of the target group of this standard, it is appropriate for the manufacturer to test the final product only.** **In conclusion, this may be interpreted differently as current wording is not clear. The Phthalate limit in IS 5405 is defined for the final product but the testing requirements is also specified on raw material stage.**
7.1 pH **The pH of pantyliner/sanitary napkins/maternity pad/period panty (top and absorbent**	**Suggestion to extend pH range 3.5 to 8.0 either for period panties only or for all products.**	**Revise the clause:** **7.1 pH** **The pH shall be from 3.5 to 8.0**		**Period panties are a more complex product form than sanitary napkins, as more materials are**

core) shall be from 3.5 to 7.5 when tested by the method given in IS 1390.				**used. Measurements have shown pH can be close to 7.5**
6 MANUFACTURE, WORKMANSHIP AND FINISH 6.1 NOTE — The requirements given in 6.1 are for guidance of the manufacturer. The manufacture, workmanship and finish may vary between different design, types, and sizes of the pantyliner/sanitary napkins/maternity pad/period panty or as per the agreement between buyer and seller. The *manufacture should use chlorine free wood pulp in the absorbent core of the product.'*	**Need clarity on the test method that is being used to test for 'chlorine free wood pulp' in the absorbent core of the product**	**Remove *'The manufacture should use chlorine free wood pulp in the absorbent core of the product.'***		**Modern wood pulp are not treated with elemental chlorine, and therefore a safety is not a concern due to chlorine exposure. Treated wood pulp also undergoes rigorous purification process.**
6 MANUFACTURE, WORKMANSHIP AND FINISH 6.2 The pantyliner/sanitary napkins/maternity pad/period panty	**Rephrase statement of: "The pantyliner/sanitary napkins/maternity pad/period panty shall have a soft feel and when**	**Replace with the following: "The pantyliner/sanitary napkins/maternity pad/period panty when worn, shall not chafe or**		**Softness is a subjective term and cannot be measured. It may vary from user to user. The observation visually and**

shall have a soft feel and when worn shall not chafe or give any uncomfortable feeling when observed visually. They shall be free from all sorts of foreign matter (unintended foreign matter that can cause injury or discomfort).	**worn shall not chafe or give any uncomfortable feeling when observed visually."**	**give any uncomfortable feeling."**		**feeling of discomfort do not complement each other in a single sentence. "Soft feel" may also impact mesh/textured top sheet products as the mesh top sheet focus is on absorbency. At present sanitary napkins with the variety of textured surfaces, feel are available.**
7.2 Ability to Withstand Pressure after Absorption Table 2 Ability to Withstand Pressure after Absorption for Pantyliner/Sanitary Napkins/Maternity Pad/Period Panty - SI No ii) and iv)	**The volume of 30mL is considered exaggerated. During most cycles, women reported the heaviest bleeding on the second day of menstruation with a blood loss of 15 (normal flow) to 22 mL (heavy flow) per day. As pad usage is minimum 2 pads per day, a volume of 20mL seems more than appropriate.**	**For sanitary napkins and period panties:** **Liquid Absorption (ml), Min: 20**		**Reference:** **<u>The FIGO Recommendations on Terminologies and Definitions for Normal and Abnormal Uterine Bleeding;</u>** ***Semin Reprod Med 2011; 29(5): 383-390*** ***DOI: 10.1055/s-0031-1287662*** **Appropriate absorbency limits will also contribute to the positive sustainability impact by rationalizing input of materials.**

Number of Tests and Criteria for Conformity 8.2.5 The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material for manufacturing the product. **8.2.6 The testing for Composability or biodegradability during composting shall be carried out once for existing products and whenever there is a change in the raw material for manufacturing the product**	**Add "if applicable" to both clauses to clarify those paragraphs are related to the OPTIONAL requirements in 7.4 and 7.5**	**Revise the clauses as given below:** **8.2.5 *(If applicable):* The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material for manufacturing the product.** **8.2.6 *(If applicable):* The testing for Composability or biodegradability during composting shall be carried out once for existing products and whenever there is a change in the raw material for manufacturing the product.**		**This proposal is to bring consistency and remove interpretational differences.**
ANNEX B B-1 TEST PROCEDURE	**In its current form, the test method is not suitable for Period Panty. Adding cutting instruction in the test method for period panty will resolve this concern.**	**Insert: For period panty, cut along the lateral seam on both the sides (left & right) and then lay the period panty flat for absorbency testing.**		**Product integrity should not get tempered during this testing.** ***Picture for Illustration Purpose:*** 

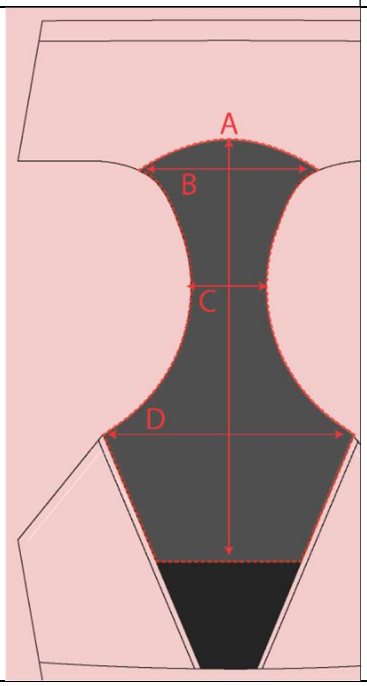
5 SIZES, Table column 4 & 5 headers **Pad Length (mm) (absorbent core only)** **Pad Width at center (mm) (absorbent core only)**	**The column names are only called "pad length" or "pad width" but they are applicable to all product types.** **The core is not always rectangular. For some products, the core shape is more anatomical. Thus the location where core width is measured shall be defined.**	**REMOVE "PAD" from the header of the column 4 & 5"** **Pad Length (mm) (absorbent core only)** **Pad Width at center (mm) (absorbent core only)**		**Removing the word "pad", as this is usually only used for menstrual pads or maternity pads, but not for pantyliners nor period panties.** **Core width shall be measured at center as this is the meaningful location to check because of the point of loading.**
5 SIZES, Table 1, SI No i) Column 3	**Size classes is not relevant for the pantyliners**	**Remove Size Class for the Pantyliners** **Proposed width: Width (mm): *Min*. 20 mm.**		**The proposals does not reflect current situation in market. For anatomical reasons, pantyliners might be less wide than 30mm thus width is lowered in the proposal as well.**
5 SIZES, Table 1, SI No ii) Sanitary Napkin	**Min pad width for sanitary napkins should be lowered.**	**Revise Pad width:** **Pad width (mm): *Min. 40mm*** **Include more size in the existing table: XL+, XXL+,XXXL, XXXL+ etc.**		**This change is to include high BMI consumer needs. High BMI consumers can have a narrow thigh gap, requiring pads with a narrow pad width.** **Companies are already selling**

				and marketing the proposed sizes.
5 SIZES, Table 1, SI No iv) Period Panty	**The values provided here are restrictive.** **In contrast to Liners, sanitary napkins and maternity pads, period panties have a maximum value for length and width in the draft revision.**	**Revise the dimensions:** **Length (mm): *>230 mm*** **Width (mm): *Min. 55 mm***		**This proposal is in line with CMD Clarification (Ref# CMD-I/2:4:1, dt. 13/12/2023; Clarification on the provisions of the product manuals - reg.)**

D) Smt. Tanya Mahajan, Menstrual Health Action Impact, (MHAI), New Delhi

NAME OF THE COMMENTATOR/ORGANIZATION: Menstrual Health Action for Impact
DOCUMENT NO: IS 17514

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)**
Clause 9.2: Ability to withstand pressure after absorption	Ability to withstand pressure upon absorption - The standard does not specify the size of the 1 kg weight, which may affect how the liquid spreads to the side area. Since the reusable pads are made of regular fabric, placing big diameter weight on top will cause the absorbed water to spread to the top layer and	We can maintain the same absorbency level for each size, but we need to define the diameter of the 1 kg weight. It should be smaller than the absorbent core width of 6 cm, ensuring the weight is distributed over a specific area rather than the entire pad.	From Karthik Thangavel, Real Relief	

	the side area. Refer to report #P2400213; the pad absorbed 30 ml, but after applying weight, it spread to the side area. Polyester fabric naturally tends to spread water both horizontally and vertically. Please refer to the video.			
Clause 9.2: Ability to withstand pressure after absorption	we need to have a clear definition "side" (it shall not show leakage at the bottom or sides of the reusable sanitary pad/sanitary napkin/period panties) in the specification; is it referred to wings area or side edge of the pads – refer picture? In SITRA report they say "Side" and "Side way"	Change to "it shall not show leakage at the bottom or side edge of the reusable sanitary pad"	From Karthik Thangavel, Real Relief	
Clause 6: Sizes	The guidelines mentioned were very specific to sanitary napkins and not relevant to panties, as the shape in the absorbent area of the panty and napkins are different.		From Shagun Maheshwari, Papaya Pads	

		<table><tr><td>Size</td><td>Width for Medium</td></tr><tr><td>A</td><td>29 cm</td></tr><tr><td>B</td><td>10.5 cm</td></tr><tr><td>C</td><td>6 cm</td></tr><tr><td>D</td><td>19 cm</td></tr></table> It can be rephrased to say that the minimal width should be Xcm for each size		
Clause 8: General Requirements Table 1: colour-fastness	The standard indicates a rating of CC-4/CS-3, whereas the international standard is 2-3. Even the dyestuff manufacturer doesn't provide such fastness properties for the dark colors.	Our suggestion is to have multiple grade levels between light/medium/dark shades.	From Ganesh Balaji, Mahina	

IS 5405		
We have completed all the required tests (pH, Bacterial and fungal activity, Staph. Aureus count, dimensions, ability to withstand pressure after absorption) but have failed the IS 5405:2019 Ability to withstand pressure after absorption. All the rest we have passed. Our pads are based on coagulation of blood, so an absorbance-based test is not the right metric for us. The result for the user is to feel dry and safe. Which we can show through	Add a test for coagulation as an alternative to absorption, test being developed by SITRA with Papaya pads	Shagun Maheshwari, Papaya Pads

testimonials as well as a test based on blood coagulation. I am in conversation with SITRA to perform this coagulation based test and should be able to get this data soon.		

Additional points of discussion:

- *From Livinguard, Real Relief, Saukhyam, Desai Foundation and Ecofemme* - There are many organisations now conducting both centralised production and partnering with SHGs for decentralised production. There are organisations that are also doing 100% SHG based production but are interested in getting certified, to be competitive in the market. In these cases, it is not possible to conduct testing for each and every facility separately as it increases the cost substantially. Can we look for an alternative pathway for SHG based production? E.g.

  - Common test for performance, material safety etc. can be accepted for all facilities under the brand as the materials and product remain the same
  - Hygiene testing can be done separately per facility with lower frequency than what is prescribed in the standard
  - Site visits can also be limited to a few select facilities, that can be randomly selected by BIS

If BIS is open to this, it can be further discussed with SHG-based organisations to understand the feasibility of this.

- From all - Request for an extension till Jan 1st-2025 for MSMEs

- From all - Communicate the standards to Ministry of Commerce so the requirements for procurement of these products can be updated on the GeMS portal, they do not match currently

- From Papaya pads - We are in the process of moving from a contract facility to our own facility. How should we approach the certification process as parts of certification, especially site visit, are linked to the production facility.

e) Ms. Monika Sathe and Ms. Roocha Khedkar, R&D, Kenvue, JNTL Consumer Health (India) Pvt. Ltd

DOCUMENT NO: Proposed Draft Revision IS 5405 : 2024 Disposable Pantyliner/Sanitary Napkins/Maternity Pad/Period Panty

As requested kindly refer below suggestion from kenvue, open for further discussion in the panel meeting.

Panty Liners - Panty liners are a thinner, smaller version of a sanitary napkin. They are made of similar absorbent material for daily use to absorb light vaginal discharge, minor menstrual flow, or spotting.

Maternity Pad –Maternity pads are generally thicker and can be longer version of a sanitary pad used to absorb postpartum bleeding that happens for weeks after childbirth.

Period Panty – Period Panties are wearable form of sanitary pad and made of absorbent material used to absorb fluid discharged during menstruation. They are also referred as Period Underwear or Period Underpants.

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)
7.2 Ability to Withstand Pressure after Absorption The pantyliner/sanitary napkins/maternity pad/period panty shall absorb coloured distilled water as given in table 2 and it shall not show leakage at the bottom or sides of the sanitary napkin, when tested according to method given in Annex B.	Scope widen to include other products	The pantyliner/sanitary napkins/maternity pad/period panty shall absorb coloured distilled water as given in table 2 and it shall not show leakage at the bottom or sides of the product, when tested according to method given in Annex B.	N/A	N/A
6 MANUFACTURE, WORKMANSHIP AND FINISH 6.1 NOTE — The	N/A	NOTE — The requirements given in 6.1 are for guidance of the manufacturer. The	N/A	N/A

requirements given in 6.1 are for guidance of the manufacturer. The manufacture, workmanship and finish may vary between different design, types, and sizes of the pantyliner/sanitary napkins/maternity pad/period panty or as per the agreement between buyer and seller. The manufacture should use chlorine free wood pulp in the absorbent core of the product.'		manufacture, workmanship and finish may vary between different design, types, and sizes of the pantyliner/sanitary napkins/maternity pad/period panty or as per the agreement between buyer and seller. The manufacture shall use Elemental or Total chlorine free bleached wood pulp in the absorbent core of the product.		
Notes in Section 4.2 (2) The requirements given in 4.1 to 4.2 are for guidance of the manufacturer. The type and shape may vary between different design of the pantyliner/sanitary napkins/maternity pad/period panty or as per the agreement between buyer and seller. Notes in Table 3:	To revise the part of statement - …. agreed between buyer and seller'	Notes in Section 4.2 (2) The requirements given in 4.1 to 4.2 are for guidance of the manufacturer. The type and shape may vary between different design of the pantyliner/sanitary napkins/maternity pad/period panty or as per manufacturer. Notes in Table 3:	Simplification	The buyer itself can be manufacturer/seller hence the agreement may not exist.

(2) The sampling plan given in table is for guidance of manufacturer/user. The other sampling plan may also be followed if agreed between buyer and seller.		(2) The sampling plan given in table is for guidance of manufacturer/user. The other sampling plan can be followed as per manufacturer		
8.2.4 The manufacturer shall perform the hygiene testing for the final product every quarter for monitoring purpose	'…. every quarter…' should be changed to every six months	The manufacturer shall perform the hygiene testing for the final product every six months for monitoring purpose.	Simplification	The products covered in this Standard are of Dry nature. Hence there is no risk of hygiene.
9 Marking: d)The absorption capacity after pressure (ml);	d) to be deleted	Not required	Simplification	The absorption capacity after pressure is 30 ml as defined in the test method. It may add confusion to consumer as various sizes/ category may have overlapping capacity. It will also restrict industry innovations.
Annex C Numbering from 'j to p'	Numbering from 'j to p' should be corrected to 'i to m'	Correct numbering from 'i to m'	Typographical error correction	Error correction

f) Shri Rajesh Shah, FIHA, Mumbai

Subject: Hygiene Industry Representation on Medical Textile Quality Control Order, 2023

Respected 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, 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**.

The size of the India baby diaper industry and the sanitary napkin industry is ~INR 6000-7000 crores and ~INR 5500-6000 crores respectively. Both the industries have been growing at a CAGR of 5.5-6.5% year on year.

In reference to the QCO for baby and fem care product which is to be implemented starting 1st Oct 2024, our industry has taken best initiatives to action the QCO. We have obtained certification for most of our manufacturing sites. However, observing the current practical challenges mentioned below, we request to propose for further extension of QCO timelines by 6 months beyond 1st Oct 2024.

Progress by the Industry: For sanitary napkins, most of the domestic manufacturing plants have obtained certification. Whereas in the baby diaper industry, few of the MSMEs as well as MNCs are still in process of obtaining the necessary certification due to the technical and process related challenges (listed below).

- Sanitary Napkin Industry: Around 50 manufacturers got certification. Others are in process to get certification
- Baby Diaper Industry: In all there are 40-50+ manufacturers in India. Of which 13 manufacturing plants are registered. 8 manufacturing plants are under review. However, rest of the industry is still preparing for the certification

We hereby would like to share Industry wide challenges and proposals as follows:

BIS Marking Fees and Clarity on pieces: There is vast difference in the marking fees for baby diapers and sanitary napkins. These products are made of almost same materials and the use is also absorption.

The industry request to align the marking fees for sanitary napkins to that of baby diapers.

Product	1 unit =	Marking fee/Unit	Per piece marking fee
Baby Diaper	100 pieces	Rs 0.1	0.001
Sanitary napkins	1000 pieces	Rs 10	0.01

Timeline concerns due to proposed Amendment in IS 17509 (Specifications – Baby Diaper)

The proposed amendment for IS 17509 introduced newer dimensions (pre mature, XX Large and XXX Large). for testing absorbency. This amendment is yet to be published and expected during August or September-2024. Post publishing final amendment, the industry as well as the BIS certified laboratories will have to work on procurement of new equipment, validation of test method and deployment. This process might take ~ 1-2 months depending on the various factors. Following that, an additional 3-4 months' time is also needed to upgrade the testing equipment for BIS certified labs and industry and to submit application for these new dimensions and secure BIS approval.

In the past few months several companies, have already obtained their BIS license which includes sizes XX Large and XXX Large. However, we understand that in August, BIS have written to a company to exclude the

previously approved XX Large size from their license. A change of decision a few months after granting the license approval have significant impact on business plans and operations which can result in a loss of business and potential out of stock situation, causing consumers to be unable to access these products that they need daily. This requires written clarification from MoT for the industry to continue manufacturing, import and marketing the products with grace period.

Inter-Lab variations (BIS empaneled) creating challenges for testing and certification. The inter-lab variations are posing challenge in the results, which is creating delays in the certification process for baby diapers. This is observed by multiple FIHA members. We propose BIS to conduct a workshop including BIS certified labs; BIS Officials and Industry for alignment in terms of the testing methods. Further, during the market surveillance this will be ongoing challenge. We should seek harmonization from BIS on this matter.

Exclusion of Maternity Pads, Panty Liners, newborn diapers from the Medical Textile QCO 2023
FIHA is of the opinion to exclude above products from the existing QCO as current sanitary Napkin standard is different than product platform above and needs detailed consultation with different stakeholders. Furthermore, we request for a longer implementation (12-24 months) for the QCO implementation of the proposed products (Maternity Pads, Panty Liners, Newborn Diapers) as we have less than two months remaining before the current implementation date of QCO for Sanitary Napkins and some of the proposed products also fall under FMCS application, which require longer approval timelines. Various industry members have already shared their opinion on the similar lines with BIS-TXD36.

Multi-site Labels
In the earlier representation, we have voiced our concern for the ongoing practice of using multi-site labels. In fact this practice is prevalent in the entire consumer goods industry. We would like BIS to reconsider Industry request and revise the statement in the corresponding manuals under IS 5405 and IS 17509. Industry hereby proposing the below text to be proposed in the Sanitary Napkin as well as Baby Diapers:

***Note**: In case a manufacturer is getting the product with the same brand name manufactured is holding BIS licences at multiple premises (units) (either on his own or through job-work basis or through a third party where he is only the marketeer) having unique BIS licenses for each such premise/ unit, under same ownership and opts for marking multiple licence numbers on the unified label, the same may be considered, provided the identification and traceability of the product, is established as envisaged*.

Utilization of the pre-printed artworks.
As these products are fast moving consumer goods. Hence, the supply chain needs the packaging material inventory for next 2-3 months to support the ongoing business. This plastic packaging inventory management will need consideration to transition to the ISI marked labels. Hence, the industry needs time to utilize the existing packaging material and parallelly to start the ISI marked packaging materials based on the BIS certification numbers.

FMCS Applications

In the sanitary napkin industry as well as in the baby diapers, there are few exceptional products which are imported in India. These products are quite innovative, and the necessary manufacturing equipment's' and the infrastructure is available only at few selected manufacturing sites globally.

To fulfil these super premium product needs of specific Indian consumer, we are importing these sanitary napkins as well as baby diapers. This might constitute ~10% of the super-premium category.

The industry has submitted applications (starting April 2024) for registering the manufacturers from Europe and Southeast Asia. These applications are under review with the respective BIS offices and the review timelines are more than 6 months. Once the certification is received, the marking activities takes at least 2-3 months to have ISI mark on the product and additional 1.5 to 2 months transit time for sea shipment to India.

BIS Marking Fees and Clarity on pieces: There is vast difference in the marking fees for baby diapers and sanitary napkins. These products are made of almost same materials and the use is also absorption.

The industry request to align the marking fees for sanitary napkins to that of baby diapers.

Product	1 unit =	Marking fee/Unit	Per piece marking fee
Baby Diaper	100 pieces	Rs 0.1	0.001
Sanitary napkins	1000 pieces	Rs 10	0.01

Implementation Timelines: Observing the above challenges, the implementation timelines of 1st Oct 2024 seems unrealistic. We, therefore, humbly request your good self to grant the extension of the implementation timelines by 6 months.

Industry Proposals

Our industry is doing a lot of efforts to work on the quality control order implementation. Necessary applications are submitted by most of the industry. However, observing the above-mentioned challenges, we therefore request for:

1. An extension of the Medical Textile quality Control Order, 2023 by another 6 month (Effective 1st April 2025).
2. Allow Industry to utilize the non-ISI marked labels to exhaust current inventory for an additional 3 months (by 30 June 2025) and thereby allow exhaustion of existing labels.
3. Soft enforcement of QCO as Industry is still learning on QCO implementation.
4. Exclusion of Maternity Pads, Panty Liners, newborn diapers in the Medical Textile QCO 2023, with a request to have detailed consultations with different stakeholders before releasing a separate QCO with 12 to 24 months of implementation timeframe.
5. Permit us to use common label artwork/ packaging material for multi-site/ premises /unit labels, as is the ongoing practice.

Yours faithfully,

Authorized Signatory
Feminine and Infant Hygiene Association

g) Shri Gaurav Bathwal, Niine Pvt. Ltd

Subject: Request for Extension of Implementation Period for the Medical Textile Quality Control Order, 2023 (Sanitary Napkins and Baby Diapers)

Respected Sir,

At the outset, we would like to express our sincere appreciation to the Bureau of Indian Standards (BIS) and Ministry of Textiles for the introduction of the Quality Control Orders (QCOs) in the medical textile sector. This initiative is a commendable step towards fostering healthy competition and encouraging the local manufacturing of high-quality goods, thereby ensuring that Indian consumers have access to superior products.

Niine Pvt. Ltd., based in Gorakhpur, Uttar Pradesh is a leading Indian manufacturer of sanitary napkins and baby diapers. Since our inception, we have been committed to delivering products that meet the highest standards of quality and hygiene. The introduction of QCOs resonates with our core values of innovation and excellence in the hygiene industry.

However, as we prepare to align with the new regulatory framework, we are encountering certain challenges that we believe could impact our ability to fully comply with the QCOs by the stipulated deadline of October 1, 2024. We seek your kind consideration of these challenges and propose an extension of the implementation timeline to ensure a smooth transition.

Price Disparity in BIS Marking Fees

There exists a significant discrepancy in the BIS marking fees between baby diapers and sanitary napkins, which poses a challenge for manufacturers like us. Despite the similarities in the raw materials and functions of these products, the current fee structure disproportionately affects the sanitary napkin segment. The following table (on the next page) illustrates this disparity:

Product	1 Unit =	Marking Fee/Unit	Per Piece Marking Fee
Baby Diapers	100 pieces	₹0.1	₹0.001
Sanitary Napkins	1000 pieces	₹10	₹0.01

We respectfully request that the marking fees for sanitary napkins be realigned to match those of baby diapers to maintain equity within the industry.

Excess Inventory of Non-BIS Marked Packaging Materials

As a manufacturer of fast-moving consumer goods, we maintain a considerable inventory of packaging materials to support our production cycles. The shift to BIS-marked packaging presents a logistical challenge, as we currently hold substantial stocks of packaging materials without the BIS marking. We request that the industry be granted additional time to deplete this existing inventory, thereby preventing wastage and financial loss.

Pending Licensing for Baby Diapers

While we have made substantial progress in obtaining the necessary certifications and licenses for our Sanitary Napkins as per IS 5405 standards, the process for Baby Diapers has been delayed due to technical complexities and the recent draft amendments to the IS 17509 standards. These amendments, which introduce new testing dimensions, are yet to be fully operationalized, and as their final publication is awaited, it is creating a bottleneck in the certification process. Due to lack of clarity, this situation necessitates further time for us to ensure compliance.

Request for Extension

In light of the challenges outlined above, we earnestly request an extension of six months for the implementation of the Medical Textile QCOs, extending the deadline to April 1, 2025. This extension would provide the industry with the necessary time to address the challenges and ensure full compliance. Additionally, we request permission to utilize the existing non-ISI marked packaging materials for an extended period to facilitate a smoother transition.

We reaffirm our commitment to the successful implementation of the QCOs and believe that the proposed extension will enable us to achieve the intended objectives without compromising on quality or regulatory compliance.

We kindly urge the Ministry of Textiles and BIS to consider our request favourably. We look forward to your positive response and continued support.

Yours sincerely,

Gaurav Bathwal
Director, Niine Pvt. Ltd

h) Shri Harsh Sethia, Shekhani Industries

Dear BIS Team,
First and foremost, I would like to express our sincere thanks for your efforts in establishing Quality Control Orders (QCOs) for hygiene products. This initiative was much needed in the industry and is a significant step forward in ensuring the safety and quality of products that consumers rely on daily.
I am writing on behalf of Sekhani Industries Private Limited, where we are involved in the manufacturing and sale of various hygiene products, including sanitary napkins, baby diapers, and other related items. We have

closely followed the development of QCOs, and we appreciate the emphasis on quality and performance standards.

Attached below are our recommended specifications for **Period panty products**. Currently, we are importing period panty for our brand, but we are in the process of setting up a manufacturing line for these products in India. We believe that sharing our insights on the specifications and performance metrics of period panties will contribute positively to the formulation of standards that benefit both manufacturers and consumers alike.

We would be grateful if you could review our recommendations and consider them during your ongoing efforts to finalise the QCOs for period panty products.

Performance test Standard					
Description	Unit	Size	Standard	Tolerane	Testing Liquid
Total Absorption	ML	Medium	40 ml	Minimum	Synthetic Blood As Similar used for Sanitary napkin
		Large	50 ml		
		Extra - Large	60 ml		
Absorption Rate					
1st 20 ml	Seconds	All Sizes	<70 seconds	Minimum	Synthetic Blood As Similar used for Sanitary napkin
2nd 20 ml	Seconds	All Sizes	<90 seconds	Minimum	Synthetic Blood As Similar used for Sanitary napkin
Rewet					
1st 20 ml	gram	All Sizes	< 4 gram	Minimum	Synthetic Blood As Similar used for Sanitary napkin
2nd 20 ml	gram	All Sizes	< 6 gram	Minimum	Synthetic Blood As Similar used for Sanitary napkin

PH Value	PH		5.5 - 8		As per BIS ph testing method

Recommend Specifications for 3 sizes

Parameter	**UOM**	**Medium**	**Large**	**Extra-Large**	**Tolerance**
Product Weight	**gms**	**33.00**	**36.00**	**39.00**	**±1.5**
Product Width	mm	600	675	725	±10
Product Length	mm	650	700	750	±10
Core Length	mm	405	405	425	±10
Core width at Front/Back	mm	105/105	105/105	105/105	±10
Core width at Center	mm	80	80	80	±10
Front Waist Elastic	Nos	14	16	18	±1
Back Waist Elastic	Nos	16	18	20	±1
Cuff Elastic	Nos	2+2	2+2	2+2	±1
Tack Down Length Front / Back	mm	80/80	80/80	80/80	±5
Curve Elastic	Nos	3+3	3+3	3+3	±1
Minimum Absorbency	ml	40	50	60	**±20**
Total Absorbancy	**ml**	**100**	**120**	**140**	**±20**

For BIS Use Only

BUREAU OF INDIAN STANDARDS

MINUTES

Second Panel meeting – Revision/Amendment of IS 5405 Sanitary Napkin

Date	**Time**	**Venue**
05 September 2024	1100 h	Video Conference through CISCO Webex

(Thursday)		

CONVENOR: Smt. Shradha Dongre, SASMIRA, Mumbai

Member Secretary, TXD 36: Shri Dharmbeer, Scientist D, Textiles, BIS New Delhi

ATTENDEES:

21) Smt. Shradha Dongre, SASMIRA, Mumbai (**Convenor**)
22) Dr. Shadhana Srivastava, ICMR New Delhi
23) Shri S. Sivakumar, SITRA, Coimbatore
24) Dr. R. Radhai, SITRA, Coimbatore
25) Shri D. Veerasubramaniam, SITRA, Coimbatore
26) Shri Nirav Mehta, M/s Dima Products Mumbai (Representing Indian Technical Textile Association/ Feminine and Infant Hygiene Association, Mumbai)
27) Ms. Roocha Khedkar/Smt. Monika Sathe, Kenvue Mumbai
28) Ms. Shivani Swamy, Livinguard Technology Pvt. Ltd., Mumbai
29) Smt. Tanya Mahajan, The Pad Products (NGO), India
30) Shri Sashank Singh, Soothe Healthcare, Noida
31) Ms. Dipti Sharma, Unicharm India, Gurugram
32) Shri Mithun Shah, Anabia Technologies, Bengaluru
33) Dr. Ruchi Aradhana, Anabia Technologies, Bengaluru
34) Shri Rohit Srivasatava, Unicharm India Pvt Ltd., Gurugram
35) Smt. Dipti Sharma, Unicharm India Pvt Ltd., Gurugram
36) Shri Prashant Jadhav, P & G, Mumbai
37) Smt. Paridhi Mantri, Soothe Healthcare, Noida
38) Smt. Meeta Singhla, Testtex India Laboratories Pvt. Limited, Mumbai
39) Shri Chandrakant, Testtex India Laboratories Pvt. Limited, Mumbai
40) Shri Karthik, Real Relief, Tamilnadu
41) Ms. Shagun Maheshwari, Papaya Pad, India
42) Shri Gaurav Bathwal, Nine Private Limited
43) Shri Vijaypal Tiwari, Nine Private Limited, Gurugram
44) Shri Harsh Sethia, Shekhani Industries, Ahmedabad
45) Shri Shrey Shekhani, Mangal Textile Mills India Pvt. Ltd., Ahmedabad
46) Shri Ganesh, Mahina Pad, Gurugram
47) Shri Dharmbeer, Member Secretary, TXD 36

Item 0 WELCOME AND INTRODUCTORY REMARKS

Smt. Shradha Dongre, SASMIRA, Mumbai (Convenor) extended a hearty welcome to the members of panel. She emphasized for active participation from the members and requested for the precise inputs so as to arrive at consensus.

Shri Dharmbeer, Scientist D and Member Secretary, TXD 36 has also welcomed the Convenor and all other members.

Item 1 COMMENTS ON PUBLISHED STANDARDS

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

The panel considered the draft revision of IS 5405 as given at **Annex 2** along with comments received from ICMR, BIS Chennai Branch Office, TZMO Group, Dima Products, P &G, MHAI, Kenvue, FIHA, Nine Private Limited, Shekhani Industries, SITRA and Papaya pad on Draft revision of IS 5405 as given at **Annex 3** of the agenda and thereon.

After deliberations, the panel recommended the following changes may be incorporated in existing draft revision of IS 5405: -

i) Foreword, first paragraph, Insert the following at the end :-

'Panty liners are a thinner, smaller version of a sanitary pad. They are made of similar absorbent material for daily use to absorb light vaginal discharge, minor menstrual flow, or spotting. Maternity pads are generally thicker and can be longer version of a sanitary pad used to absorb postpartum bleeding that happens for weeks after childbirth. Period panties are wearable form of sanitary pad and made of absorbent material used to absorb fluid discharged during menstruation. They are also referred as period underwear or period underpants.'

ii) The title of the standard shall be updated as 'IS 5405 : 2024 Disposable Sanitary Pad/Pantyliner/Maternity Pad/Period Panty.'

iii) The term 'pantyliner/sanitary napkins/maternity pad/period panty' shall be updated as 'sanitary pad/panty liner/maternity pad/period panty' in the existing standard

iv) Clause 3.2, Absorbent core, third sentence, Substitute 'lumps (unintended)' for 'lumps.'

v) Clause 4.1 (a &b), Replace 'thick and thin napkin' with 'Sanitary pad.'

vi) Clause 4.1 — Delete 'Note.'

vii) Clause 4.2 — Insert the following new note at the end:

'NOTE — The requirements given in **4.1** to **4.2** are for guidance of the manufacturer. The type and shape may vary between different design of the sanitary pad/pantyliner/maternity pad/period panty or as per the agreement between buyer and seller or manufacturers product design.

viii) Clause 5, Table 1, Substitute 'Length (mm) (absorbent core only)' for 'Pad length (mm) (absorbent core only)'.

ix) Clause 5, Table 1, Substitute 'Width (mm) (absorbent core only)' for 'Pad width (mm) (absorbent core only)'

x) Clause 5, Table 1, Period panty, length of absorbent core is to be updated as > 230 mm and width of absorbent core min 55 mm.

xi) The following note shall be included under clause 5, Table 1 :-

'NOTE —

1) The actual dimension of absorbent core may differ as per the product design of manufacturer. If required, the manufacturer may also provide the figure/schematic diagram for measurement of dimension of absorbent core length and width of the product.

2) The recommended dimension (for reference and guidance only) of absorbent core length and width for other size class/type of sanitary pad/pantyliner/maternity pad/period panty not covered in Table 1 shall be declared by the manufacture.'

xii) Clause 6.1, fifth line, substitute 'of the filler for 'for wing formation.'

xiii) Clause 6.1, tenth line, substitute 'heat and pressure or other methods' for 'heat and pressure.'

xiv) Clause 6.2, first sentence, Substitute for the following for the existing :-

The sanitary pad/pantyliner/maternity pad/period panty shall have a soft feel and when worn shall not chafe or give any uncomfortable feeling.

xv) Clause 7.2, second line , Substitute 'product' for 'sanitary napkin.'

xvi) Clause 7.2, B-1, Insert the following new note :-

'NOTES —

1) The length and width of 1 kg weight should have dimension of 150 mm x 50 mm with a tolerance of $\pm$ 1 mm.

2) For period panty, cut along the lateral seam on both the sides (left & right) and then lay the period panty flat for absorbency testing.'

xvii) The following note shall be included under clause 8.1.2, Table 1 :-

'NOTE — The sampling plan given in table 3 is for guidance of manufacturer/user. The other sampling plan may also be followed if agreed between buyer and seller or as per manufacturers quality assurance plans.

xviii) Clause 7.6, add the following new clause :-

7.7 Anti-Bacterial Activity Value (Optional)

If agreed between the buyer and the seller, the raw material used for the product or final product shall have antibacterial activity value greater than or equal to 2 when tested by the absorption method prescribed in IS/ISO 20743.

xix) Clause 8.2.6, Insert the following new clause :-

'8.2.7 The anti-bacterial activity testing shall be carried out once for existing raw material or final product and whenever there is a change in the raw material or source of supply of raw material for manufacturing the product.

xx) Clause 9.1, first line , Substitute 'Each consumer pack' for 'Each pack.'

xxi) Clause 9.1 — Delete 'd.'

xxii) The panel requested Smt. Roocha Khedkar/Smt. Monika Sathe to share the requirement (limit) for volatile organic compound test and Dixon/furan based on their inhouse data/International practice within 30 days.

xxiii) The panel requested Ms Shagun Maheshwari to share inputs within 30 days on test based on blood coagulation which may be considered as an alternative method after validation for absorbency test.

xxiv) The panel requested Shri Shri Mithun Shah, Anabia Technologies, Bengaluru to share the requirement and test method for 100 % biodegradable sanitary napkin within 30 days and 100 % flushable sanitary napkin within 3 months.

xxv) The panel requested member secretary to prepare the revised draft revision of IS 5405 : 2019 based on above changes within 07 days. BIS may carry out editorial changes in the draft amendment/standard.

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

ANNEX 5

(Item 5.1)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

For Comments Only

Proposed Draft Revision

IS 5405 : 2024 Disposable Sanitary Pad/Pantyliner/Maternity Pad/Period Panty

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FOREWORD

(Formal clause will be added later)

Sanitary pad/panty liner/maternity pad/period panty is an absorbent hygiene material used to absorb fluid discharged during menstruation. As compared to cloth and other materials (husks, ashes, etc.) used during menstruation, it provides better hygiene and protection against leakage. Panty liners are a thinner, smaller version of a sanitary pad. They are made of similar absorbent material for daily use to absorb light vaginal discharge, minor menstrual flow, or spotting. Maternity pads are generally thicker and can be longer version of a sanitary pad used to absorb postpartum bleeding that happens for weeks after childbirth. Period panties are wearable form of sanitary pad and made of absorbent material used to absorb fluid discharged during menstruation. Period panties are also referred as period underwear or period underpants.

This standard was originally published in 1969; and subsequently revised in 1980 and 2019. The third revision has been made to incorporate the following major changes:-

k) All amendments have been incorporated.
l) Title and scope of the standard has been updated.
m) Material and sizes have been modified.
n) Requirement of pantyliner, maternity pad and period panty have been specified.
o) Manufacture, workmanship and finish have been modified.
p) The procedure and requirement of ability to withstand pressure after absorption have been modified.
q) pH and hygiene testing requirement have been updated.
r) The requirement of compostability has been updated.
s) Optional requirement of anti-bacterial activity test has been specified.

t) Sampling and criteria for conformity has been modified.
u) Marking clause has been modified.
v) References to Indian Standard have been updated.

This standard contains clause **5.1** which calls for an agreement between the purchaser and the supplier regarding dimensions. However, recommended dimensions have been specified.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (second revision)'.The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Draft Indian Standard

IS 5405 : 2024 DISPOSABLE SANITARY PAD/ PANTYLINER/ MATERNITY PAD/PERIOD PANTY — SPECIFICATION

(*Third Revision*)

1 SCOPE

This standard covers the requirements for disposable (non-reusable) sanitary pad/ pantyliner/maternity pad/period panty for external use.

2 REFERENCES

The standards given in Annex A contain provisions which, through reference in this text, constitute provisions of this standard. 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.

3 MATERIALS

All types of sanitary pad/pantyliner/maternity pad/period panty basically consist of three major components:

d) cover or the top sheet;
e) absorbent core, and
f) the barrier or bottom sheet.

3.1 Cover/Top sheet

The cover/top sheet is the material which comes under contact with skin during use. The cover of sanitary pad/pantyliner/maternity pad/period panty shall be of good quality cotton, rayon knitted sleeve or gauze, non-woven fabric or any other materials with sufficient porosity to permit the assembled product to meet the absorbency requirements. If cotton gauze is used, it shall conform to IS 758.

3.2 Absorbent Core

An absorbent core forming the middle layer(s) shall consist of filler materials, such as cellulose pulp, cellulose wadding, tissue, cotton, wood pulp, other absorbent and super absorbent materials or combination of these materials, etc. It shall be free from lumps (unintended), oil spots, dirt or foreign material (unintended foreign matter that can cause injury or discomfort) when examined visually.

3.3 Barrier or Bottom Sheet

The barrier shall be made of suitable leak proof material so that it meets the requirement specified in **7.2**.

'NOTE — The requirements given in **3.1** to **3.3** are for guidance of the manufacturer. The material and design may vary between different types and sizes of the sanitary pad/pantyliner/maternity pad/period panty or as per the agreement between buyer and seller.'

4 TYPE AND SHAPES OF SANITARY PAD/PANTYLINER/MATERNITY PAD/PERIOD PANTY

4.1 The sanitary pad/pantyliner/maternity pad/period panty shall be of following types:

k) Sanitary pad
l) Pantyliner
m) Maternity pad; and
n) Period panty

4.2 Sanitary pad/pantyliner/maternity pad/period panty can be of various shapes and design such as wings/no wings, tab/tab-less etc. or as per purchaser's needs.

NOTES —

3) Sanitary pad/pantyliner/maternity pad/period panty with wings provide better grip on the undergarments so that product remains in its position under dynamic conditions. Some products can also be folded to be carried in a small pouch.
4) The requirements given in **4.1** to **4.2** are for guidance of the manufacturer. The type and shape may vary between different design of the sanitary pad/pantyliner/maternity pad/period panty or as per the agreement between buyer and seller or manufacturers product design.

5 SIZES

Size of sanitary pad/pantyliner/maternity pad/period panty shall be as agreed to between the purchaser and the supplier. Sizes of sanitary pad/pantyliner/maternity pad/period panty shall be variable depending on the absorbent capacity, purchaser's needs and wing features. The recommended sizes are classified as follows in table 1:

Table 1 Size of Sanitary Pad/Pantyliner/Maternity Pad/Period Panty
(for reference and guidance only)

(*Clause* 5)

Sl No (1)	Name of product (2)	Size class (3)	Length (mm) (absorbent core only) (4)	Width (mm) (absorbent core only) (5)
i)	Sanitary pad	Regular	≤ 210	*Min* 55
		Large	211 to 240	
		Extra - large	241 to 280	
		XXL	≥ 281	
ii)	Pantyliner	Small	≤ 135	*Min* 30
		Regular	136 to 179	
		Large	≥ 180	
iii)	Maternity pad	-	≥ 281	*Min* 80
iv)	Period panty	-	> 230	*Min* 55

'NOTE —

3) The actual dimension of absorbent core may differ as per the product design of manufacturer. If required, the manufacturer may also provide the figure/schematic diagram for measurement of dimension of absorbent core length and width of the product.
4) The recommended dimension (for reference and guidance only) of absorbent core length and width for other size class/type of sanitary pad/pantyliner/maternity pad/period panty not covered in Table 1 shall be declared by the manufacture.'

6 MANUFACTURE, WORKMANSHIP AND FINISH

6.1 The wood pulp or other absorbent filler shall be arranged and neatly cut to the required size and shape of the sanitary pad/pantyliner/maternity pad/period panty without any wrinkles and distortion. The absorbent material is deposited on to a pre-glued or without glue cover in such a way that it does not cause lump formation with the effect of sudden pressure. The covering fabric should cover the filler completely and shall extend beyond the width of the filler or beyond the length of the filler to form tabs or loops at each end. The absorbent along with the cover is then fed to the embossing unit, if any pattern is required to be embossed. Finally, a pre-glued barrier is applied on to other side of absorbent filler, forming a complete sanitary pad/pantyliner/maternity pad/period panty structure. A sanitary pad/pantyliner/maternity pad/period panty is then sealed using heat and pressure or other methods along the periphery or alternatively, it can be stitched or glued, depending upon the type of material used. In case of tab-less sanitary pad/pantyliner/maternity pad/period panty, an adhesive system or other suitable method may be introduced for holding the sanitary pad/pantyliner/maternity pad/period panty securely in position. The barrier is applied with adhesives with release paper to fix the sanitary pad/pantyliner/maternity pad/period panty to the undergarment, for the tab-less sanitary pad/pantyliner/maternity pad/period panty.

'NOTE — The requirements given in **6.1** are for guidance of the manufacturer. The manufacture, workmanship and finish may vary between different design, types, and sizes of the sanitary pad/pantyliner/maternity pad/period panty or as per the agreement between buyer and seller or as per manufacturers design. The manufacture should use chlorine free wood pulp in the absorbent core of the product.'

6.2 The sanitary pad/pantyliner/maternity pad/period panty shall have a soft feel and when worn shall not chafe or give any uncomfortable feeling. They shall be free from all sorts of foreign matter (unintended foreign matter that can cause injury or discomfort).

7 REQUIREMENTS

7.1 *p*H Value

The *p*H of sanitary pad/pantyliner/maternity pad/period panty (top and absorbent core) shall be from 3.5 to 7.5 when tested by the method given in IS 1390.

'NOTE — If the required weight of the test specimen in not sufficient in one sample, then more no. of samples of the same lot may be taken for testing of the product .

7.2 Ability to Withstand Pressure after Absorption

The sanitary pad/pantyliner/maternity pad/period panty shall absorb coloured distilled water as given in table 2 and it shall not show leakage at the bottom or side edges of the product, when tested according to method given in Annex B.

Table 2 Ability to Withstand Pressure after Absorption for Sanitary Pad/Pantyliner/Maternity Pad/Period Panty

(*Clause* 7.2, Annex B)

Sl No	**Name of product**	**Liquid Absorption (ml),** *Min*
(1)	(2)	(3)
i)	Sanitary pad	30
ii)	Pantyliner	1
iii)	Maternity pad	50
iv)	Period panty	30

7.3 Hygiene Testing Requirement

Total viable count (total number of bacteria and fungi) shall not be more than 1 000 cfu/gm and *Staphylococcus aureus* shall be absent.

7.3.1 *Bacterial and Fungal Bioburden*

The sanitary pad/pantyliner/maternity pad/period panty shall be tested for bacterial and fungal bioburden in accordance with method given in **7.3.1.1**. For selecting sample item portion (SIP), appropriate eluent and methods of extraction; IS/ISO 11737 (Part 1) shall be referred.

7.3.1.1 *Test method*

A sample of 5 gm cut from the centre portion of the sanitary pad/pantyliner/maternity pad/period panty shall be checked for its absorbency in eluent such as 0.85 percent sodium chloride or equivalent medium till it reaches saturation limit. Add eluent either ten times the absorbent quantity of the sanitary pad/pantyliner/maternity pad/period panty or the quantity in which the sanitary pad/pantyliner/maternity pad/period panty completely immerse. The sanitary pad/pantyliner/maternity pad/period panty shall be shaken vigorously in the eluent and the liquid shall be extracted from it. Report the quantity of the eluent used for extraction, time and frequency of shaking in the test report. The extract shall be serially diluted and plated out on respective mediums, that is, plate count agar (PCA) for bacterial bioburden and sabouraud chloramphenicol agar (SCA) for fungal bioburden. Incubate PCA plates at 30-35°C for 24 h and count colonies. Continue incubation upto 72 h, re-examine the plates after 48 h and 72 h, and report the results that have not resulted in overgrowth. Similarly incubate SCA plates at 20-25°C for 3 days and count the fungi. Re-examine after incubation for 5 and 7 days. Report the results from incubation time that does not result in over growth. The typical colony characteristics are shown in Fig. 1.

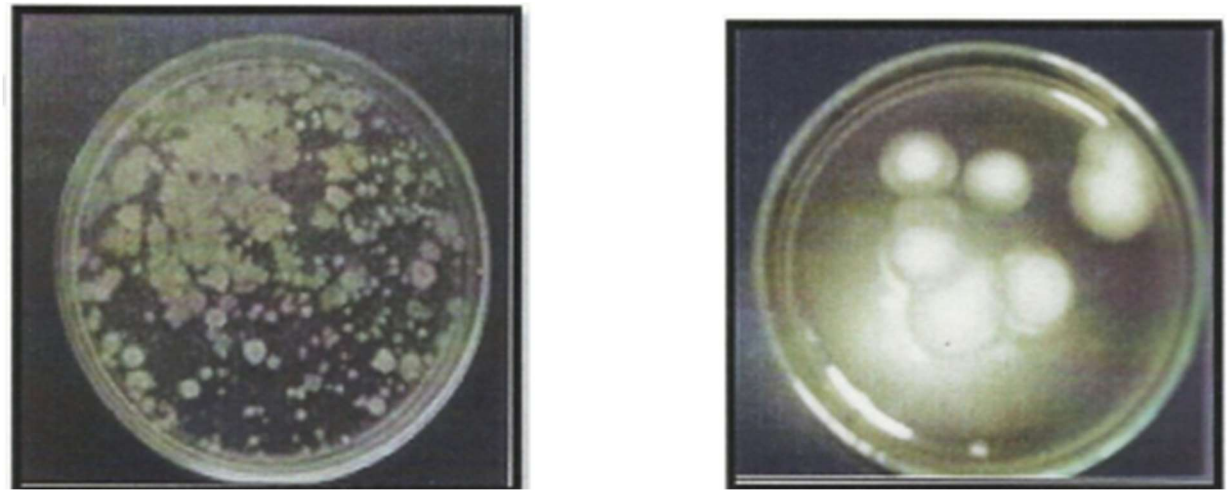
7.3.2 *Test for Common Skin Pathogen — Staphylococcus Aureus*

The sanitary pad/pantyliner/maternity pad/period panty shall be tested for the presence of Staphylococcus aureus in accordance with method given in **7.3.2.1.** For the preparation of medium such as cooked salt medium, baird-parker medium and method for coagulase test; IS 5887 (Part 2) shall be referred.

7.3.2.1 *Test method*

A sample of 5 gm cut from the centre portion of the sanitary pad/pantyliner/maternity pad/period panty shall be completely immersed in appropriate volume of enrichment medium like cooked salt medium or equivalent medium. Incubate for enrichment purpose at 37°C for 24 h. Report the quantity of the medium used for enrichment in the test report. The incubated sample shall be shaken vigorously in the medium and the liquid shall be extracted from the sanitary pad/pantyliner/maternity pad/period panty. The extract shall be streaked onto a Staphylococcal

isolation medium, such as Baird-Parker medium or equivalent and incubated at 37°C for 24 - 48 h and examine for growth. The result is considered positive if black colonies with a narrow white margin, surrounded by a zone of clearance are seen. Suspect colonies must show coagulase activity to confirm presence of Staphylococcus aureus. The typical colony characteristic is shown in Fig. 2.



(A) **(B)**

Fig. 1 Typical Colony Characteristics of Bacterial Bioburden (A) and Fungal Bioburden (B)

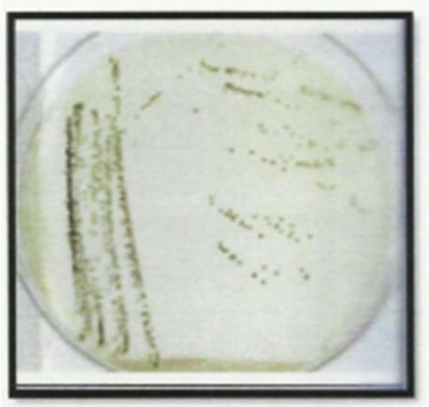


Fig. 2 Typical Colony Characteristics of *Staphylococcus Aureus*

'NOTE — If the required weight of the test specimen under clause 7.3.1.1 and 7.3.2.1 is not sufficient in one sample, then more no. of samples of the same lot may be taken for preparation of test specimen.'

7.3.3 Good Manufacturing Practice Guideline for Hygiene Requirement

The sanitary pad/pantyliner/maternity pad/period panty shall be manufactured under good hygienic conditions. The general guidelines for good manufacturing practice to maintain hygiene requirement at manufacturing facility are given in Annex C.

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

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. The biocompatibility of the material shall be detected by evaluating cytotoxicity, irritation and skin sensitization test as per IS/ISO 10993 Part 5, IS 17932 (Part 7) and IS 17932 (Part 6) respectively.

For cytotoxicity, the material shall show reactivity as ‘non-cytotoxic’ when tested as per IS/ISO 10995 Part 5.

Similarly, the material shall be ‘Non-irritant and Non-sensitizer’ when tested as per IS 17932 (Part 7) and IS 17932 (Part 6) respectively. For preparation of samples for these tests, IS/ISO 10993 Part 12 shall be referred.

7.5 Phthalate Test

The amount of phthalate present in sanitary pad/pantyliner/maternity pad/period panty 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.

7.6 Compostability (Optional)

The manufacturer who are claiming their product as compostable shall pass the test on the final product as per IS/ISO 17088.

7.7 Anti-Bacterial Activity Value (Optional)

If claimed by the manufacturer, the raw material used for the product or final product shall have antibacterial activity value greater than or equal to 2 when tested by the absorption method prescribed in IS/ISO 20743.

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 Lot

All the sanitary pad/pantyliner/maternity pad/period panty of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot.

8.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

8.1.2 The number of sanitary pad/pantyliner/maternity pad/period panty to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, column 3 and column 5 of Table 3.

8.1.3 These sanitary pad/pantyliner/maternity pad/period panty shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

Table 3 Number of Sanitary Pad/Pantyliner/Maternity Pad/Period Panty to be Selected
(*Clause* 8.1.2)

Sl No.	**Lot Size**	**Non-Destructive Testing**		**Destructive Testing**	
		No. of Products to be Selected	Acceptance Number	No. of Products to be Selected	Acceptance Number
	N	*n*	*a*	n_1	a_1
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13	1	5	0
ii)	281 - 500	13	1	5	0
iii)	501 - 1 200	20	1	5	0
iv)	1 201 - 3 200	32	2	8	0
v)	3 201 - 10 000	32	2	8	0
vi)	10 001 - 35 000	50	3	8	0
vii)	35 001 - 150 000	80	5	13	0
viii)	150 001 - 500 000	80	5	13	0
ix)	500 001 and over	125	7	13	0

NOTES —

4) For hygiene testing, biocompatibility evaluation, compostability, anti-bacterial activity test refer clause **8.2.4**, **8.2.5, 8.2.6** and **8.2.7** respectively.

5) The sampling plan given in table 3 is for guidance of manufacturer/user. The other sampling plan may also be followed if agreed between buyer and seller or as per manufacturers quality assurance plans.

8.2 Number of Tests and Criteria for Conformity

8.2.1 All sanitary pad/pantyliner/maternity pad/period panty to be selected as per column 3 of Table 3 shall be examined for workmanship and finish.

8.2.1.1 Any sanitary pad/pantyliner/maternity pad/period panty 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 3. Otherwise, the lot shall be rejected.

8.2.2 Out of the sample already found satisfactory according to **8.2.1.1**, a sub-sample as per column 5 of Table 3 shall be taken. This sub-sample shall be further tested for the remaining requirements.

8.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective sanitary pad/pantyliner/maternity pad/period panty found in the sample (*see* **8.2.2**) is less than or equal to the acceptance number as given in column 6 of Table 3.

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.

8.2.5 The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material for manufacturing the product.

8.2.6 The testing for compostability shall be carried out once for existing products and whenever there is a change in the raw material for manufacturing the product.

8.2.7 The anti-bacterial activity testing shall be carried out once for existing raw material or final product and whenever there is a change in the raw material or source of supply of raw material for manufacturing the product.

9 MARKING

9.1 Each consumer pack shall be legibly and indelibly marked with the manufacturer’s name or trade mark, size, type and number of sanitary pad/pantyliner/maternity pad/period panty contained in the pack in addition to the following:

h) Directions of use;

i) Disposability instructions. The manufacturer shall provide the instruction to users for safe disposal of the product as per *Solid Waste Management Rules*, 2016 or any other rules and regulation published from time to time;
j) Batch/Lot no. and date of manufacturing;
k) The information whether the product is compostable (if applicable).
l) 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);
m) Additional feature of antibacterial (if applicable) ; and
n) Any other information required by law in force or agreed between the buyer and the seller.

9.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the Bureau of Indian Standards Act, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

10 PACKING

Sanitary pad/pantyliner/maternity pad/period panty shall be packed in rigid or flexible packages that protect the product from contaminants during shipment and storage. This package could be constructed of materials, such as carton board, polyethylene, polypropylene, polyester or other safe materials that provide sufficient protection to the product. The package should be free of any torn or damaged areas.

ANNEX A
(*Clause* 2)
LIST OF REFERRED STANDRDS

IS No./Other Publication	*Title*
758 : 2023	Specification for cotton gauze, absorbent, non-sterilized (*fourth revision*)
1390 : 2022/ ISO 3071 : 2020	Textiles — Determination of *p*H of aqueous extract (*third revision*)
4905 : 2015	Random sampling and randomization procedures (*first revision*)

5887 (Part 2) : 1976	Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of Staphylococcus aureus and faecal Streptococci (*first revision*)
9873 (Part 6) : 2021/ ISO 8124-6 : 2018	Safety of toys Part 6 Determination of certain phthalate esters in toys and children's products (*first revision*)
17932 (Part 6) : 2023	Biological evaluation of medical devices Part 6 Tests for skin sensitization
17932 (Part 7) : 2024	Biological evaluation of medical devices Part 7 Tests for irritation
IS/ISO 10993-5 : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 10993-12 : 2021	Biological evaluation of medical devices Part 12 Sample preparation and reference materials
IS/ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
IS/ISO 17088 : 2021	Compostable plastics — Specification (*second revision*)
IS/ISO 20743 : 2021	Textiles — Determination of antibacterial activity of textile products (*first revision*)

ANNEX B

(*Clause* 7.2)

METHOD FOR DETERMINATION OF ABILITY TO WITHSTAND PRESSURE AFTER ABSORPTION

B-1 TEST PROCEDURE

Lay the sanitary pad/pantyliner/maternity pad/period panty on a flat level transparent surface, so that underside of sanitary pad/pantyliner/maternity pad/period panty can be observed. Drip at the rate of 1 ml (pantyliner)/5 ml (other

product) per min, coloured distilled water as given in table 2 maintained at temperature of 27°C ± 2°C on to the centre of the sanitary pad/pantyliner/maternity pad/period panty from a height of 1-2 mm. After the sanitary pad/pantyliner/maternity pad/period panty has absorbed full amount of coloured distilled water, keep a standard weight of 1 kg for 1 min on the portion where coloured distilled water was absorbed. Observe the bottom and side edges of sanitary pad/pantyliner/maternity pad/period panty for any leak through. Test sample passes if liquid does not leak through and fails if liquid leak through.

'NOTES —

3) The dimension of 1 kg weight should have length and width of 150 mm x 50 mm with a tolerance of ± 1 mm.
4) For period panty, cut along the lateral seam on both the sides (left and right) and then lay the period panty flat for absorbency testing.'

B-2 Add 0.01 g colour of Bromocresol Purple (Grade – Chemical analytical grade or equivalent) in 1 000 ml of distilled water and stir evenly to get uniform coloured solution.

ANNEX C

(*Clause* 7.3.3)

GOOD MANUFACTURING PRACTICE FOR HYGIENE REQUIREMENT

Maintaining hygiene at production facility is essential for ensuring products are appropriate for consumers use. Following are recommended guidelines for ensuring hygiene at facilities:

i) Location should be free from objectionable odours, smoke, dust and other contaminants.
j) Separate areas shall be demarcated for storing raw materials, production and final product storage.
k) Separate area shall be demarcated for storing personal effects and personal protective equipment of unit workers to minimize risk of contamination.
l) Toilet and hand-washing station shall be positioned away from storage/production area.
m) Provision of 70 percent isopropyl alcohol (IPA) solution for hand sanitization inside the production facility.
n) Appropriate lighting and proper ventilation of the facility shall be ensured.
o) Flooring shall be either concrete, tiled or with chips to ensure ease of cleaning. Floors, walls, ceilings, doors and windows shall be easy to clean and without crevices or openings that shall not allow accumulation of dirt.
p) Regular pest control measures shall be put in place.
j) Adequate receptacles for disposing waste generated within the facility shall be made available and shall be frequently emptied and cleaned.

k) Poster/sign encouraging safety and hygiene practices like use of personal protective equipment, use of hand sanitizer etc. shall be displayed.

m) Pre-packaged finished product shall be checked thoroughly and ensured to be free from foreign particles, dirt, hair, and other visible contaminants.

n) Hand hygiene shall be practised during manufacturing.

p) A cleaning and maintenance schedule shall be drawn up for cleaning of the facility, toilets, washing areas, waste receptacles and for cleaning/disinfection of the equipment

ANNEX 6

(Item 5.2)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

IS 17334 : 2019, MEDICAL TEXTILES — SURGICAL GOWNS AND SURGICAL DRAPES — SPECIFICATION

a) EXTRACT OF THE MINUTES OF 23RD MEETING OF TXD 36 HELD ON 04 AUGUST 2023

After deliberation, the committee decided that the following changes shall be incorporated in draft revision of IS 17334: -

i) The title of the standard is to be updated as 'Medical and Surgical Gowns and Surgical Drapes — Specification'.
ii) The levels given in the standard are to be updated as 1, 2, 3 and 4 (instead of the present 0, 1, 2, and 3) for both gowns and drape.
iii) The Isolation gown and patient gown are to be included in the existing standard. In Isolation gowns the critical area is the entire gown including the back and the joints and a diagram of critical definition is to be included. For a patient gown, following note is to be included under performance table: -

The patient gown shall confirm level 1 of table 1, If agreed by the buyer and seller.

iv) It was suggested that the dry and wet microbial tests are not required for level 4 gown and drapes.
v) It was suggested that cleanliness–microbial (CFU/100 cm^2) test is required in case of unsterile gown and drapes.
vi) A clarification note to be put up under performance table 1 in case of gown for level 4 when a sample fails in blood resistance test, viral tests shall not be carried out and the sample shall be reported as non-compliance/failure to the standard.
vii) The blood resistance and viral resistance test for gown (level 4) shall be performed for pressure cycle upto 14 kPa, procedure D as per IS 16546 and IS 16545 respectively.
viii) Impact penetration test for level 2 and level 3 (≤ 1.0 g) gown and drapes shall be included as per IS 17375: 2020/ISO 18695 : 2007.
ix) In hydrostatic resistance (cmwc) test, the rate of rising is performed at 60 cmWc/min.

x) In particle release [log10 (lint count)], the particle size range is to be mentioned as 3 micrometer to 25 micrometer when testing as per IS 15891 part 10.

xi) Breathability test (water vapour transmission rate), [g/m2/day, *Max*] - 800 as per Annex F of IS 16390 is to be included in level 4 as an optional requirement.

xii) The general guidelines/recommendations to use different levels of medical protective gown/drape for healthcare application and surgeries in hospitals are provided as follows : -

General Guidelines / recommendations for use of different levels of Medical protective Gowns & Drapes (for guidance only):

Performance Level	**Anticipated risk of exposure**
Level 1	• Minimal risk to the patient independent of anesthesia • Minimally invasive procedures with little or no body fluid loss • Often done in an office setting with the operating room principally for anesthesia and monitoring
Level 2	• Minimal to moderately invasive procedure • Mild body fluid loss • Mild risk to patient independent of anesthesia
Level 3	• Moderate to significantly invasive procedure • Moderate body fluid loss • Moderate risk to patient independent of anesthesia
Level 4	• Highly invasive procedure • High body fluid loss • Major/critical risk to patient independent of anesthesia • Usual post-operative ICU stay with invasive monitoring

xiii) The requirement of resistance to dry and wet bacterial penetration test may be included in level 2 and level 3. The committee requested SITRA to suggest the optimum value based on testing of

samples/practical significance of protection to user/International Practice within 15 days. It was requested that following stakeholders send samples to SITRA for testing of dry and wet bacterial penetration test: -

e) Dr. Sanjiiv Rehlan, FICCI/PWMAI (Shalex Overseas), New Delhi
f) Shri Sumit Marwah, Dispoline India Private Limited, Bengaluru
g) Shri Khalil Khan, Surya Textech, Chandigarh
h) Shri Apurva Ranka, Alpha Foam Private Limited, Pune

Member Secretary may co-ordinate with Dr. Santhani, SITRA for additional information and applicable values for resistance to dry and wet bacterial penetration test.

xiv) The requirement of cytotoxicity in biocompatibility test is to be updated as 'non-cytotoxic' .

xv) It was decided that the size of gown and drape shall be as per agreement between the buyer and the seller. The size of gown shall be designated based on the measurement of height and chest. In case of elastic cuff/waist, it should have proper fit and should be adhered with glue to minimize risk of exposure.

xvi) Reference to Indian standard shall be updated.

xvii) Amendment 1 shall be incorporated.

xviii) Any other editorial changes.

Based on the above changes, BIS shall prepare the revised draft of IS 17334 and the same shall be issued in wide circulation for a period of **two months** for eliciting technical comments from stakeholders. BIS may carry out the editorial changes in the draft if required.

b) Dr. R. Radhai, SITRA

Test Results report received from SITRA in last 6 months on wet bacterial penetration test

1. The results of the surgical gown tested as per IS 16545, IS 16548 and IS 16549.

Sample Particulars	**VPRT**	**DMPRT**	**WBPRT**
Pass criteria	**(pass or fail)**	**<2 log CFU or <300 CFU**	**6**

91 GSM White Non woven fabric	Pass at 14KPa	<2 CFU	5.8
66 GSM White Breathable fabric	Pass at 14KPa	<2 CFU	5.4
66 GSM Green Breathable Fabric	Pass at 14KPa	<2 CFU	5.3
Nanoparticles coated Breathable viral barrier fabric	Pass at 20KPa	<2 CFU	5.8
High performance Breathable sterile	Pass at 20KPa	<2 CFU	5.81
Surgical gown Reinforced fabric	Pass at 14KPa	<2 CFU	4.36
43 Spunmelt medical blue	Pass at 14KPa	<2 CFU	5.2
50 Spunmelt medical blue	Pass at 20KPa	<2 CFU	5.88
Hyh-mayo cover reinforced zone	Pass at 14KPa	<2 CFU	5.06
43 GSM SMMS Fabric	Pass at 14KPa	<2 CFU	5.73
Surgical gown 35GSM	Pass at 7KPa	<2 CFU	3.72

Disposable Surgical gown	Pass at 14KPa	<2 CFU	5.67
Disposable surgical drape	Pass at 14KPa	<2 CFU	4.59
Non-reinforced gown	Pass at 14KPa	<2 CFU	4.83
Non-reinforced gown	Pass at 14KPa	<2 CFU	5.06
SMS Laminated Gown	Pass at 14KPa	<2 CFU	4.81
SSMMS Laminated Gown	Pass at 14KPa	<2 CFU	5.53
Absorbent Laminated Gown	Pass at 14KPa	<2 CFU	5.47
59 GSM with inner film	Pass at 20KPa	<2 CFU	5.07
83 GSM coverall	Pass at 20KPa	<2 CFU	5.62
75 GSM Laminated Gown	Pass at 20KPa	<2 CFU	4.83
SMMS 43 GSM laminated Reinforced gown	Pass at 20 KPa	<2 CFU	5.78
SMMS 43 GSM Non-reinforced gown	Pass at 14KPa	<2 CFU	5.02
43 GSM gown Reinforced	Pass at 20KPa	<2 CFU	5.67

43 GSM Reinforced gown	Pass at 20KPa	<2 CFU	5.92
43 GSM gown Non-Reinforced	Pass at 20KPa	<2 CFU	5.43

ANNEX 7

(Item 5.2)

DRAFT AMENDMENT FOR APPROVAL FOR WIDE CIRCULATION

IS 17334 : 2019 MEDICAL TEXTILES — SURGICAL GOWNS AND SURGICAL DRAPES — SPECIFICATION

भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDRADS

Draft for comments only Doc No.: TXD 03 (XXXXX)

PROPOSED DRAFT AMENDMENT NO. 2 SEPTEMBER 2024

TO

IS 17334 : 2019 MEDICAL TEXTILES — SURGICAL GOWNS AND SURGICAL DRAPES — SPECIFICATION

[(*Page* 3, *Table* 1*, Sl no. (x), column* 5)] — Substitute '≥ 2.8 (for critical zones)' for '6.0 (for critical zones).'

[(*Page* 3, *Table* 2*, Sl no. (ix), column* 5)] — Substitute '≥ 2.8 (for critical zones)' for '6.0 (for critical zones).'

[(*Page* 3, *Table* 1*, Sl no. (xi), column (3) to column (6)*)] — Substitute 'non-cytotoxic' for 'None'.

[(*Page* 3, *Table* 2*, Sl no. (x), column (3) to column (6)*)] — Substitute 'non-cytotoxic' for 'None'.

ANNEX 8

(Item 5.2)

DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION

IS 17334 : 2019, Medical Textiles — Surgical Gowns and Surgical Drapes — Specification

भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDRADS

Draft for comments only Doc No.: TXD 36 (xxxxx)
xxxxx 2024

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भारतीय मानक **मसौदा**

चिकित्सीय वस्त्रादि — चिकित्सीय एवं सर्जिकल गाउन एवं सर्जिकल ड्रैप — विशिष्ट

(IS 17334 का *पहला पुनरीक्षण*)

Draft *Indian Standard*

Medical Textiles — Medical and Surgical Gowns and Surgical Drapes — Specification
(*First Revision* of IS 17334)

ICS 11.140; 59.080.01

Technical Textiles for Medtech Applications Sectional Committee, TXD 36

last date for receipt of comments is XXXX 2024

FOREWORD

(Formal clauses will be added later)

Surgical gowns and surgical drapes are intended to be used to minimize the transmission of infective agents between patients and clinical staff during the surgical and other invasive procedures.

This standard addresses the performance of surgical gowns and surgical drapes designed to protect against exposure of healthcare workers to blood, body fluids, and other potentially infectious materials during surgery and other

healthcare procedures. This standard defines testing and reporting performance requirements levels for surgical gowns and surgical drapes manufacturers in order to provide information to end users that can be used in making informed decisions in the selection and purchase of surgical gowns and surgical drapes according to the anticipated exposures.

This standard was originally published in 2019. The present revision has been made in the light of experience gained since its first adoption and to incorporate the following major changes:

i) Amendment has been incorporated in this standard.
ii) Title of the standard has been updated.
iii) The levels given in the standard for surgical gown and surgical drape have been updated.
iv) The requirement of patient gown and isolation gown have been specified.
v) The requirement for blood resistance, particle release, cleanliness–microbial, biocompatibility evaluation (cytotoxicity) have been updated.
vi) The requirement for viral resistance test has been updated for level 4 gown.
vii) The requirement of impact penetration test has been specified for level 2 and level 3 surgical gown and surgical drapes.
viii) The requirement of resistance to dry and wet bacterial penetration test have been updated for level 2 and level 3 surgical gown and surgical drape.
ix) The requirement of breathability test (water vapour transmission rate) has been modified.
x) The general guidelines/recommendations to use different levels of surgical gown and surgical drape have been updated.
xi) References to Indian Standard have been updated.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*).’ The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Draft *Indian Standard*

Medical Textiles — Medical and Surgical Gowns and Surgical Drapes — Specification
(*First Revision* of IS 17334)

1 SCOPE

1.1 This standard specifies requirements for single use and reusable surgical gowns and surgical drapes intended for medical use.

1.2 This standard is intended to be used primarily by manufacturers of surgical gowns and surgical drapes in qualifying, classifying, packaging, labelling, and sterilization of surgical gowns and surgical drapes, so that healthcare workers can make more informed decisions of selection of right surgical gown and surgical drape in accordance with the protection level and risk involved in the procedure.

1.3 This standard does not include universal procedure packs designed for specific procedures, however, contents of customized procedure packs shall be manufactured in accordance with this standard.

2 REFERENCES

The standards listed in Annex A contain provisions which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated are 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.

3 TERMS AND DEFINITIONS

For the purposes of this standard, the following terms shall apply:

3.1 Barrier Properties — Ability of a protective material to resist the penetration of liquids and resistance to airborne and liquid borne microorganisms at different state (*see* **3.9** and **3.24**).

3.2 Biocompatibility — The ability to be in contact with a living system without producing an adverse effect.

3.3 Blood-borne Pathogen — Infectious microorganisms including virus carried in blood or other body fluids.

3.4 Body Fluids — Any liquid produced (secreted/ excreted) by body.

3.5 Colony Forming Unit (CFU) — Unit by which culturable number of microorganisms is expressed.
3.6 Cleanliness–microbial — Freedom from population of viable microorganism on a product and/ or a package.

3.7 Cleanliness–particulate Matter — Freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact.

3.8 Critical Product Area — Product area with a greater probability to be involved in the transfer of infective agents to or from the wound, for example, front and sleeves of surgical gowns.

3.9 Dry Microbial Penetration — Migration of microorganisms through a barrier material in dry state.

3.10 Infective Agent — Microorganism that has been shown to potentially cause infections.

3.11 Invasive Surgical Procedure — Surgical procedure penetrating skin or mucosa

3.12 Less Critical Product Area — Product area where direct contact with blood, body fluids, and other potentially infectious materials (OPIMs) is less likely to occur.

3.13 Liquid Penetration — Migration of liquid(s) through the material.

3.14 Manufacturer — Means processing of raw material or inputs in any manner that results in emergence of a new product having a distinct name, character and use. The term "manufacturer" shall be construed accordingly.

3.15 Microbial Penetration — Migration of microorganisms, from one side of the material through the other.

3.16 Particle Release — Particle release from fiber fragments and other particles during mechanical stress.

3.17 Performance Level — Discrete standard defined to classify products according to the performance requirements of this standard.

3.18 Reusable Product — Product intended by the manufacturer to be reprocessed and reused.

3.19 Single-use Product — Product intended by the manufacturer to be used only once.

3.20 Sterile Field — An area created by placing sterile surgical drapes around the patient's surgical site and on the stand that will hold sterile instruments and other items needed during surgery.

3.21 Surgical Gown — Protective clothing that is intended to be worn by healthcare workers during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate matter.

3.22 Surgical Drape — A covering for the patient for the prevention of transfer of infective agents, such as microorganisms, body fluids and particulate material. "Surgical drapes are used during surgery to prevent contact with unprepared surfaces and to maintain the sterility of environmental surfaces, equipment and the patient's surroundings".

3.23 Synthetic Blood — Mixture of red dye/surfactant, thickening agent, and distilled water having a surface tension and viscosity representative of blood and other body fluids and the colour of blood.

3.24 Wet Microbial Penetration — Migration of microorganisms through a barrier material in wet state.

4 WORKMANSHIP AND FINISH

4.1 A manufacturing and processing specification shall be designed and validated for the product, including visual and hygienic cleanliness. The validation shall include all steps involved in manufacturing and processing.

4.2 The key manufacturing and processing variables shall be identified, monitored and recorded. The type and frequency of routine monitoring shall be documented.

4.3 During manufacturing and processing, the control of decontamination, disinfection procedures and the traceability of sterilization shall be maintained.

'NOTE — The requirements given in 4.1 to 4.3 are for guidance of the manufacturer. Reference may also be made to the Medical Devices Rules 2017.'

5 GENERAL REQUIREMENTS

5.1 The size of gown and drape shall be as per agreement between the buyer and the seller. The size of gown shall be designated based on the measurement of height and chest. In case of elastic cuff/waist, it should have proper fit and should be adhered with glue to minimize risk of exposure.

5.1.1 Product (s) shall meet all the requirements specified in this standard throughout their useful life. If the manufacturer does not specify critical and/or noncritical area of a product, the product shall meet at least level "1" performance requirements as given in Table 1 and Table 2.

5.2 Manufacturing and Processing Requirements and Documentation

5.2.1 The manufacturer shall establish a formal quality management system including requirements for the product development, design, production, testing, packaging, labeling, distribution and provision of related services as per medical device rules, 2017 for surgical gown and surgical drape. The quality management system shall include a risk management procedure where inputs for product realization shall include the outputs from risk management.

5.2.2 For reusable products, processing and lifecycle control shall be included in the quality management system. The requirements specified in this standard shall be met and documented that the fitness for the intended purpose has been established for each use, both for single-use and reusable surgical gowns and surgical drapes.

5.2.3 Microbiological monitoring (as per ISO 14698-1), air monitoring of clean room (as per ISO 14644-1), sterilization (as per IS/ISO 11135), packaging [as per IS/ISO 11607 (Part 1 and Part 2)], validation [as per IS/ISO

11137 (Part 1 and 2), ISO 11138-t 7] and residual sterility (IS/ISO 10993-7) shall be maintained by the manufacture.

'NOTE — The requirements given are for guidance of the manufacturer. Reference may also be made to the Medical Devices Rules 2017.'

5.3 Barrier Properties

The final performance requirement level shall be based on the performance of the critical zone component. The classification of the product shall indicate the performance of the critical zone component having the lowest barrier performance. The information for principle of critical area for guidance has been given in Annex B.

The performance of seams between and within critical zones shall meet the requirements of this standard. The performance of seams between critical and less critical zones shall meet at least the requirements of the adjacent less critical zone. Non-critical areas of the surgical gowns and surgical drapes can have one level less as compared to the standard earmarked for the surgical gowns and surgical drapes.

The performance requirements of reusable products shall have to be met after declared wash cycle.

6 PERFORMANCE REQUIREMENTS

6.1 The manufacturer shall ensure the maintenance of required performance level after sterilization of the material and testing shall be performed on the finished product. If the product is intended to be used after sterilization, testing shall be carried out on products after sterilization with the exception of microbial cleanliness.

Test specimens shall be taken from different products of the same lot. If multiple tests are to be performed (for example, the critical zone consists of more than one component, such as the base material, a seam, and a point of attachment), then test specimens for each component may be taken from the same product.

If the test area of the finished product is too small to perform the test, a representative sample of the same material may be used. The representative sample shall be treated in the same way as the finished product.

During manufacture and processing, testing shall be carried out within a formal quality system.

6.2 Surgical gowns and surgical drapes shall conform to the requirements specified when tested according to the method given in Table 1 and Table 2 respectively.

6.3 The general guidelines/recommendations to use different levels of surgical gown/surgical drape for healthcare application and surgeries in hospitals have been given in Table 3.

7 MARKING

7.1 Each pack of surgical gown/surgical drape shall be legibly and indelibly marked with following information:

a) Name of the product ;

b) Dimension /size of the product;

c) Manufacturer's name, initials or trade-mark, if any;

d) Month and year of manufacture, batch /lot number;

e) Sterilized or un-sterilized (or) it can be sterile or unsterile;

f) Method of sterilization and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization;

g) An indication that the device has been specified by the manufacturer for single-use only;

h) If the product is multiple use, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of reuses. Where products are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the device will still comply with "the essential principles of safety and performance of medical devices";

j) Performance level; and

k) Any other statutory requirement as required by the law in force.

Table 1 Performance Requirements for Surgical Gowns

(*Clauses* **5.1, 6.2, 8.1.1, 8.2.2** and **9.1**)

Sl No.	**Characteristics**	**Requirement**				**Method of Test,**
		Level 1	Level 2	Level 3	Level 4	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
i)	Impact penetration (g)	≤ 4.5	≤ 1.0	≤ 1.0	NA	IS 17375
ii)	Hydrostatic resistance (cmwc) the rate of rising at 60 cmWc/min	NA	≥ 20	≥ 50	NA	IS 391
iii)	Blood resistance, pressure cycle upto	NA	NA	NA	Pass	IS 16546

	14 kPa, procedure D					
iv)	Viral resistance, pressure cycle upto 14 kPa, procedure D	—	—	—	Pass	IS 16545
v)	Particle release [log10 (lint count)] Particle size from 3.0 to 25.0 Microns	≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0	IS 15891 (Part 10)
vi)	Tensile strength (dry and wet) (N)	≥ 20	≥ 20	≥ 20	≥ 20	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)
vii)	Bursting strength (dry and wet) (kPa)	≥ 40	≥ 40	≥ 40	≥ 40	IS 1966 (Part 1)
viii)	Cleanliness– microbial (CFU/100 cm^2) (for unsterile gown)	≤ 300	≤ 300	≤ 300	≤ 300	IS/ISO 11737-1
ix)	Resistance to microbial penetration — Dry (CFU)	NA	≤ 300 (for less critical zones)	≤ 300 (for less critical zones)	NA	IS 16548
x)	Resistance to microbial penetration — Wet (I_B)	NA	≥ 2 (for critical zones)	≥ 2 (for critical zones))	—	IS 16549
xi)	Biocompatibility Evaluation Test *(see Note)					
	a) Cytotoxicity	non-cytotoxic	non-cytotoxic	non-cytotoxic	non-cytotoxic	IS/ISO 10993-5
	b) Irritation	Non-irritant	Non-irritant	Non-irritant	Non-irritant	IS 17932 (Part 7)
	c) Skin sensitization	Non - sensitizer	Non - sensitizer	Non - sensitizer	Non - sensitizer	IS 17932 (Part 6)

xii)	Breathability test (water vapour transmission rate), [g/m2/day, *Max*]	NA	NA	NA	800	Annex F of IS 16390
*Remarks: Confirm the biocompatibility of raw material at designed stage for all levels. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product.						

NOTES —

1) The patient gown shall confirm level 1 of table 1, If agreed by the buyer and seller. In Isolation gowns the critical area is the entire gown including the back and the joints.
2) In case of gown for level 4 when a sample fails in blood resistance test, viral tests shall not be carried out and the sample shall be reported as non-compliance/failure to the standard.

Table 2 Performance Requirements for Surgical Drapes
(*Clauses* **5.1, 6.2, 8.1.1** and **8.2.2**)

Sl No.	**Characteristics**	**Requirement**				**Method of Test,**
		Level 1	Level 2	Level 3	Level 4	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
i)	Impact penetration (g)	≤ 4.5	≤ 1.0	≤ 1.0	NA	ISO 18695
ii)	Hydrostatic resistance (cmwc), the rate of rising at 60 cmWc/min	NA	≥ 20	≥ 50	≥ 100	ISO 811
iii)	Blood resistance pressure cycle upto 14 kPa, procedure D	NA	NA	NA	Pass	IS 16546
iv)	Particle release [log10 (lint count)], Particle size from 3.0 to 25.0 Microns	≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0	IS 15891 (Part 10)
v)	Tensile strength (dry and wet) (N)	≥ 20	≥ 20	≥ 20	≥ 20	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)

vi)	Bursting strength (dry and wet) (kPa)	≥ 40	≥ 40	≥ 40	≥ 40	IS 1966 (Part 1)
vii)	Cleanliness– microbial (CFU/100 cm^2) (for unsterile drape)	≤ 300	≤ 300	≤ 300	≤ 300	ISO 11737-1
viii)	Resistance to microbial penetration — Dry (CFU)	NA	≤ 300 (for less critical zones)	≤ 300 (for less critical zones)	NA	IS 16548
ix)	Resistance to microbial penetration — Wet (I_B)	NA	≥ 2 (for critical zones)	≥ 2 (for critical zones))	—	IS 16549
x)	Biocompatibility evaluation * (see Note)	-	-	-	-	
	a) Cytotoxicity	non-cytotoxic	non-cytotoxic	non-cytotoxic	non-cytotoxic	IS/ISO 10993-5
	b) Irritation	Non-irritant	Non-irritant	Non-irritant	Non-irritant	IS 17932 (Part 7)
	c) Skin sensitization	Non - sensitizer	Non - sensitizer	Non - sensitizer	Non - sensitizer	IS 17932 (Part 6)

* Remarks: Confirm the biocompatibility of raw material at designed stage for all levels. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product.

Table 3 General Guidelines/Recommendations for Use of Different Levels of Surgical Gowns/Surgical Drapes

(*Clause* 6.3)

Performance Level	**Anticipated risk of exposure**

Level 1	• Minimal risk to the patient independent of anesthesia • Minimally invasive procedures with little or no body fluid loss • Often done in an office setting with the operating room principally for anesthesia and monitoring
Level 2	• Minimal to moderately invasive procedure • Mild body fluid loss • Mild risk to patient independent of anesthesia
Level 3	• Moderate to significantly invasive procedure • Moderate body fluid loss • Moderate risk to patient independent of anesthesia
Level 4	• Highly invasive procedure • High body fluid loss • Major/critical risk to patient independent of anesthesia • Usual post-operative ICU stay with invasive monitoring

Each product or package, containing surgical gowns, surgical drapes, having a critical area shall be prominently labeled identifying the areas with different performance levels and the performance level of the relevant area(s).

Labelling and marking requirements shall be followed as per Medical Device Rules, 2017.

7.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 Lot

All the surgical gowns or surgical drapes of the same material and dimensions produced under similar conditions of manufacture and sterilization shall constitute a lot.

8.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

NOTES

1 For level 1, 2, 3 and 4 surgical gowns, the conformance of the performance requirements as given in Table 1 may be accepted at fabric stage (except cleanliness microbial, resistance to blood and resistance to viral) for a product if desired by buyer/ user. In such cases, the traceability certificate for conformance of the performance requirement of fabric shall be maintained by the product manufacturer for each lot.

2 Similarly, for level 1, 2, 3 and 4 surgical drapes, the conformance of the performance requirements as given in Table 2 may be accepted at fabric stage (except cleanliness microbial and resistance to blood) for a product if desired by buyer/user. In such cases, the traceability certificate for conformance of the performance requirement of fabric shall be maintained by the product manufacturer for each lot.

8.1.2 The number of surgical gowns or surgical drapes to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 1, 2 and 4 of Table 4.

8.1.3 These surgical gowns/ surgical drapes shall be selected at random from the lot as per procedure given in IS 4905.

8.2 Number of Tests and Criteria for Conformity

8.2.1 All the surgical gowns/surgical drapes as per column 2 of Table 4 shall be examined for workmanship and finish (**4.1** to **4.3**).

8.2.1.1 Any surgical gowns/ surgical drapes 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 3 of Table 4. Otherwise, the lot shall be rejected.

Table 4 Number of Surgical Gown/ Surgical Drape to be selected
(*Clauses* **8.1.2, 8.2.1, 8.2.1.1, 8.2.2** and **8.2.3)**

Sl No.	**Lot Size**	**Non-destructive Testing**		**Destructive Testing**	
		No. of Gown/Drape to be Selected	Acceptance Number	No. of Gown/Drape to be Selected	Acceptance Number
	N	N	a	n_1	a_1
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 50	5	0	2	0
ii)	51 to 150	8	0	3	0
iii)	151 to 280	13	1	3	0
iv)	281 to 500	20	2	3	0
v)	501 to 1 200	32	3	5	0
vi)	1 201 to 3 200	50	5	5	0

vii)	3 201 and above	80	7	5	0

NOTE - The sampling plan given in table 4 is for guidance of manufacturer/user. The other sampling plan may also be followed if agreed between buyer and seller or as per manufacturers quality assurance plans.

8.2.2 Out of the sample already found satisfactory according to **8.2.1.1**, a sub-sample as per column 4 of Table 4 shall be taken. This sub-sample shall be further tested for the remaining requirements as given in Table 1 and Table 2.

8.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective surgical gowns/ surgical drapes found in the sample (as per **8.2.2**) is less than or equal to the acceptance number as given in column 5 of Table 4.

9 EDUCATION

The manufacturer may provide technical information and/or training explaining the performance level classification system and its implications for the end user. Thereafter, the end-user is responsible for making judicious selections of products according to:

a) the performance level of the product, and

b) the anticipated degree of exposure of health care personnel to blood, body fluids, and OPIM during a given procedure or activity.

'NOTE — The requirements given are for guidance of the manufacturer and user.'

9.1 Information on Critical and Less Critical Areas

The manufacturer shall differentiate between the critical and less critical areas of the product, if applicable, and identify the different areas.

10 PACKAGING AND STERILIZATION

For packaging of the products, requirements as per IS/ ISO 11607-1 and 2 shall be followed.

For packaging and sterilization, the Medical Device Rule, 2017 shall be followed.

Validation of sterilization process shall be done as per IS/ISO 11135, IS/ISO 11137 -1 and 2, ISO 11138-7 and, IS/ISO 10993-7 standards.

ANNEX A
(*Clause* **2**)

LIST OF REFERRED STANDARDS

IS/Other Publication	*Title*
IS 391 : 2020/ISO 811 : 2018	Textile fabrics — Determination of resistance to water penetration — Hydrostatic pressure test (*second revision*)
IS 1966 (Part 1) : 2022 /ISO 13938-1 : 2019	Textiles — Bursting properties of fabrics Part 1 Hydraulic method for determination of bursting strength and bursting distension (*third revision*)
IS 1969 (Part 1) : 2018 /ISO 13934-1 : 2013	Textiles — Tensile properties of fabrics: Part 1 Determination of maximum force and elongation at maximum force using the strip method (*fourth revision*)
IS 4905: 2015/ISO 24153 : 2009	Random sampling and randomization procedures (*first revision*)
IS 15891 (Part 3): 2011/ISO 9073-3 : 1989	Textiles — Test methods for nonwovens: Part 3 Determination of tensile strength and elongation
IS 15891 (Part 10): 2017/ISO 9073-10 : 2003	Textiles — Test methods for nonwovens: Part 10 Lint and other particles generation in dry state
IS 16390 : 2015	Agro textiles — Nylon knitted seamless gloves for tobacco harvesters — Specification
IS 16545 : 2016/ISO 16604 : 2004	Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X174 bacteriophage
IS 16546 : 2016/ISO 16603 : 2004	Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood
IS 16548 : 2016/ISO 22612 : 2005	Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration

IS 16549 : 2020/ISO 22610 : 2018	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration (*first revision*)
IS 17375 : 2020/ISO 18695 : 2007	Textiles — Determination of resistance to water penetration — Impact penetration test
IS 17932 (Part 6) : 2023	Biological evaluation of medical devices Part 6 Tests for skin sensitization
17932 (Part 7) : 2024	Biological evaluation of medical devices Part 7 Tests for irritation
IS 18469 (Part 7) : 2023 /ISO 11138-7 : 2019	Sterilization of health care products — Biological indicators Part 7 Guidance for the selection use and interpretation of results
IS/ISO 10993-5: 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 10993-7: 2018	Biological evaluation of medical devices Part 7 Ethylene oxide sterilization residuals
IS/ISO 11137-1: 2006	Sterilization of health care products — Radiation: Part 1 requirements for development, validation and routine control of a sterilization process for medical devices
IS/ISO 11137-2: 2013	Sterilization of health care products — Radiation: Part 2 establishing the sterilization dose
IS/ISO 11135: 2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
IS/ISO 11607-1: 2019	Packaging for terminally sterilized medical devices Part 1 Requirements for materials, sterile barrier systems and packaging systems (*first revision*)
IS/ISO 11607-2: 2019	Packaging for terminally sterilized medical devices Part 2 Validation requirements for forming, sealing and assembly processes (*first revision*)
IS/ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
ISO 14698-1: 2003	Cleanrooms and associated controlled environments — Bio contamination control — Part 1: General principles and methods

ISO 14644-1: 2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration

ANNEX B
(*Clause* **5.3**)

B-1 PRINCIPLES OF THE CRITICAL ZONE

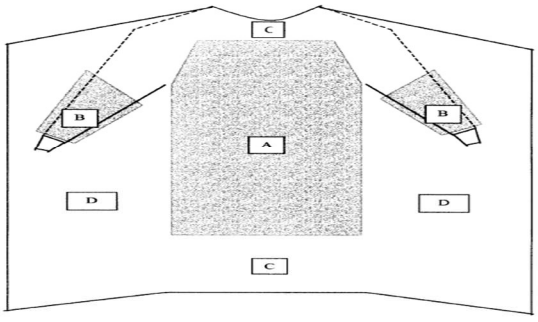
The critical zone can be described as an area approximately 12 inches around the fenestration of a drape where it is thought that reinforcement is needed to resist the penetration and strike through of fluids. Additionally, the critical zone (see Fig. 1) on surgical gown encompasses the front area from mid-chest to waist and the sleeves to 2 inches above the elbows.

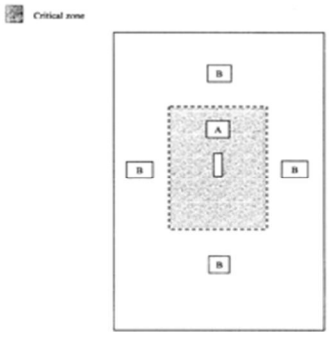
However, there are two important factors as related to the critical zone. Fluid is often not always contained in the proximity of the critical zone. For example, during an arthroscopic procedure a large amount of fluid can be used during the procedure and is not contained within the critical zone of the arthroscopic drape.

Specialty drapes, such as extremity drapes, may have a reinforced critical zone (*see* Fig. 2). However, due to the amount of fluids that may be encountered and/or manipulation of the body parts the surgical team should consider draping reinforcement of the areas outside of the critical zone. For example, during a hip arthroplasty, the leg is placed through several maneuvers to initially dislocate the joint, facilitate bone excision and placement of the prostheses, put the joint back into place, and further maneuvers to test the prostheses prior to closing the surgical wound. This calls for draping reinforcement of the entire leg and foot in order to prevent an SSI.

In this situation, it may be considered that the critical zone should be further expanded outside of the manufacturers region of reinforcement around the fenestration, thus further suggesting that the critical zone is a fluctuating zone that dependent on the procedure to be performed.

The final performance requirement level of the product shall be based on the performance of the critical zone component.





A and B - Critical zone
C and D - Less critical zone

FIG. 1 SURGICAL GOWN

A - Critical zone
B - Less critical zone

FIG. 2 SURGICAL DRAPE

ANNEX 9

(Item 6.1)

COMMENTS ON PUBLISHED STANDARDS

IS 17509 : 2021, DISPOSABLE BABY DIAPER SPECIFICATION

a) Shri Alok Birla, Swara Baby Products, Madhya Pardesh

Sir, with all due respect we need your support/ suggestion to understand how to read the procedure for determination of ABSORPTION CAPACITY AND RATE OF ABSORPTION, as stated in your specifications for disposable baby diapers IS17509:2021 (ICS 61.020, 59.080.99).

In your above specifications, in clause B-4, sub-head clause B-4.4 states that we have to "Gently place the provided weight on the acquisition plate". Again there is a sub-head clause B-4.4 says "Fill the measuring cylinder with the respective amount of saline solution from Table 2 (see 7.2) depending on the diaper size." Then sub-head clause B-4.9 says, repeat step 4.4 to 4.8 another two times on the same diaper.

So, what we have understood is that, to get the final results, we have to follow step 4.4 (starting) to 4.8 three times. Confusion point is, while repeating the cycle for the 2nd & 3rd time, do we need to remove the weight before to follow sub-head 4.8 and place it again as stated in sub-head 4.4?

Request please help us to get clarity. Your guidance will be of great value to Industry. Looking forward for your support and cooperation as always.

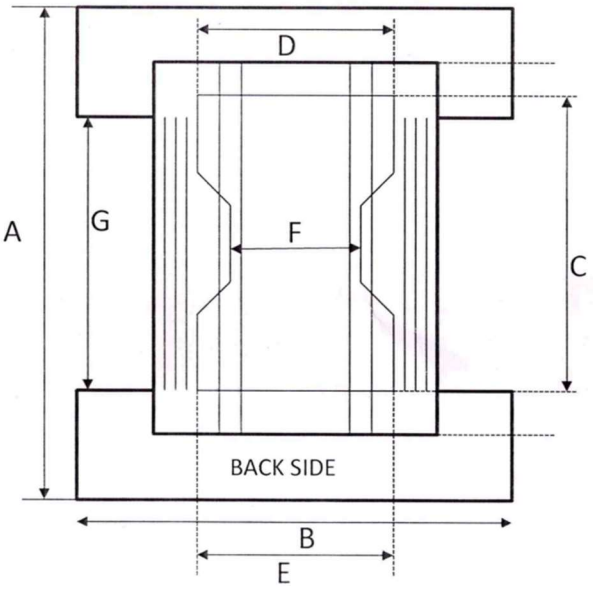
b) <u>Rajkot Branch Office Comments</u>

Figure 1 illustrates the dimensions of a baby diaper. While the figure effectively represents the overall size and key measurements using alphabetic labels, it lacks specific designations for the diaper crotch and core crotch.

It is recommended that the figure be revised to include clear labels for diaper crotch and core crotch, enhancing its clarity and comprehensiveness.

DIAPER PARTS

A – DIAPER LENGTH
B – DIAPER WIDTH
C – ABSORBENT CORE LENGTH
D - ABSORBENT CORE WIDTH FRONT
E - ABSORBENT CORE WIDTH BACK
F - CORE CROTCH
G – DIAPER CROTCH



It seems there's a potential inconsistency between Clause B-6.3 and B-6.4 of IS 17509:2021. B-6.3 specifies placing the weight and cover plate for 2 minutes, while B-6.4 suggests removing them after 5 minutes.

To ensure clarity and adherence to the standard, I suggest the following interpretation and additional step:

Procedure:

i) Place the weight and cover plate on the filter paper stack for 2 minutes. This step aligns with Clause B-6.3. ii) Leave the weight and cover plate in place for an additional 3 minutes. This step is added to reconcile the 5-minute duration mentioned in Clause B-6.4. iii) Remove the weight and cover plate after a total of 5 minutes. This final step ensures compliance with both clauses.

ANNEX 10

(Item 6.1)

COMMENTS ON PUBLISHED STANDARDS

IS 17509 : 2021 DISPOSABLE BABY DIAPER — SPECIFICATION

भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDRADS

Draft for comments only Doc No.: TXD 36 (XXXXX)

PROPOSED DRAFT AMENDMENT NO. 3 SEPTEMBER 2024

TO

IS 17509 : 2021 DISPOSABLE BABY DIAPER — SPECIFICATION

(*Page* 7, *clause* **B 2.2,** *see* amendment 2 also) **—** Substitute the following for the existing:

'B 2.2 — A rigid cover plate , with weight , total weight : 6300 g (plate 605.3 g, weight 5694.7 g) representing a pressure of 4.41 kPa(0.64 psi) for small, medium, large, X Large, XX Large and XXX Large sizes . The dimensions of the plate shall be around 200 mm x 70 mm and inner diameter of cylinder shall be 50 mm (*see* Fig. 4).

B 2.2.1 A rigid cover plate , with weight , total weight : 2500 g (plate 605.3 g, weight 1894.7 g) representing a pressure of 1.75 kPa (0.25 psi) for premature and new born sizes . The dimensions of the plate shall be around 200 mm x 70 mm and inner diameter of cylinder shall be 40 mm (*see* Fig. 4).'

(*Page* 7, *clause* **B 4.9**) **—** Substitute the following for the existing:

'B-4.9 Repeat step **4.4** to **4.8** another 2 times on same diaper without removing the weight.'

(*Page* 8, *clause* **B 6.4,** *first line*) **—** Substitute '2' for '5.'

ANNEX 11

(Item 6.2)

COMMENTS ON PUBLISHED STANDARDS

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

Smt. Tanya Mahajan, MHAI, New Delhi

FORMAT FOR SENDING COMMENTS ON BIS DOCUMENTS

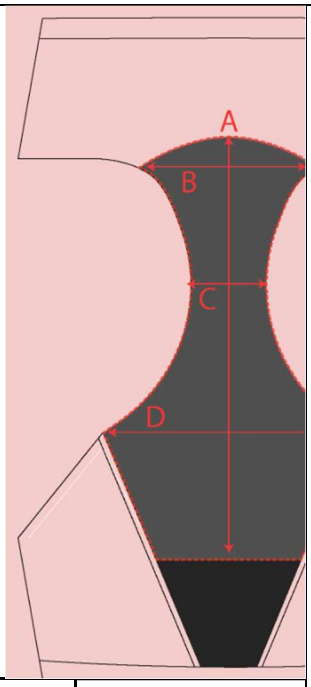
(Please use A4 size sheet of paper only and type within fields indicated. Comments on each clause/sub clause/table/fig etc. be started on a fresh box. Information in column 3 should include reasons for the comments and suggestions for modified working of the clauses when the existing text is found not acceptable. Adherence to this format facilitates Secretariat's work)

Please e-mail your comments to txd@bis.gov.in or faxed on 011-23231282.
NAME OF THE COMMENTATOR/ORGANIZATION: Menstrual Health Action for Impact

DOCUMENT NO: IS 17514

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)**

Clause 9.2: Ability to withstand pressure after absorption	**Ability to withstand pressure upon absorption - The standard does not specify the size of the 1 kg weight, which may affect how the liquid spreads to the side area. Since the reusable pads are made of regular fabric, placing big diameter weight on top will cause the absorbed water to spread to the top layer and the side area. Refer to report #P2400213; the pad absorbed 30 ml, but after applying weight, it spread to the side area. Polyester fabric naturally tends to spread water both horizontally and vertically. Please refer to the video.**	**We can maintain the same absorbency level for each size, but we need to define the diameter of the 1 kg weight. It should be smaller than the absorbent core width of 6 cm, ensuring the weight is distributed over a specific area rather than the entire pad.**	**From Karthik Thangavel, Real Relief**	
Clause 9.2: Ability to withstand pressure after absorption	**we need to have a clear definition "side" (it shall not show leakage at the bottom or sides of the reusable sanitary pad/sanitary napkin/period panties) in the specification; is it referred to wings area or side edge of the pads – refer picture? In SITRA report they say "Side" and "Side way"**	**Change to "it shall not show leakage at the bottom or side edge of the reusable sanitary pad"**	**From Karthik Thangavel, Real Relief**	

<table>
<tr>
<td>Clause 6: Sizes</td>
<td>The guidelines mentioned were very specific to sanitary napkins and not relevant to panties, as the shape in the absorbent area of the panty and napkins are different.</td>
<td>


<table>
<tr><th>Size</th><th>Width for Medium</th></tr>
<tr><td>A</td><td>29 cm</td></tr>
<tr><td>B</td><td>10.5 cm</td></tr>
<tr><td>C</td><td>6 cm</td></tr>
<tr><td>D</td><td>19 cm</td></tr>
</table>
It can be rephrased to say that the minimal width should be Xcm for each size
</td>
<td>From Shagun Maheshwari, Papaya Pads</td>
<td></td>
</tr>
</table>

Clause 8: General Requirements Table 1: colour-fastness	**The standard indicates a rating of CC-4/CS-3, whereas the international standard is 2-3. Even the dyestuff manufacturer doesn't provide such fastness properties for the dark colors.**	**Our suggestion is to have multiple grade levels between light/medium/dark shades.**	**From Ganesh Balaji, Mahina**	

ANNEX 12

(Item 6.3)

COMMENTS ON PUBLISHED STANDARDS

IS 17630 : 2021, MEDICAL TEXTILES — BEDSHEET AND PILLOW COVER — SPECIFICATION

Shri Dhanaanjay D Joshi, Alok Industries

We Alok Industries Ltd applied for Medical Textiles - Bedsheet ,Pillow cover & Duvet set under -IS 17630:2021

All specified testing is pass except Particle release IS 15891-10 enclosed herewith SITRA Test Report ,

After failure report we have comment given as CAPA as follows ,

Particle Release Test is applicable for Non-Woven fabric & not for Woven polycotton blend fabric. Woven fabric cannot pass Particle Release Test . Non-woven fabric having Thermal bonding. BIS must give waiver to Particle Release Test for Woven fabric which already requested .

This woven fabric goes in vigorous processing route like –

Singe – Desize – Pretreatment on CBR – Polyester OBA with Heat set on stenter – Rebleach on CBR – Final finish with finishing chemicals with Cotton OBA – calendar.

We are humbly requested to consider this technical limitation for Woven fabric & give us waiver for Particle Release Test .