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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: -

- 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 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:

- 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	<i>Min 55</i>
		Large	211 to 240	
		Extra - large	241 to 280	
		XXL	≥ 281	
iii)	Maternity pad	-	≥ 281	<i>Min 80</i>
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 is 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)

SI 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 $27^{\circ}\text{C} \pm 2^{\circ}\text{C}$ 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*.

ANNEX 2

(Item 1.1)

For Comments Only

Proposed Draft Revision

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

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

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)

SI 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 pH Value

The pH 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 is 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)

SI 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

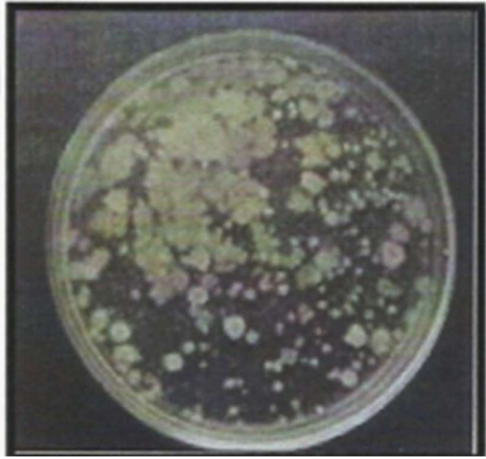
A sample of 5 gm cut from the centre portion of the pantyliner/sanitary napkins/maternity pad/period panty shall be checked for its absorbency in eluent such as 0.85 percent sodium chloride or equivalent medium till it reaches saturation limit. Add eluent either ten times the absorbent quantity of the 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)

SI 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
(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 STANDARDS

<i>IS No./Other Publication</i>	<i>Title</i>
758 : 2023	Specification for cotton gauze, absorbent, non-sterilized (<i>fourth revision</i>)
1390 : 2022/ ISO 3071 : 2020	Textiles — Determination of <i>pH</i> of aqueous extract (<i>third revision</i>)
4905 : 2015	Random sampling and randomization procedures (<i>first revision</i>)
5887 (Part 2) : 1976	Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of <i>Staphylococcus aureus</i> and faecal <i>Streptococci</i> (<i>first revision</i>)
9873 (Part 6) : 2021/ ISO 8124-6 : 2018	Safety of toys Part 6 Determination of certain phthalate esters in toys and children's products (<i>first revision</i>)
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

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 $27^{\circ}\text{C} \pm 2^{\circ}\text{C}$ 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 to 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	-	-	-
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NAME OF THE COMMENTATOR/ORGANIZATION: Torwriskie Zakłady MaterialOw Opatrunkowych SA

DOCUMENT NO:

Data for products: sanitary pads and pantyliners under Bella brand

Item, Clause Sub-Clause	Comments	Specific Proposal	Remarks	Technical References and justification on which (2), (3), (4) are based
No. Commented upon (Use Separate Box afresh)		(Draft clause to be add/amended)		
(1)	(2)	(3)	(4)	(5)
5 SIZES	we recommend changing ranges for sanitary pads and the absorbent core of	Pantyliner sizes: small ≤ 134 Regular 135 to 157 Large ≥ 158 Pad width (mm) (absorbent core only) min 20		Based on the global offer of TZMO SA for pantyliners

	pantyline rs			
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 Bacterial and Fungal Bioburden	We propose to add information about the specific methodology	We propose a provision that microbiological tests microbiological tests are carried out in accordance with EU Pharmacopoeia X.		Based on the tests made in EU
7.6 Phthalate Test	Changing of the Regulation on the presence of	Regulation of the presence of phthalates in hygiene products includes,		the REACH Directive

	phthalates in hygienic products	<p>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.</p>		
8.1.3 selection	Changing of sampling	<p>In view of the reference in the draft IS standard to the fact that these standards are created in</p>		ISO 2859-1

		accordance with ISO standards we recommend the 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		Based on the EU requirements

		written obligatorily		
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	N/A	Panty Liner should be of following types:	N/A	N/A

<p>following types:</p> <p>a) thick napkins; and</p> <p>b) thin napkins</p>		<p>a) Thick pantyliner</p> <p>b) Thin pantyliner</p>		
<p>Section 5</p> <p>SIZES</p> <p>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:</p>	N/A	<p>The recommended sizes mentioned below as Note (a Section)5</p>	N/A	N/A
<p>(ANNEX B)</p> <p>Section 7.2</p> <p>Ability to Withstand</p>	<p>If it will be implemented</p>	<p>The Panty liner should absorb 0,5 ml of colored distilled water and the test will</p>	N/A	<p><u>Patient education:</u></p> <p><u>Vaginal discharge in</u></p>

Pressure after Absorption	then modification required as per product category	be executed as per "B-1 TEST PROCEDURE"		<u>adult women</u> <u>(Beyond the Basics):</u> 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.
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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
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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 discomfort) when examined visually.		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 (<i>unintended</i>), oil spots, dirt or foreign material (unintended foreign matter that can cause injury or discomfort) when examined visually.	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.	
4.1 The pantyliner / sanitary napkins / maternity pad / period panty shall be of following types: f) Thick napkins g) Thin napkins		4.1 The pantyliner / sanitary napkins / maternity pad / period panty shall be of following types: a) Thick napkins b) Thin napkins	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	

<p>h) Pantyliner i) Maternity pad; and j) Period panty</p>		<p>a) <i>Sanitary Napkins</i> b) Maternity pad c) Period panty d) Pantyliner</p>	<p>fluff + compressed sheet are used used to manufacture thin napkins.</p> <p>There is no difference in the test parameters between Thin and Thick Sanitary Napkins</p> <p>This will also keep innovation space open.</p>	
<p>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 / sanitary napkins / maternity pad/ period panty or as per the agreement between buyer and seller.</p>		<p>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 or manufacturers product design.</p>	<p>The products are FMCG and are used by the consumers. The end consumers are not in direct touch with the manufacturers.</p> <p>A note can be added that in case of institutional buyer, the buyer and seller can have their own agreement and arrangement.</p>	
<p>5 Sizes</p>		<p>Under Sanitary Napkins</p> <p>XXL 281 to 320</p> <p>XXXL >= 321</p>	<p>Based on the market requirements, recently several pads are introduced in the Indian market, which has total pad length over 320 to 420 mm.</p> <p>This calls for an additional size so that consumers will have clarity</p>	
<p>5 Sizes</p>		<p>Panty liner (total length) Small <= 139mm Regular 140mm - 170mm</p>	<p>In many Panty liners, the absorbent</p>	

		Large $\geq 171\text{mm}$	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 is 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 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 holding the	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 / 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,	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 shape of the napkins.” This way we keep future scope for innovation.	Sanitary Napkin tab-less  Sanitary Napkin with tab  Napkin without wings 

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.		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 <i>or cover</i> 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	The products are FMCG and are used by the consumers.	

		<p>manufacturer / user. The other sampling plan may also be followed as per manufacturers quality assurance plans if agreed between buyer and seller.</p>	<p>The end consumers are not in direct touch with the manufacturers.</p>	
<p>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.</p>		<p>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.</p>		
<p>9 Marking d) The absorption capacity after pressure (ml);</p>		<p>Remove d) The absorption capacity after pressure (ml);</p>	<p>The absorption capacity is fixed in the standards, irrespective of the size of respective products.</p> <p>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.</p>	

C) Shri Prashant Jadhav, Procter and Gamble, Mumbai

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

<p>Item, Clause Sub-Clause No.</p> <p>Commented upon (Use Separate Box afresh) revision draft IS 5405</p>	<p>Comments</p>	<p>Specific Proposal (Draft clause to be added/amended)</p>	<p>Remarks</p>	<p>Technical References and justification on which (2), (3), (4) are based</p>
(1)	(2)	(3)	(4)	(5)
<p>5 SIZES</p> <p>Table 1 Size of Pantyliner/Sanitary Napkin/Maternity Pad/Period Panty</p> <p><i>(for reference and guidance only)</i></p>		<p>PROPOSAL 1</p> <p>Remove Table 1 & use the following statement:</p> <p>Size of pantyliner/sanitary napkins/maternity pad/period panty shall be as agreed to between the purchaser and the supplier.</p> <p>Sizes of pantyliner/sanitary napkins/maternity pad/period panty shall be variable depending on the absorbent capacity, purchaser's needs and</p>		<p>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; recent experiences have shown that laboratories have failed product samples on the ground of not meeting the dimensions as per the table.</p> <p>Removing the table eliminates</p>

		<p>wing features. Size As declared in the label with a tolerance of ± 10 mm.</p> <p>PROPOSAL 2</p> <p>Make this as an OPTIONAL requirement by adding word “OPTIONAL” in the header:</p> <p>5 SIZES (OPTIONAL)</p>		<p>interpretational differences that may arise due to its presence.</p>
<p>9. Marking</p> <p>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</p>	<p>“Type of Pads” here would refer to “Thin” or “Thick” sanitary napkins according to draft proposal</p>	<p>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:</p>	<p>Editorial comment</p>	<p>“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”.</p> <p>Any additional</p>

<p>in addition to the following:</p>		<p>a) product identifier (e.g. pantyliner, sanitary napkin, maternity pad/period panty)</p>		<p>labelling obligation would not increase the consumer knowledge.</p>
<p>9. Marking 9.1 (d) The absorption capacity after pressure (ml)</p>	<p>It is not required to display all technical parameters on the product label.</p>	<p>Remove this element from the labelling requirements.</p>	<p>Technical comment</p>	<p>All certified products have to comply with minimum absorbency capacity which is already guaranteed by the standard.</p> <p>Overall absorbency is not a meaningful parameter for a consumer.</p> <p>The consumer chooses the product according to the fitment/size.</p>
<p>9. Marking 9.1 Each pack shall be legibly and indelibly marked with the</p>	<p>Current version of the standards states “Each consumer pack” whereas the draft</p>	<p>Keep the current labelling requirements to “each consumer pack” as given below:</p>		<p>“Each pack” can also include shippers and secondary packaging. It is not</p>

<p>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:</p>	<p>standard mentions "Each pack". <i>Does this mean that all packaging, including customer and secondary packaging will have to include these marking requirements?</i></p>	<p>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:</p>		<p>meaningful to keep all labelling requirements in secondary packaging that are not consumer-facing SKUs.</p>
<p>7.6 Phthalate Test</p> <p>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</p>	<p>Suggest removing testing at raw material stage for various reasons (see column 5)</p>	<p>Adopt the clause from IS 17509 (Disposable Baby Diaper)</p> <p>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).</p>	<p>Technical</p>	<p>1. Harmonization with IS 17509 (Disposable Baby Diapers) is suggested. In IS 17509, Phthalate testing is mandated on Finished Product only.</p> <p>2. Scope of IS 5405 is the final product. Thus, for consistency of the target group of this</p>


<p>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.</p>				<p>standard, it is appropriate for the manufacturer to test the final product only.</p> <p>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.</p>
<p>7.1 pH The pH 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</p>	<p>Suggestion to extend pH range 3.5 to 8.0 either for period panties only or for all products.</p>	<p>Revise the clause: 7.1 pH The pH shall be from 3.5 to 8.0</p>		<p>Period panties are a more complex product form than sanitary napkins, as more materials are used. Measurements have shown pH</p>

<p>given in IS 1390.</p>				<p>can be close to 7.5</p>
<p>6 MANUFACTURE, WORKMANSHIP AND FINISH</p> <p>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</p>	<p>Need clarity on the test method that is being used to test for ‘chlorine free wood pulp’ in the absorbent core of the product</p>	<p>Remove <i>‘The manufacture should use chlorine free wood pulp in the absorbent core of the product.’</i></p>		<p>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.</p>

<p>seller. The <i>manufacture should use chlorine free wood pulp in the absorbent core of the product.</i>'</p>			
<p>6 MANUFACTURE, WORKMANSHIP AND FINISH</p> <p>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).</p>	<p>Rephrase statement of:</p> <p>“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.”</p>	<p>Replace with the following:</p> <p>“The pantyliner/sanitary napkins/maternity pad/period panty when worn, shall not chafe or give any uncomfortable feeling.”</p>	<p>Softness is a subjective term and cannot be measured. It may vary from user to user. The observation visually and 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.</p> <p>At present sanitary napkins with the variety of textured surfaces, feel are available.</p>

<p>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)</p>	<p>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.</p>	<p>For sanitary napkins and period panties:</p> <p>Liquid Absorption (ml), Min: 20</p>	<p>Reference:</p> <p><u>The FIGO Recommendations on Terminologies and Definitions for Normal and Abnormal Uterine Bleeding;</u></p> <p><i>Semin Reprod Med 2011; 29(5): 383-390</i></p> <p>DOI: <i>10.1055/s-0031-1287662</i></p> <p>Appropriate absorbency limits will also contribute to the positive sustainability impact by rationalizing input of materials.</p>
<p>Number of Tests and Criteria for Conformity 8.2.5 The biocompatibility evaluation shall be</p>	<p>Add “if applicable” to both clauses to clarify those paragraphs are related to the</p>	<p>Revise the clauses as given below:</p> <p>8.2.5 (If applicable): The biocompatibility evaluation</p>	<p>This proposal is to bring consistency and remove interpretational differences.</p>

<p>carried out once for existing raw material and whenever there is a change in the raw material for manufacturing the product.</p> <p>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</p>	<p>OPTIONAL requirements in 7.4 and 7.5</p>	<p>shall be carried out once for existing raw material and whenever there is a change in the raw material for manufacturing the product.</p> <p>8.2.6 <i>(If applicable):</i> 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.</p>		
<p>ANNEX B</p> <p>B-1 TEST PROCEDURE</p>	<p>In its current form, the test method is not suitable for Period Panty. Adding cutting instruction in the test method for</p>	<p>Insert:</p> <p>For period panty, cut along the lateral seam on both the sides (left & right) and then lay the</p>		<p>Product integrity should not get tempered during this testing.</p> <p><i>Picture for Illustration Purpose:</i></p>

	period panty will resolve this concern.	period panty flat for absorbency testing.		
<p>5 SIZES, Table column 4 & 5 headers</p> <p>Pad Length (mm) (absorbent core only)</p> <p>Pad Width at center (mm) (absorbent core only)</p>	<p>The column names are only called “pad length” or “pad width” but they are applicable to all product types.</p> <p>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.</p>	<p>REMOVE “PAD” from the header of the column 4 & 5”</p> <p>Pad Length (mm) (absorbent core only)</p> <p>Pad Width at center (mm) (absorbent core only)</p>		<p>Removing the word “pad”, as this is usually only used for menstrual pads or maternity pads, but not for pantyliners nor period panties.</p> <p>Core width shall be measured at center as this is the meaningful location to check because of the point of loading.</p>
<p>5 SIZES, Table 1, SI No i) Column 3</p>	<p>Size classes is not relevant for the pantyliners</p>	<p>Remove Size Class for the Pantyliners</p> <p>Proposed width:</p> <p>Width (mm): Min. 20 mm.</p>		<p>The proposals does not reflect current situation in market. For anatomical reasons, pantyliners might be less wide than 30mm thus</p>

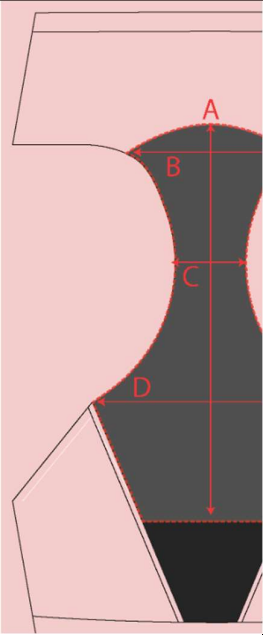
				width is lowered in the proposal as well.
5 SIZES, Table 1, SI No ii) Sanitary Napkin	Min pad width for sanitary napkins should be lowered.	Revise Pad width: Pad width (mm): <i>Min. 40mm</i> Include more size in the existing table: XL+, XXL+,XXXL, XXXL+ etc.		This change is to include high BMI consumer 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): <i>>230 mm</i> Width (mm): <i>Min. 55 mm</i>		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 the side area. Refer to report #P2400213; the pad absorbed 30 ml, but after applying weight, it spread to the side area.	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	

	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.	 <table border="1" data-bbox="784 1633 1117 1837"> <tr> <td>Size</td> <td>Width for Medium</td> </tr> <tr> <td>A</td> <td>29 cm</td> </tr> </table>	Size	Width for Medium	A	29 cm	From Shagun Maheshwari, Papaya Pads	
Size	Width for Medium							
A	29 cm							

		<table border="1"> <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>	B	10.5 cm	C	6 cm	D	19 cm		
B	10.5 cm									
C	6 cm									
D	19 cm									
		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 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.

Add a test for coagulation as an alternative to absorption, test being developed by SITRA with Papaya pads

Shagun Maheshwari,
Papaya Pads

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 requirements given in 6.1 are for guidance of the manufacturer. The	N/A	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	N/A	N/A

<p>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.’</p>		<p>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.</p>		
<p>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: (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.</p>	<p>To revise the part of statement - agreed between buyer and seller’</p>	<p>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: (2) The sampling plan given in table is for guidance of manufacturer/user . The other sampling plan can be followed as per manufacturer</p>	<p>Simplification</p>	<p>The buyer itself can be manufacturer/seller hence the agreement may not exist.</p>

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
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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 Absorbency	ml	100	120	140	±20