For BIS Use Only

BUREAU OF INDIAN STANDARDS

AGENDA

Technical Textiles for Medtech Applications Sectional Committee, TXD 36 **27th Meeting**

Date	Time	Venue
16 July 2024 (Tuesday)	1030 h	Video Conference through CISCO Webex

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

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

Item 0 WELCOME & INTRODUCTORY REMARKS

Item 1 CONFIRMATION OF THE MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the 26th meeting of the TXD 36 committee held on 15 April 2024 through CISCO Webex videoconferencing was circulated vide our reference TXD 36/A 2.26 email dated 27 April 2024. No comments were received on the minutes.

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

Item 2 SCOPE AND COMPOSITION OF TXD 36

2.1 As directed by Competent Authority of BIS, the memberships of the following organizations were terminated due to absence from two consecutive meeting :-

i) National Physical Laboratory, New Delhi
ii) Bussiness Coordination House, New Delhi

2.1.1 The Committee may **NOTE**.

2.2 The following organization have been co-opted as members of TXD 36 as per the decision of Textiles Division Council (TXDC) meeting held on 04th June 2024 :-

i) Association of Healthcare Providers India (AHPI), New Delhi
ii) National Accreditation Board for Hospitals and Healthcare Providers, New Delhi

2.2.1 The Committee may **NOTE**.

2.3 The present scope and composition of the committee is given at **Annex 1 (Pages 7-9).**

2.3.1 The Committee may **REVIEW**.

2.4 M/s Tynor Orthotics Pvt. Ltd., Mohali has requested for membership in TXD 36. The name of representative are a) Shri Neeraj Mehra b) Dr. Chetan Mittal.

Shri Neeraj Mehra is an Industrial Engineer graduate from Thapar University plus Masters in Operations Management from SCDL. He has 20 years of experience and representing as General Manager – Quality of M/s Tynor Orthotics. Dr. Chetan Mittal has done Master in Medical Science and Technology (MMST) (Major: Biomedical engineering) and Bachelor of Medicine and Bachelor of Surgery (MBBS). Shri Chetan is a medical doctor and a technologist, with an expertise in leading development and delivery of clinical care solutions. He has led multiple projects R&D across integrated mother and child care, cardiac care and oncology involving cross-functional teams.

Tynor is known for producing a wide range of orthopedic and healthcare products. Some products manufactured by M/s Tynor Orthotics like Abdominal binder, Knee Cap, Lumbo Sacral Belt, Wrist and Forearm Splint, Ankle Binder, Wrist and Forearm Splint, Chest Binder etc are under scope of TXD 36.

2.4.1 The Committee may **DECIDE.**

Item 3 ISSUES ARISING OUT OF PREVIOUS MEETING OF TXD 36

3.1 Summary of actions taken on the various decisions of the 26th meeting is given at **Annex 2 (Pages 10-12).**

3.1.1 The Committee may **NOTE**.

Item 4 DRAFT AMENDMENTS FOR FINALIZATION

4.1 As decided by the committee in last meeting, the following draft amendments were issued in wide circulation vide our letter reference no. TXD 36/25701 dated 28 May 2024 for eliciting comments from stake holders for 30 days : -

i) Amendment No. 2 to IS 17509 : 2021 Disposable Baby Diaper — Specification, Doc: TXD 36 (25701)
ii) Amendment No. 1 to IS 758 : 2023 Medical Textiles — Absorbent Cotton Gauze — Specification (Fifth Revision), Doc: TXD 36 (25704)
iii) Amendment No. 1 to IS 863 : 2023, Medical Textiles — Cotton Bandage Cloth — Specification (Third Revision) Doc: TXD 36 (25705)

The last date for comments was 26 June 2024.

The draft amendments as issued under wide circulation are given at **Annex 3 (Pages 13-17).**

The comments received from M/s Swara Baby Products, P & G, Kimberly-Clark India Pvt. Ltd. Unicharm India on amendment No. 2 to IS 17509 : 2021 are given at **Annex 4 (Pages 18-26).**

The comments received from M/s G Surgiwear Limited and CMD 2, BIS on Amendment 1 to IS 758 : 2023 and Amendment No. 1 to IS 863 : 2023 are given at **Annex 5 (Page 27).**

4.1.1 The Committee may **DECIDE.**

5.1 DRAFT AMENDMENT FOR APPROVAL FOR WIDE CIRCULATION

i) IS 18266 : 2023, Textiles — Medical Respirator — Specification

In the last meeting, the committee decided that BIS shall prepare the draft amendment in consultation with M/s Venus Safety and Health Pvt Limited, Mumbai.

The comments received from Shri N.K. Kansara, Ex-DDG, BIS vide email dated 18 March 2024 are given at **Annex 6 (Pages 28-29).**

The inputs received from M/s Venus Safety and Health Pvt Limited are given at **Annex 7 (Pages 30-39).**

The proposed draft amendment 1 to IS 18266 : 2023 is given at **Annex 8 (Pages 40-41).**

5.1.1 The Committee may **DECIDE.**

Item 6 NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD

6.1 Shri Neeraj Mehra, GM – Quality, M/s Tynor Orthotics Pvt. Ltd., Mohali has requested BIS for formulation of standard on various new items on orthopedic and healthcare products.

The list of products are given at **Annex 9 (Pages 42-43).**

The inputs received on new subjects - Knee Cap, Lumbo Sacral Belt, Wrist and Forearm Splint, Ankle Binder, Wrist and Forearm Splint, Chest Binder are given at **Annex 10 (Pages 44-45).**

6.1.1 The Committee may **DECIDE.**

Item 7 INTERNATIONAL ACTIVITIES

7.1 The 4th plenary meeting of ISO/TC 338 'Menstrual Product' was held on 26-27 June 2024 at Copenhagen, Denmark in hybrid mode. Since the subject matter being dealt by ISO/TC 338 are important from India’s perspective, critical and sensitive in nature so a strong representation at the plenary meeting was proposed to represent India during the meeting.

The following delegation of experts participated in the 4th plenary meeting in hybrid mode to represent India's point of view: -

1) Shri Dharmbeer, Sc-D, Textiles, Member Secretary TXD 36 **(Head of Delegation) (Virtual Mode)**
2) Shri S. Sivakumar, (Head, Medical Textiles), SITRA, Coimbatore **(Physical Mode)**
3) Smt. Tanya Mahajan, The Pad Project (NGO), India **(Physical Mode)**
4) Ms. Shivani Swamy, Livinguard Technologies Pvt. Ltd., Mumbai **(Physical Mode)**
5) Dr. E. Santhini, SITRA, Coimbatore **(Virtual Mode)**
6) Shri Nirav Mehta, Dima Products, Mumbai **(Virtual Mode)**
7) Ms. Roocha Khedkar, Kenvue, Mumbai **(Virtual Mode)**

The agenda of plenary meeting and resolution of ISO/TC 338 and status report of Working group WG 1 and Adhoc group are given at **Annex 11 (Pages 46-62).**

The report of panel meeting of Adhoc group (AHG 1) on terminology held on 24 June 2024 is given at **Annex 12 (Pages 63-66).**

The brief report on outcomes of plenary meeting is given at **Annex 13 (Page 67).**

The report of working group ISO/TC338/WG1 Safety, Performance and General requirements of Menstrual Products held on 25-26 June 2024 is yet to be received.

7.1.1 The Committee may **NOTE.**

7.2 Ballot ISO/NP 25199 'Guidelines for Processing of Multiple-Use Healthcare Textiles'

It is informed that BIS is a Participating member of the ISO/TC 304 'Healthcare Organization Management'. India has submitted a new work item proposal ISO/NP 25199 'Guidelines for Processing of Multiple-Use Healthcare Textiles' through Hospital Planning Sectional Committee, MHD 14 in ISO TC 304 and the closing date for voting was 12 July 2024.

The inputs/feedback submitted by Textiles Department to Hospital Planning Sectional Committee, MHD 14 for voting is given **at Annex 14 (Pages 68-69).**

It was informed that Dr. Sanjiiv Rehlan, FICCI/Shalex Medtech, New Delhi is the proposed Project Leader from India for this NWIP. The key dated proposed in the NWIP Form 4 are as follows :-

Proposed date for first meeting: 2024-08-23

Circulation of 1st Working Draft (if any) to experts: 2024-08-18

Committee Draft consultation (if any): 2025-07-11

DIS submission*: 2026-07-10

Publication*: 2027-07-09

The new work item proposal form 4 and the working draft on 'Guidelines for Processing of Multiple-Use Healthcare Textiles' as submitted to ISO TC 304 Secretariat are given at **Annex 15 (Pages 70-112).**

7.2.1 The Committee may **REVIEW and DECIDE.**

Item 8 COMMENTS ON PUBLISHED STANDARDS

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

BIS has received feedback from stakeholder on the following aspects related to IS 5405 -2019 and requested TXD 36 members/stakeholders vide email dated 21 May 2024 to share their inputs :-

1) Whether disposable pantyliner and maternity pad are covered in IS 5405 or not. If not, what are the different requirements/variety other than given in IS 5405 :2019. Please share inputs on additional size/dimension, variety, performance requirement and test method.
2) Is it possible in practical to manufacturer 100 % flushable sanitary napkin and/or 100 % biodegradable sanitary napkin. Whether we need to include these additional requirements in the existing standard. What could be the procedure, requirement, and test method.
3) Whether dioxin and furan chemical substances traces are found/relevant in disposable sanitary pad. What could be the possible requirement and test method.

The inputs/comments received from SITRA, Dima Products, Kenvue, P &G, ICMR, Soothe Healthcare and Anabio Technologies | are given at **Annex 16 (Pages 113-131).**

8.1.1 The Committee may **DECIDE.**

8.2 BIS has requested TXD 36 members/stakeholders vide email dated 21 May 2024 to share their inputs/comments :-

Sl No	IS No.	Title
1	IS 17786 : 2022	Medical Textiles — Underpad — Specification
2	IS 17787 : 2021	Medical Textiles — Nonwoven Wipes — Specification
3	IS 17788 : 2021	Medical Textiles — Nonwoven Fabric for Wipes — Specification
4	IS 17508 : 2020	Disposable Adult Incontinence Diaper - Specification

The comments received from Ginni Filaments, Kenvue and Unicharm India on IS 17787 : 2021 and IS 17788 : 2021 are given at **Annex 17 (Pages 132-137).**

8.2.1 The Committee may **DECIDE.**

Item 9.1 REVIEW OF PRE-2000 STANDARDS/DUE FOR REVIEW

9.1 In the last meeting, the committee requested experts/committee member to send their comments and suggestion for standards due for review/pre-2000 standards. The comments received from SITRA are given in

The list of standards due for 5 year review are given at **Annex 18 (Pages 138-142).**

The list of pre-2000 standards are given at **Annex 19 (Page 143).**

9.1.1 The Committee may **DECIDE.**

Item 10 DATE AND PLACE OF NEXT MEETING

Item 11 ANY OTHER BUSINESS

ANNEX 1

(Item 2.1)

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

Scope: 'To formulate Indian Standards for terminology, testing and specifications for technical textiles for medtech applications **(including medical devices made of textile material)** such as healthcare and hygiene textile products, implantable and non-implantable and extra corporeal textile products.'

Meeting(s) held	**Date & Place**
25th Meeting	05th January, 2024 (Through VC)
26th Meeting	15th April, 2024 (Through VC)

SL NO.	ORGANIZATION REPRESENTED	NAME OF THE REPERESENTATIVE PRINCIPAL/(ALTERNATE)	ATTENDANCE
1.	**Director, SITRA**	**Dr. Prakash Vasudevan** (Chairman)	2/2
2.	3 M India Limited New Delhi	Smt. Prabha Hegde	2/2
3.	Alpha Foam Ltd., Pune	Shri Rajiv Ranka (Shri Apurva Ranka)	2/2
4.	Association of Healthcare Providers, New Delhi	Capt. Baban Rai (Dr. Sunil Khetarpal)	0/0
5.	Association of Indian Medical Device Industry (AiMeD), New Delhi	Shri Amit Kumar (Smt. Rama Venugopal)	2/2
6.	All Indian Institute of Medical Sciences, New Delhi	Dr. Vijaydeep Siddharth (Dr. Anoop Daga) (Dr. Sidhartha Satpathy)	1/2
7.	Central Drugs Standard Control Organization, New Delhi	Mr. Aseem Sahu (Ms. Shyamni Sasidharan)	1/2
8.	Cologenesis Healthcare Pvt. Ltd, Salem	Shri R Krishana Kumar (Shri K. Ramprasad)	1/2

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

25.	Maulana Azad Medical College, New Delhi	Dr. Pawanindra Lal (Dr. KirtiNath Saxena)	2/2
26.	Medline Healthcare Industries Pvt. Ltd, Pune	Mr. Anothony D' Costa (Shri Dhaval Ghuge)	1/2
27.	Ministry of Textiles (NTTM), New Delhi	Shri Ajay Pandit	1/2
28.	Nobel Hygiene, Mumbai	Shri Joy Devassy (Smt. Sneha Gupta)	2/2
29.	PGIMER, Chandigarh	Dr. Pankaj Arora (Dr. Vijay Tadia)	2/2
30.	Procter and Gamble Co., Mumbai	Shri Prashant Jadhav (Shri Girish Parhate)	2/2
31.	Surya Textech, Chandigarh	Shri Khalil Khan (Shri Yogesh Yadav)	2/2
32.	Textiles Committee Mumbai	Shri Kartikeyan Dhanda (Dr. P. Ravichandran)	2/2
33.	The Pad Project (NGO), India	Smt. Tanya Mahajan	2/2
34.	The South India Textile Research Association, Coimbatore — 641014	Shri S. Sivakumar (Dr. E. Santhini)	1/2
35.	The Synthetics & Art Silk Mills Research Association, Mumbai	Dr Manisha Mathur (Smt. Shradha Dongre)	2/2

ANNEX 2
(Item 3.1)

SUMMARY OF ACTIONS TAKEN ON THE MINUTES OF 26th MEETING OF TXD 36

Item No.	Decision	Action taken
2.1	Certain modifications were suggested in the composition of the committee.	Updated composition is given in **Annex 1**
4.1	**DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION** **4.1 IS 17334: 2019, Medical Textiles — Surgical Gowns and Surgical Drapes — Specification** It was requested that following stakeholders shall send samples to SITRA for testing of dry and wet bacterial penetration test : - a) Dr. Sanjiiv Rehlan, FICCI (Shalex Medtech), New Delhi b) Shri Sumit Marwah, Dispoline India Private Limited, Bengaluru c) Shri Khalil Khan, Surya Textech, Chandigarh d) Shri Apurva Ranka, Alpha Foam Private Limited, Pune	The preliminary draft under preparation.
4.2	**DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION** **IS 16111: 2013, Elastic Bandage** It was decided that KOB Medical Textiles and Dr. Sabharwal Wound Care shall provide technical inputs regarding range and uses of short, medium and long stretch bandage.	The inputs are yet to be received. The preliminary draft under preparation.
4.3	**DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION**	

	Medical Textiles – Nonwoven Gauze Swab (Sterile and Non-Sterile) – Specification M/s Ginni filaments shall share the comparative testing results (5 domestic samples and 5 International samples of different lots, each from 2 different NABL approved lab) for tensile strength (N/5 cm) as per IS 15891 (Part 3) : 2024/ISO 9073-3:2023] in machine direction and cross direction	The test reports are yet to be received. The preliminary draft under preparation.
4.4	**DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION** **Medical Textiles -Scrub Suit – Specification** The committee decided that the draft standard so prepared shall be issued in wide circulation for 30 days for eliciting technical comments from stakeholders.	The preliminary draft under preparation.
4.5	**DRAFT STANDARD FOR APPROVAL FOR WIDE CIRCULATION** **Medical Textile — Sterilization Wraps — Specifications** The committee decided that the draft standard so prepared shall be issued in wide circulation for 30 days for eliciting technical comments from stakeholders.	The preliminary draft under preparation.
5.1	**COMMENTS ON PUBLISHED STANDARDS** **IS 17509: 2021, Disposable Baby Diaper — Specification** The committee decided that the draft amendment shall be issued in wide circulation for 30 days.	Coming up under discussion in agenda item **4.1**.
5.2	**COMMENTS ON PUBLISHED STANDARDS** **IS 18266: 2023, Textiles — Medical Respirator — Specification**	Coming up under discussion in agenda item 5.1.

	The committee decided that the draft amendment shall be issued in wide circulation for 30 days.	
5.3	**COMMENTS ON PUBLISHED STANDARDS** i) IS 863: 2023, Medical Textiles - Cotton bandage cloth - Specification (third revision) ii) IS 758: 2023, Medical Textiles — Absorbent Cotton Gauze — Specification (Fifth Revision) The committee decided that the draft amendments shall be issued in wide circulation for 30 days.	Coming up under discussion in agenda item 4**.1.**
6.1	**NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD** **Chitosan Haemostatic Dressings** The committee decided that Shri Saurabh, Axio Bio-Solutions Private Limited shall share the working draft on Chitosan Haemostatic Dressings based on inhouse technical data, scientific data and International Practice.	The working draft document is yet to be received.
7.1	**REVIEW OF PUBLISHED STANDARDS** The committee requested experts/committee member to send their comments and suggestion for standards due for review within 15 days.	Coming up under discussion in agenda item **9.1.**
7.2	**PRE-2000 STANDARDS** The committee requested experts/committee member to send their comments and suggestion on pre-2000 standards	Coming up under discussion in agenda item **9.1.**

ANNEX 3
(Item 4.*1*)

DRAFT AMENDMENT FOR FINALIZATION

Doc: TXD 36 (25701)

DRAFT AMENDMENT NO. 2 MAY 2024

TO

IS 17509 : 2021 DISPOSABLE BABY DIAPER — SPECIFICATION

(*Page* 1, *clause* **6.1**) **—** Substitute the following for the existing:

'6.1 On the basis on the weight of premature baby, infant and/or toddler, the baby diapers are classified in the following types:

Category	**Weight of the premature baby, infant and or toddler**
Premature Baby	Up to 2 kg
New Born	2 – 5 kg
Small	3 – 8 kg
Medium	6 – 11 kg
Large	9 – 11 kg
X Large	13 + kg
XX Large	15 – 25 kg
XXX Large	17 + kg

The weight of baby diaper may vary between different types as per the agreement between the buyer and the seller.'

(*Page* 2, *clause* **6.2**, *Table* 1) **—** Substitute the following for the existing:

'6.2 The dimensions of the diaper shall ensure proper and comfortable fit for the baby. The dimension may vary between different types and sizes of the diapers or as per the agreement between buyer and seller. The recommended dimensions of baby diaper are given in Table 1 (*see* Fig 1):

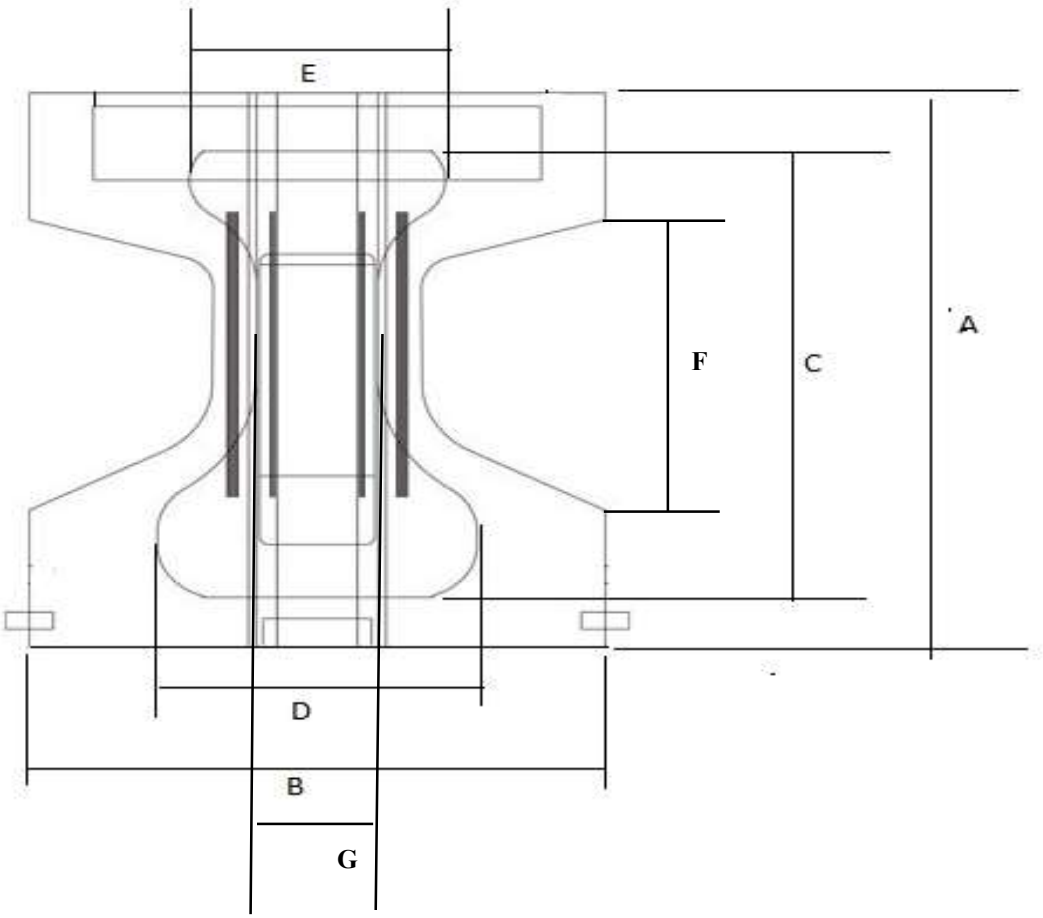


FIG. 1 SCHEMATIC SHOWING SIZE OF BABY DIAPER (FOR REFERENCE ONLY)

Table 1 Dimensions of Baby Diaper (mm)
(For reference only)
(*Clause* 6.2)

Size	**Diaper Length (A)**	**Diaper Width (B)**	**Absorbent core Length (C)**	**Absorbent core width back (D)**	**Absorbent core width front (E)**	**Diaper Crotch (F)**	**Core Crotch (G)**
Premature Baby	320 ± 10	250 ± 05	260 ± 10	100 ± 10	100 ± 10	185 ± 10	80 ± 05
New Born	350 ± 10	260 ± 05	285 ± 10	110 ± 10	110± 10	195 ± 10	85± 05
Small	390 ± 10	260 ± 05	300 ± 10	110 ± 10	110 ± 10	195 ± 10	85± 05
Medium	440 ± 10	310 ± 05	340 ± 10	110 ± 10	110 ± 10	195 ± 10	85± 05
Large	480 ± 10	310 ± 05	370 ± 10	110 ± 10	110 ± 10	215 ± 10	85± 05
X Large	520 ± 20	310 ± 05	370 ± 10	110 ± 10	110 ± 10	215 ± 10	85± 05

XX Large	560 ± 20	420 ± 05	380 ± 10	110 ± 10	110 ± 10	250 ± 10	80 ± 05
XXX Large	580 ±10	440 ±10	410 ±10	125 ±10	125 ±10	250 ±10	125 ±10

Note — The recommended dimension and tolerance (for reference) for premature baby and other variety not covered in Table 1 shall be declared by the manufacture.

(*Page* 2, *clause* **7.2**, *Table* 2) **—** Substitute the following for the existing:

Table 2 Requirement of Disposable Baby Diaper

(*Clause* 7.2)

	Size	**Number of Gushes**	**Requirement**
Minimum absorption capacity	Premature baby	3	3 x 10 ml
	New born	3	3 x 20 ml
	Small	3	3 x 35 ml
	Medium	3	3 x 50 ml
	Large	3	3 x 60 ml
	X Large	3	3 x 70 ml
	XX Large	3	3 x 75 ml
	XXX Large	3	3 x 75 ml
Rate of absorption per gush (s), *Max*	All sizes	-	First gush – 40 Second gush – 60 Third gush -90
Rewet under load, (gm), *Max*	All sizes	-	5

(*Page* 6, *clause* **B-2.2,** *second sentence*) **—** Substitute the following for the existing:

'The dimensions of the plate shall be around 200 mm × 70 mm and inner diameter of cylinder shall be 40 mm (premature baby, new born, small) (*see* Fig. 4), 50 mm (medium, large) and 60 mm (X Large, XX Large and XXX Large).'

TO

IS 758 : 2023 MEDICAL TEXTILES — ABSORBENT COTTON GAUZE — SPECIFICATION
(*Fifth Revision*)

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

(*Page* 1, *clause* **4.2**) **—** Insert the following new clause after **4.2** :-

'**4.3 Cleanliness–Microbial/ Bioburden Test**

The cotton gauze shall confirm the requirement of cleanliness–microbial/ bioburden for sterile and non-sterile product. For sterile product, 'no viable microorganism shall be present' and for non-sterile product, it shall be ≤ 300 (CFU/100 cm^2) when tested in accordance with ISO 11737 (Part 1).'

[(*Page* 2, *Table* 1, *Sl No (ix), col* 4)] **—** Substitute 'Viewing under ultraviolet light at 365 nm' for 'Viewing under ultraviolet light.'

[(*Page* 2, *Table* 1, *Sl No (x)*] **—** Delete.

(*Page* 4, *clause* **2,** *Annex* A) **—** Substitute 'ISO 11737-1 : 2018 Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products' for 'IS 10150 : 1981 Guide for sterilization of medical products.'

Doc: TXD 36 (25705)

DRAFT AMENDMENT NO. 1 MAY 2024

TO

IS 863 : 2023 MEDICAL TEXTILES — COTTON BANDAGE CLOTH— SPECIFICATION
(*Third Revision*)

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

(*Page* 1, *clause* **4.2**) **—** Insert the following new clause after **4.2** :-

‘**4.3 Cleanliness–Microbial/ Bioburden Test**

The bandage cloth shall confirm the requirement of cleanliness–microbial/ bioburden for sterile and non-sterile product. For sterile product, ‘no viable microorganism shall be present’ and for non-sterile product, it shall be ≤ 300 (CFU/100 cm^2) when tested in accordance with ISO 11737 (Part 1).’

[(*Page* 2, *Table* 1, *Sl No (viii), col* 4)] **—** Substitute ‘Viewing under ultraviolet light at 365 nm’ for ‘Viewing under ultraviolet light.’

[(*Page* 2, *Table* 1, *Sl No (x)*] **—** Delete.

(*Page* 4, *clause* **2,** *Annex* A) **—** Substitute ‘ISO 11737-1 : 2018 Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products’ for ‘IS 10150 : 1981 Guide for sterilization of medical products.’

ANNEX 4
(Item 4.*1*)

DRAFT AMENDMENT FOR FINALIZATION

Comments on Amendment No. 2 to IS 17509 : 2021 Disposable Baby Diaper — Specification, Doc: TXD 36 (25701)

a) Comments of Shri Ashish Naik, Swara Baby Products, Madhya Pradesh

Point # 01

In the meeting, it was decided that M/s Swara Baby Products Pvt Ltd., Madhya Pradeshwill share inhouse data, scientific data and NABL Approved test report results on the following aspects: -

Rate of absorption per gush (s) for new born, small, medium, large, extra-large.

As per our inhouse data below are the observation –

NB Diaper (3 x 20 ml)			
NB Sample	Rate of Absorption		
	Gush 1	Gush 2	Gush 3
Sample 1	4	14	21
Sample 2	5	18	25
Sample 3	6	16	23
Max	**6**	**18**	**25**

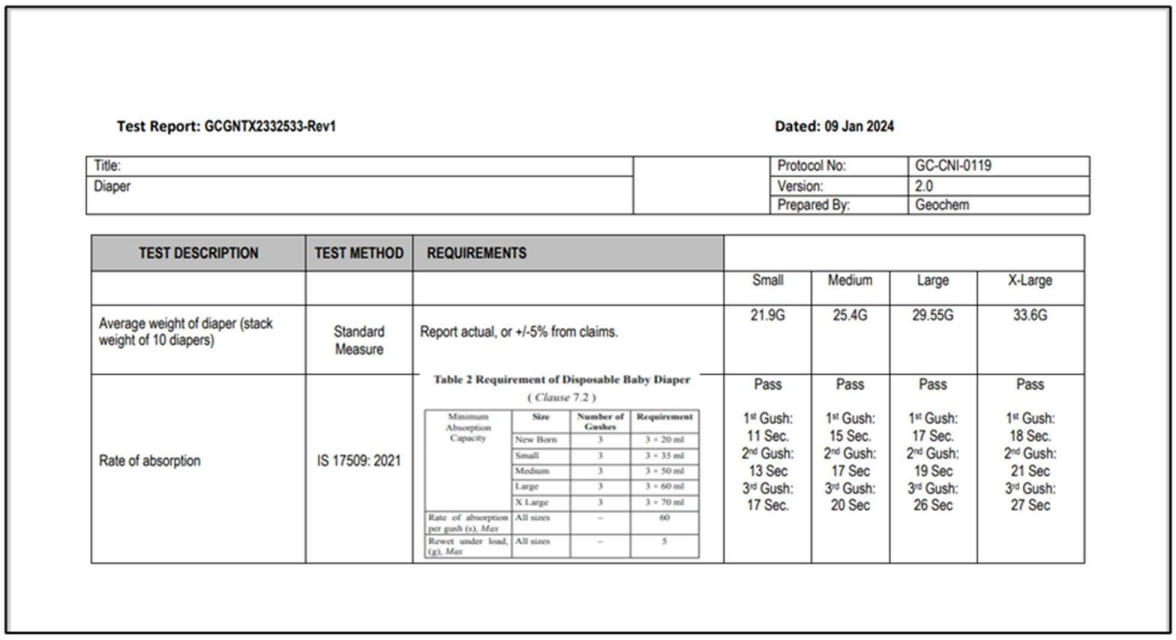
Small Diaper (3 x 35 ml)			
S Sample	Rate of Absorption		
	Gush 1	Gush 2	Gush 3
Sample 1	6	22	30
Sample 2	6	24	32
Sample 3	8	25	31
Max	**8**	**25**	**32**

Medium Diaper (3 x 50 ml)			
M Sample	Rate of Absorption		
	Gush 1	Gush 2	Gush 3
Sample 1	23	43	57
Sample 2	25	43	56
Sample 3	24	40	58
Max	**25**	**43**	**58**

Large Diaper (3 x 60 ml)			
L Sample	Rate of Absorption		
	Gush 1	Gush 2	Gush 3
Sample 1	23	46	56
Sample 2	23	47	58
Sample 3	24	47	57
Max	**24**	**47**	**58**

Extra Large Diaper (3 x 70 ml)			
XL Sample	**Rate of Absorption**		
	Gush 1	**Gush 2**	**Gush 3**
Sample 1	22	50	58
Sample 2	26	45	55
Sample 3	24	47	58
Max	**26**	**50**	**58**

- We are certified with IS17509:2021 standard and our inhouse lab is fully equipped with allrequired equipment.
- Please also find results of NABL.



Test Report: GCGNTX2332533-Rev1 **Dated: 09 Jan 2024**

Title:		Protocol No:	GC-CNI-0119
Diaper		Version:	2.0
		Prepared By:	Geochem

TEST DESCRIPTION	TEST METHOD	REQUIREMENTS	Small	Medium	Large	X-Large
Average weight of diaper (stack weight of 10 diapers)	Standard Measure	Report actual, or +/-5% from claims.	21.9G	25.4G	29.55G	33.6G
Rate of absorption	IS 17509: 2021	Table 2 Requirement of Disposable Baby Diaper (*Clause* 7.2)	Pass 1st Gush: 11 Sec. 2nd Gush: 13 Sec 3rd Gush: 17 Sec.	Pass 1st Gush: 15 Sec. 2nd Gush: 17 Sec 3rd Gush: 20 Sec	Pass 1st Gush: 17 Sec. 2nd Gush: 19 Sec 3rd Gush: 26 Sec	Pass 1st Gush: 18 Sec. 2nd Gush: 21 Sec 3rd Gush: 27 Sec

Minimum Absorption Capacity	Size	Number of Gushes	Requirement
	New Born	3	3 × 20 ml
	Small	3	3 × 35 ml
	Medium	3	3 × 50 ml
	Large	3	3 × 60 ml
	X Large	3	3 × 70 ml
Rate of absorption per gush (s), *Max*	All sizes	–	60
Rewet under load, (g), *Max*	All sizes	–	5

Point # 02

Weight (kg), Dimension (mm), Minimum Absorption Capacity (ml), Rate of absorption pergush (s), Rewet under load, (g), Max for addition of new variety - double extra-large & Triple extra-large.

Please note details below –

Recommended Disposable Baby Diaper - Specification	
S.No.	Description
6	Type & Sizes
Types	*Weight of the Infant and or Toddler*
XX Large	15-25 kg
XXX Large	17 + Kg

6.2	Baby Diaper Dimensions						
Size	Diaper Length	Diaper Width	Diaper Crotch	Absorbent Core Length	AbsorbentCore Width Back	Absorbent Core Width Front	Core Crotch
XX Large	530 ±10	380 ±10	250 ±10	370 ±10	125 ±10	125 ±10	125 ±10
XXX Large	580 ±10	440 ±10	250 ±10	410 ±10	125 ±10	125 ±10	125 ±10
Dimensions (Size) of Baby Diaper is only for reference. It may vary as per buyer agreement & product category (Pant Style or Tape Style Diaper)							

7.2	Minimum Absorption Capacity		
Minimum Absorption Capacity		No of Gushes	Requirement
	XX Large	3	3 x 70 ml
	XXX Large	3	3 x 70 ml
	It should remain same 3 X 70 ml for XXL & XXXL size as core length is vary as perproduct category. As For XXXL Baby pant core length is 410 mm and for Baby open Diaper core length is 370 mm which is similar as Baby pant XL size		
Rewet Under Load (2.5kg) (Max. (g)	All Sizes	5 gm	

Point # 03

Any changes required in existing test method (Annex B) for testing apparatus, reagents,weight of rigid cover plate and test method/procedure.

Recommendation 01,

Change in rate of absorption -

		1st gush	2nd gush	3rd gush
Rate of Absorption per Gush(S), Max	New Born	≤ 40 sec	≤ 60 sec	≤ 90 sec
	Small	≤ 40 sec	≤ 60 sec	≤ 90 sec
	Medium	≤ 40 sec	≤ 60 sec	≤ 90 sec
	Large	≤ 40 sec	≤ 60 sec	≤ 90 sec
	X Large	≤ 40 sec	≤ 60 sec	≤ 90 sec
	XX Large	≤ 40 sec	≤ 60 sec	≤ 90 sec
	XXX Large	≤ 40 sec	≤ 60 sec	≤ 90 sec
Rewet Under Load(2.5 kg) Max. (g)	All sizes	05 gm		

Recommendation 02,

Change in dosing diameter of testing apparatus -

Gush sizes for NB-20 ml, S-35 ml, M-50 ml,L-60 ml and Xl-70 ml but dosing diameter for all sizesis same (Around 40 mm).

As per inhouse results, we can see the variation in rate of absorption from NB to XL. So we havefollowing recommendations:

a. Please change dosing diameter in NB and S sizes from around 40 mm to 40 mm.
b. Please change dosing diameter in M and L Sizes from around 40mm to 50 mm.
c. Please change dosing diameter in XL, XXL and XXXL Sizes from around 40 mm to 60 mm.

- These changes are required to maintain core density more or less the same from NB to XXL.
- Also, since the target area changes with the baby growing in age.

Recommendation 03,

No load requirement -

As per global industry standard rate of absorption is ≤ 60 sec without load.

So please review & keep the test method similar as global industry standard i.e. ≤ 60 sec withoutload for all 3 gushes.

Because, in case of adult diaper (IS17508) rate of absorption is defined ≤ 90 sec without load forsingle gush.

Whereas we observed that the adult patient who is bed ridden using a diaper all the time, the diaper is under load only.

b) Comments of Prashant Jadhav, P&G Mumbai.

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Specific Proposal (Draft clause to be add/amended	Justification	Comments/ Remarks	References

Draft Amendment 2 IS 17509, May 2024 Table 2 Requirement of Disposable Baby Diaper; Rate of absorption per gush (s), Max. All Sizes: First gush: 40 Second gush: 60 Third gush: 90 Rewet under load, (gm), Max. (All sizes) 5 gm	**Proposal:** Table 2 Requirement of Disposable Baby Diaper; Rate of absorption per gush (s), Max. All Sizes: *First gush: 60* *Second gush: 120* *Third gush: 180* Rewet under load, (gm), Max. (All sizes) 3 gm	1. A diaper have a top sheet or liner that allows liquid to pass through quickly, directing it to the absorbent core while keeping the surface of the diaper dry. 2. We believe that rate of absorption is important but rewet is more important with respect to the concern on incidence of rash. 3. This is so because high rewet can increase the contact time between urine and the baby's skin, compromise the skin's protective function, and increase the probability of diaper rash occurrence. 4. Minimum Rewet is necessary. The purpose of this test is to examine the ability of diapers' top sheet to resist transportation back on to the skin of a liquid which has already penetrated the top sheet. The rewet under load	Based on the justification provided, we propose the Rate of Absorption to be not more than 5 minutes and Rewet under load not more than 3 g.	1. Kenya Standard for Disposable Baby Diapers specification, KS EAS 969:2020. 2. Evidence-Based Consensus Recommendations for Skin Care in Healthy, Full-Term Neonates in India, Piyush Gupta et al 3.

		simulates the effect of a baby sitting on a wet diaper. The lesser the rewet value, the better the performance of the diaper" 5. On the basis of studies, the bath time for the babies should not be more than 5-10 minutes implying urine contact time ~ 300 seconds will be less likely resulting in any concern for babies. 6. Diapers do have cuffs at all peripheries which does not allow urine leakage from the diaper. 7. After each gush (subsequent urination) the speed of urine acquisition naturally reduces due to the load & previous saturation.		

c) Ms Komal Sharma, Kimberley Clark, Mumbai-India

As per the latest draft amendment in BIS standard 17509:2021 (DRAFT AMENDMENT NO. 2 MAY 2024), there are some changes in test instrument for checking **Minimum Absorption Capacity, Rate of Absorption per gush and Rewet Under Load.**

As per the draft amendment, '*The dimensions of the plate shall be around 200 mm × 70 mm and inner diameter of cylinder shall be 40 mm (premature baby, new born, small) (see Fig. 4), 50 mm (medium, large) and 60 mm (X Large, XX Large and XXX Large).*'

There is a technical constraint here to make an equipment set up for X Large, XX Large and XXX Large, as the diameter of cylinder shall be **60 mm** but in relation to it the plate dimension is **200 mm x 70 mm**. It is very difficult to accommodate **60 mm** diameter cylinder slot in a **70 mm** plate. Also, the cylinder thickness is **5 mm + 5 mm= 10 mm** which makes it furthermore difficult to make an equipment satisfying the requirement.

Hence, we recommend to keep the dimensions of equipment as per medium size or else kindly review the plate/cylinder dimensions for X Large, XX Large and XXX Large and suggest feasible dimensions.

d) Shri Rohit Srivastava, Unicharm Gurgaon

Thank you for the amendment confirmation on the inclusion of Preemies and XXL in Baby Diaper category from BIS under Clause 6(1) in Page 1 (mail dated 28th May 2024).

Also the rate of Absorption gets revised to 40/60/90 in Gush 1/2/3 which is now in better conditions with the amendment.

But we would like to request for additional consideration on the content on the amendment under Clause 6.1 in Page 1 that is related with the "Weight" : Our standard is upto 3 kg for Premature Babies and for New Born it is 3-5 kg . Hence would request to change the Premature Babies to Upto 3 kg .

ANNEX 5
(Item 4.*1*)

DRAFT AMENDMENTS FOR FINALIZATION

Comments on Amendment No. 1 to IS 758 : 2023 Medical Textiles — Absorbent Cotton Gauze — Specification (Fifth Revision), Doc: TXD 36 (25704) and Amendment No. 1 to IS 863 : 2023, Medical Textiles — Cotton Bandage Cloth — Specification (Third Revision) Doc: TXD 36 (25705)

a) Dr. G D Agrawal, G Surgiwear Limited

This comment is against the language used for sterile products " No viable organism should be detected". The statement is very wrong. Any sterilisation process in this world will not be able to all and every organism in the product. All have their pros and cons. A reduction of 10-9 is supposed to sterile. Looking at this some viable organisms are always present.

b) Shri Harish Meena, Scientist B, CMD 2 BIS

Comments	**Proposed Change**
For the determination of Cleanliness– Microbial/ Bioburden Test, ISO 11737 (Part 1) has been referred as a test method standard. However, ISO 11737 (Part 1) does not contain any method for determination of the Bioburden, although it provides guidance on the enumeration and microbial characterization of the population of viable microorganisms on or in a health care product, component, raw material and package. But, no method for the numerical evaluation of bioburden has been mentioned. There are instances such as IS 5405, IS 17508 & IS 17509, where the said standard has been referred for the selection of SIP(Sample Item Portion), appropriate eluent and method of extraction for determination of Bioburden, but test method has been defined separately in the product ISS.	A test method for the determination of Bioburden need to be defined separately in the ISS along the lines as given in IS 5405, IS 17508 and IS 17509.

ANNEX 6
(Item 5.1)

DRAFT AMENDMENT FOR APPROVAL FOR WIDE CIRCULATION

Comments on IS 18266 : 2023, Textiles — Medical Respirator — Specification

Shri N.K. Kansara Comments

For IS 18266, I have the following comments:

1. Para 3 under Foreword mentions that the A medical respirator is a respiratory protective device designed to achieve a very close facial fit and covers at least the nose, mouth and may cover the chin. A respirator is worn by healthcare personnel (HCP) to reduce the wearer's risk of inhaling hazardous airborne particles such as dusts, fumes, vapors, infectious agents and aerosol/fluids (for example splashes, sprays) for use in healthcare settings.

2. Foreword mentions of what this product is not but does not elaborate on the difference vis-à-vis the Surgical Face Mask and Filtering Half Mask. It may also be mentioned when one would use this product instead of the other two.

3. The Definition given under Clause 3.9 of the standard is exactly the same as the 3rd para under Foreword, which doesn't seems to good editorially.

4. It would be appropriate to add some more information regarding the use of the product and the need to have a standard and the role of important stakeholders such as the regulatory bodies, the healthcare professionals who use it and the patients who are within the healthcare setting environment. Some information of their classification (IN95 & IN99) and their significance may also be mentioned.

5. Components of the Respirators also need to be described. This would also take care of the requirement of Head Harness which has been prescribed under Clause 4.3.

6. Illustrative sketch(es) of Medical Respirators and Do's & Don'ts for its use may be added as bulleted information rather than paragraphic detail as presently given under Annex C.

7. Clause C-8 a) tends to indicate that a medical respirator may have exhalation valves, vents, or other openings and if so than it is not be worn by the user. If it so, then this should be suitably reflected in the text of the standard, as requirement, i.e., Medical Respirator should not have exhalation valves, vents, or other openings.

8. Clause 6.1 e) - Instruction for use (it could be 'instructions' also) to be marked on each piece of medical respirator – whether it would be feasible to legibly mark.

9. Requirement for Biocompatibility Evaluation as given under Table 1 Sl. No. vii) is optional and doesn't have aspect related to flammability. However, the Note 2 under the Table makes two 'shall' statements and also requires to do test of flammability of the raw material. Therefore, it would be appropriate to prescribe requirements for the raw materials and cover it there to make a user friendly standard.
10. Classification of the Medical Respirators also need to be defined specifically and then related to the corresponding performance tests.

ANNEX 7
(Item 5.1)

DRAFT AMENDMENT FOR APPROVAL FOR WIDE CIRCULATION

Inputs received from M/s Venus Safety and Health Pvt Limited on IS 18266 : 2023, Textiles — Medical Respirator — Specification

Please find point wise reply to your queries:

1. **Information regarding the use of the product and the need to have a standard**.

a) Use of the medical respirator:
A medical respirator is used to protect healthcare personnel from inhaling infectious agents, aerosolized fluids such as splashes and sprays, and also particulates matters during high-risk clinical tasks where a close facial fit is essential

b) Need to have standard:

I. Medical respirators require tests for Splash (fluid penetration) resistance and biocompatibility (cytotoxicity, irritation and sensitization) to ensure protection against infectious agents and bodily fluids, which IS 9473 does not include.

II. Medical respirators must not have exhalation valves to prevent the escape of unfiltered air and reduce the risk of spreading infectious agents, unlike IS 9473 which permits these valves.

III. IS 9473 is generally for industrial respirators and mine work, including tests like the Coal & Dolomite clogging test that are specific to these environments and necessitate an additional prefilter layer, making them irrelevant to medical settings.

IV. Medical respirators must comply with FDA requirements for medical devices, including specific packaging and labeling standards, which differ from the industrial standards under IS 9473.

2. When one would not use medical respirator.

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

3. Components and suggestive components along with head harness and figure of the Respirators also need to be described. Head Harness which has been prescribed under Clause 4.3

Respiratory components details are mentioned in standard IS 8347 which reference is already given in Annex A of IS 18266:2023. Please find enclosed a figure of Medical respirator with components details.

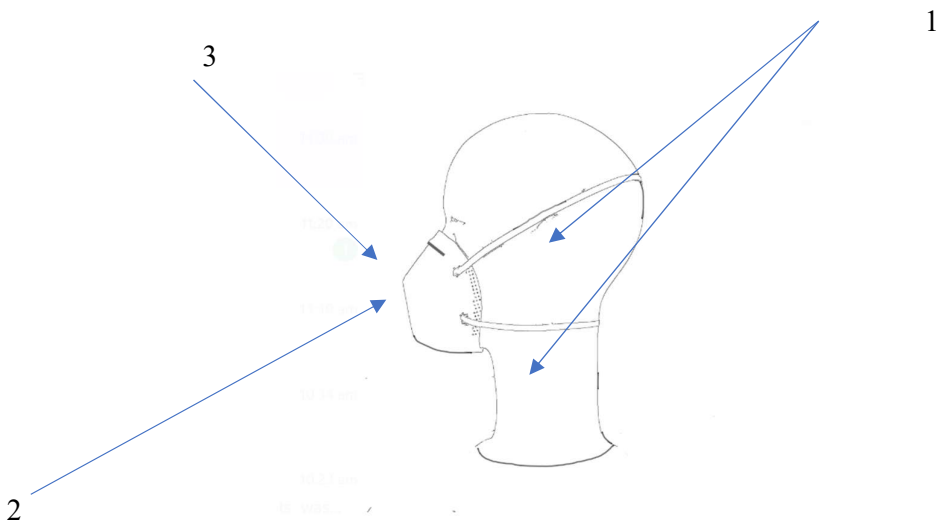


Figure 1: Medical Respirator Components

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

Note: Nose pad & head harness adjuster are optional

Date:	05-04-2024	Document No.: **IS 18266:2023**	Title of the Document: Textiles-Medical Respirator-Specification	
Name of the Commentator/		VENUS SAFETY & HEALTH PVT.LTD	Abbreviation of the Commentator/Organization: VENUS	
(Comments on each clause/subclause/table/fig, etc be started on a fresh box. Information in column 5 should include reasons for the comments/suggestions for modified wordings of the clauses when the existing text/provision is found not acceptable. Adherence to this format facilitates Secretariat's work)				

Sr no.	**Abbreviation of the Commentator/Organization**	**Clause/ Subclause No. (e.g. 3.1)**	**Paragraph No. /Figure No. / Table No. /(e.g. Table 1)**	**Type of Comment[1)]**	**Comments/Suggestions along with Justification for the Proposed Change**	**Proposed Change/Modified Wordings**	**Committee Decision**

1	VENUS	Foreword		te	Para 3 under Foreword mentions that the A medical respirator is a respiratory protective device designed to achieve a very close facial fit and covers at least the nose, mouth and may cover the chin. A respirator is worn by healthcare personnel (HCP) to reduce the wearer's risk of inhaling hazardous airborne particles such as dusts, fumes, vapors, infectious agents and aerosol/fluids (for example splashes, sprays) for use in healthcare settings	None	
2	VENUS	Foreword		te	Foreword mentions of what this product is not but does not elaborate on the difference vis-à-vis the Surgical Face Mask and Filtering Half Mask. It may also be mentioned when one would use this product instead of the other two	Refer point 5 for reply	

3	VENUS	Foreword		te	The Definition given under Clause 3.9 of the standard is exactly the same as the 3rd para under Foreword, which doesn't seems to good editorially	Refer point 5 for reply	
4	VENUS	Foreword		te	It would be appropriate to add some more information regarding the use of the product and the need to have a standard and the role of important stakeholders such as the regulatory bodies, the healthcare professionals who use it and the patients who are within the healthcare setting environment. Some information of their classification (IN95 & IN99) and their significance may also be mentioned	Refer point 5 for reply	

5	VENUS	Foreword			A medical respirator is a respiratory protective device designed to achieve a very close facial fit and covers at least the nose, mouth and may cover the chin. A respirator is worn by healthcare personnel (HCP) to reduce the wearer's risk of inhaling hazardous airborne particles such as dusts, fumes, vapors, infectious agents and aerosol/fluids (for example splashes, sprays) for use in healthcare settings. This standard does not cover the requirement of surgical face mask which has been covered in 'IS 16289 : 2014 Medical textiles — Surgical face mask — Specification' and for respiratory filtering half masks which has been covered in IS 9473 : 2002 Respiratory protective	"Foreword This Indian standard..... Textile divison council Workers, primarily those..... to life and health A Medical respirator..... healthcare settings *In the prepration of this standard the below are also referred NIOSH approved Surgical N95's regulated under USA 42 CFR 84 and its references , US 21 CFR 878 and its references* This standard does not cover the requirement of surgical face mask which has been covered in 'IS 16289 : 2014 Medical textiles — Surgical face mask — Specification'; for respiratory filtering half masks which has been covered in IS 9473 : 2002 Respiratory protective devices — Filtering half masks to protect against particles —Specification (first revision);	

					devices — Filtering half masks to protect against particles — Specification (first revision).	*and IS 19022:2023 Medical textiles—Barrier face covering—Specification.* *The standards test criteria does not cover performance requirements for products designed for specific diseases and /or infection prevention (including, but not limited to, protection against Methicillin resistant Staphylococcus aureus (MRSA), Haemophilus influenzae, or H1N1, Viral or bacterial filteration performance (e.g., filters 95% of bacteria), Antimicrobial (antiviral/antibacterial) function, Hypoallergenicity (e.g., for users of sensitive skin), Filteration of surgical smoke or plumes or or technologies including Antimicrobial coatings, Drug delivery systems, products containg nanoscale technologies.* The composition..... in Annex D	

						For the purpose .....in this standards"	
6	VENUS	Clause 4.3		te	Components of the Respirators also need to be described. This would also take care of the requirement of Head Harness which has been prescribed under Clause 4.3.	Annex A (Clause 2) refers to IS 8347 and it clarifies the comments	
7	VENUS	Clause 5.2		te	Illustrative sketch(es) of Medical Respirators and Do's & Don'ts for its use may be added as bulleted information rather than	Following changes addition in italics or deletion in strike thro recomneded "Annex C (Clause 5.2) To be supplied with every pack	

					paragraphic detail as presently given under Annex C	Information of use users"	
9	VENUS	Clause 6.1		te	Clause 6.1 e) - Instruction for use (it could be 'instructions' also) to be marked on each piece of medical respirator – whether it would be feasible to legibly mark	Following changes addition in italics or deletion in strike thro recomneded "6.1 Marking 6.1 Each piece .....information a).....product d)..... class of respirator *Each smallest commercial pack shall be legibly marked with* e).... for use k)....buyer and seller	
10	VENUS	Clause 5.1		te	Requirement for Biocompatibility Evaluation as given under Table 1 Sl. No. vii) is optional and doesn't have aspect related to flammability. However, the Note 2 under the Table makes two 'shall' statements and also requires to do test of flammability of the raw material. Therefore, it would be appropriate to prescribe requirements for the raw materials and	Following changes addition in italics or deletion in strike thro recomneded clause 5.1 Table 1 Notes "2 The requirement of biocompatibility evaluation and flammability of raw material shall be confirmed at designed *design stage* for applicable respirators that claim biocompatibility & flammability. "	

					cover it there to make a user friendly standard.		
11	VENUS	Clause 5		te	Classification of the Medical Respirators also need to be defined specifically and then related to the corresponding performance tests	Following changes addition in italics or deletion in strike thro recomneded Clause C1 may be modified as " ..... levels of IN95 & IN99 *The Medical Respirators are classified into two classes based on performance 1. IN95 Filtering out at least 95 % particles should be use by healthcare personnel (HCP) during all health care setting 2. IN99 Filtering out at least 99% particles should be use by healthcare personnel (HCP) during high risk situation or for improved fit factor"*	
12	VENUS	Clause 5.2		te	Clause C-8 a) tends to indicate that a medical respirator may have exhalation valves, vents, or other openings and if so than it is not be worn by the	Following changes addition in italics or deletion in strike thro recomneded Clause "C-8 Do not wear medical respirator a) if they have exhalation valve	

					user. If it so, then this should be suitably reflected in the text of the standard, as requirement, i.e., Medical Respirator should not have exhalation valves, vents, or other openings.	*non embeded in the filter media*, vents or other opening;"	
13	VENUS	Clause 5.2		te		Following changes addition in italics or deletion in strike thro recomneded Clause "C-4 The considerable variations in results.....such information from their suppliers. *Refer IS 9163 clause 10.8 Respirator fit testing*	

ANNEX 8
(Item 5.1)

DRAFT AMENDMENT FOR APPROVAL FOR WIDE CIRCULATION

Doc: TXD 36 (25703)

PROPOSED DRAFT AMENDMENT NO. 1 JUNE 2024

TO

IS 18266 : 2023 TEXTILES — MEDICAL RESPIRATOR — SPECIFICATION

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

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

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

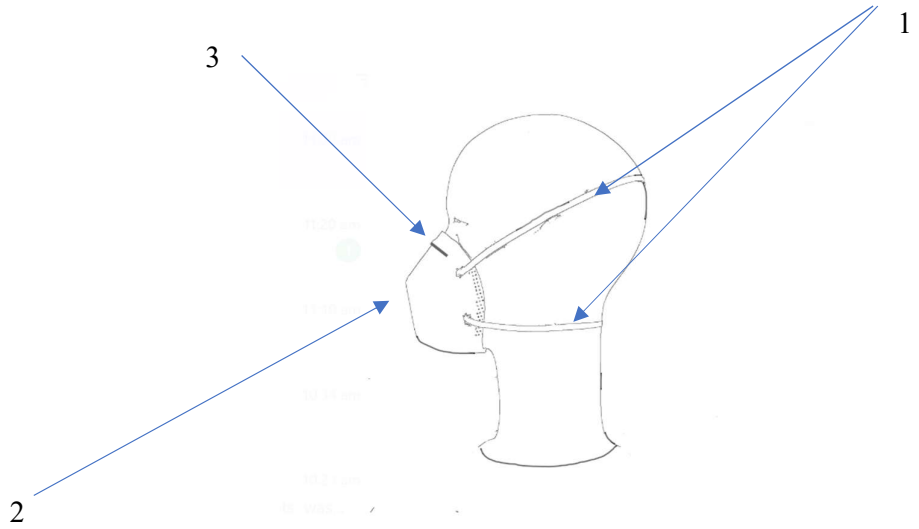


FIG. 1 MEDICAL RESPIRATOR COMPONENTS (FOR GUIDANCE ONLY)

4. Head Harness
5. Filter (Fabric layers)

6. Nose clip

Note - Nose pad and head harness adjuster are optional.

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

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

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

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

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

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

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

ANNEX 9
(Item 6.1)

NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD

a) List of subjects received from Shri Neeraj Mehra, GM – Quality, Tynor Orthotics Pvt. Ltd., Mohali

S.No.	PRODUCT NAME	BIS Standard
1	Abdominal Support 9"/23cm	IS 17350 : 2020 / IS 10603
2	Abdominal Belt	IS 17350 : 2020 / IS 10603
3	Lumbo Sacral Belt	Not available
4	Contoured L.S. Support	Not available
5	Rib Belt	Not available
6	Chest Binder	Not available
7	Taylor's Brace Short / Long	IS 11242
8	Posture Corrector	Not available
9	Cervical Collar Soft with Support	IS 11569 : 2023
10	Cervical Orthosis	Not available
11	Cervical Pillow Regular	IS 7888
12	Pouch Arm Sling Tropical / Baggy	Not available
13	Elastic Shoulder Immobiliser	Not available
14	Clavicle Brace	Not available
15	Ankle Binder	Not available
16	Knee Cap (Pair)	Not available
17	Knee Cap Open Patella	Not available
18	Elastic Knee Support	Not available
19	Functional Knee Support	Not available
20	R.O.M. Knee Brace 18"/46cm, 22"/56cm	Not available
21	Knee Immobiliser 19"/48cm, 14"/36cm, 22"/56cm	Not available
22	Wrist Brace with Thumb	Not available
23	Tennis Elbow Support	Not available
24	Elbow Support	Not available
25	Wrist Splint (Ambidextrous)	Not available
26	Wrist Brace Double lock	
27	Thumb Spica Splint	Not available
28	Heating Pad Ortho	IS 5161:1969
29	Coccyx Cushion Seat	IS 7888
30	Medical Compression Stocking Thigh High Class 2 (Pair)	IS 16467 : 2016
31	Knee Support Hinged (Neoprene)	Not available
32	Knee Wrap (Neoprene)	Not available
33	Knee Support Sportif (Neoprene)	Not available
34	Knee Wrap Hinged (Neoprene)	Not available
35	Insole Full Silicone (Pair)	Not available

36	Heel Cushion Silicone (Pair)	Not available
37	Walking Stick L type	IS 5145 : 1969
38	Walking Stick Quadripod	Not available
39	Elbow Crutch Adjustable	Not available
40	Walker Invalid	Not available
41	Commode Chair	Not available
42	Wheel Chair	IS 7454

ANNEX 10
(Item 6.1)

NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD

a) Inputs from Shri Neeraj Mehra, GM – Quality, Tynor Orthotics Pvt. Ltd., Mohali

S. No.	PRODUCT NAME	Material	Tests
1	Lumbo Sacral Belt	Polyester fabric, Elastic tape, Hook and Loop fastener,PU foam, Splint, Piping, EPF laminated cloth, Polyester sewing thread	Biometric / Fitment Cyclic Fatigue Test Color Fastness Test Abrasion & Pilling Visual Defects - Wrinkle, loose threads, Uncut thread length not >5mm, SPI, Stain free, Cuts, Hole, Needle holes
2	Pouch Arm Sling	PU foam laminated 3 layer polyester fabric, PE laminated 3 layer polyester fabric, Hook and Loop fastener,Buckle clamp, Piping, Polyester sewing thread, Polyester Niwar	Biometric / Fitment Load Bearing Test of Pouch Color Fastness Test Abrasion & Pilling Visual Defects - Wrinkle, loose threads, Uncut thread length not >5mm, SPI, Stain free, Cuts, Hole, Needle holes
3	Ankle Binder	Elastic loop tape, Hook fastener, Rib cloth, yarn, Polyester sewing thread, Elastic tape	Biometric / Fitment Stretch & Stretch Recovery Cyclic Fatigue Test Color Fastness Test Abrasion & Pilling Visual Defects - Wrinkle, loose threads, , SPI, Stain free, Cuts, Hole, Needle holes
4	Knee Cap	Rib cloth, yarn, Elastic tape	Biometric / Fitment Compression on Body Stretch & Stretch Recovery Cyclic Fatigue Test Color Fastness Test Abrasion & Pilling Visual Defects - Wrinkle, loose threads, Uncut thread length not >5mm, SPI, Stain free, Cuts, Hole, Needle holes

5	Wrist and Forearm Splint	Polyester lycra fabric, Spacer laminated fabric, Looped fabric, Hook fastener, Elastic loop tape, Buckle, splint, piping, Polyester sewing thread	Biometric / Fitment Cyclic Fatigue Test Color Fastness Test Abrasion & Pilling Visual Defects - Wrinkle, loose threads, Uncut thread length not >5mm, SPI, Stain free, Cuts, Hole, Needle holes, Shape of Splint

ANNEX 11
(Item 7.1)

INTERNATIONAL ACTIVITIES

AGENDA OF PLENARY MEETING AND RESOLUTION OF ISO/TC 338 AND STATUS REPORT OF WORKING GROUP WG 1 AND ADHOC GROUP

ISO/TC 338 **N 108**

ISO/TC 338 "Menstrual products"
Secretariat: **SIS**
Committee manager: **Acaralp Jenny Mrs**

ISO TC 338 Plenary meeting agenda (REVISED) Copenhagen June 2024

Document type	Related content	Document date	Expected action
Meeting/Agenda	Meeting: : København (Denmark) 25 Jun 2024	2024-06-19	

AGENDA (REVISED) N 108

ISO/TC 338 MENSTRUAL PRODUCTS
4th meeting
Copenhagen, June 2024

Number and title of Committee ISO/TC 338 Menstrual products	
Secretariat Swedish Institute for Standards, SIS	Meeting Meeting dates: 26-27 June, 2024
Host DS, Danish Standards **More information:** https://www.ds.dk/en/about-danish-standards/how-to-get-to-danish-standards	Place Address: Danish Standards Foundation Göteborg Plads 1 DK- 2150 Nordhavn Tel: +45 39 96 61 01
Zoom link (same link both days) Meeting URL: https://sis.zoom.us/j/87149522475?pwd=IGRJNihbFq9tPo9KSJHJpzjNtsVlNo.1 Meeting ID: 871 4952 2475 Password: 348691	UNFPA offices located UN City, address: Msrmorvej 51, 2100 København, Denmark

Additional information

This meeting is intended as Face-to-Face meeting (with a virtual option) in Copenhagen, Denmark. A Zoom meeting link will be sent out before the meeting.

- The plenary meeting takes place on June 26 at 13.00-16.30 (CET) at Danish Standards and on June 27 at 9.00-15.00 (CET) at UNFPA in Copenhagen.

- Please note that the ambition is to use the meeting on 26th for formal TC issues and decisions, while the 27th is intended for informative presentations, (therefore, the meeting time for the 27th has been adjusted to accommodate presentations, exhibitions and open discussions including lunch at UNFPA. Note that no important meeting decisions will be taken after the initial called 12:00 meeting closure time)

For meeting information and meeting schedule, see N 99.

See N 98 for Practical information and information about the Social event etc.
Registration social event (boat tour + dinner): https://sd.iso.org/meetings/140881/events/3048

ISO Meetings portal: https://sd.iso.org/meetings/140881

Training – Writing Standards
On June 25 at 09.00-12.00 (CET) there will be a training session on Writing Standards arranged, for registration see tab Sessions & event in ISO meetings portal and the plenary meeting:
https://sd.iso.org/meetings/140881/events/2972

#	Items	Action (e.g for vote for discussion for information)	N-Doc Number*	Time allocated (min)
1.	Opening of the meeting (at 13.00 – 16.30 CET, June 26- Danish Standards) • Coffee Break at approx.14.30*			**5**
2.	Welcome from host			**5**
3.	Roll call of delegates			**15**
4.	Work environment: Presentation on the ISO Code of Ethics and Conduct Direct link to the ISO Code of Ethics and Conduct			**5**
5.	Adoption of the agenda		N	**5**
6.	Appointment of the resolution drafting committee			**5**
7.	Report of the Committee Manager/Chair		N 95	**10**
8.	SIS information on possible twinning arrangements			**10**
9.	ISO/CS information - Information on Online Standards Development (OSD)			**20**
10.	Report - WG 1 Safety, performance and general requirements of menstrual products			**20**
11.	Report- AHG 1 Terminology		N 102	**15**
12.	Report - TG 1 Strategic Business Plan		N 106	**10**

13.	Strategic Business Plan / Disbandment of TG 1			**10**
14. **14.1** **14.2** **14.3** **14.4** **14.5** **14.6**	**Liaison reports** EDANA UNFPA ISO/TC 6 Paper Board and pulps/ SC 2 Test methods and quality specifications for paper and board ISO/TC 173 SC 3 Aids for ostomy and incontinence ISO/TC 38 Textiles ISO/TC 133 Clothing sizing system- size designation, size measurement methods and digital fittings		 N 96 N 107 N 101 N104 N105	**20**
15.	Review of liaisons (to be done at least every 2 years or at every committee meeting) and confirmation of Liaison Representatives			**10**
16.	Status of all items of the portfolio and actions to be taken • Current work programme • Update on target dates for work in progress			**10**
17. **17.1**	Items for future work Introduction to a test method of menstrual pads			**15**
18.	Communication (updating of Committee website (if any), Press - releases on publication, etc.)			**10**
	Day two, 09:00-15:00 at UNFPA (to access the UN city building, you will need to go through a security check. We recommend that you show up at **8.40** and don't forget to bring your picture ID/passport)			
19.	Opening – Welcoming from Karen Hong Chief for SCMU			**5**
20.	Approval of resolutions – (starting at 9.00 at UNFPA)			**15**
21.	Next TC and WG meetings			**15**
22.	Guided round tour UN City (at 9.30-10.15) *			**45**
23.	Presentation- "Sustainability, human health and social criteria", Emma Dawes, Soil Association (10:15)			**30**
	Break (10:45-11:00) *			
24.	Presentation - Introduction to Single - Use Menstrual Products, Marta Roche, Edana (at 11.00)			**45**
25.	Presentation – LEIFS- Let it flow safely" Insights into a research project about the safety of menstrual products – Elisabeth Mertl, OFI			**15**
	Lunch break approx.12.30-13.30*			
26.	Presentation - Experiences from the field, Adrian Dongus, SHF, The Sanitation & Hygiene Fund			**25**
27.	Presentation from the hosting organization, Linda Serwaa, UNFPA			**30**
28.	Exhibition – Menstrual Hygiene kit/ Experience exchange and open discussions* **Expected closure at 15.00**			**20**

	* Only on site			

Additional relevant information on meetings can be found:
• My ISO job
• TMB/SMB Guidance on effective virtual and hybrid meetings
• ISO Helpdesk knowledge base
• ISO/IEC Directives, Part 1, Clause 4 and Annex SK

ISO/TC 338 **N 109**

ISO/TC 338 "Menstrual products"
Secretariat: **SIS**
Committee manager: **Acaralp Jenny Mrs**

WG1 status report for 4th plenary meeting of ISO_TC338

Document type	Related content	Document date	Expected action
Meeting/WG report	Meeting: : København (Denmark) 25 Jun 2024	2024-06-23	

Status report of ISO/TC 338/WG 1
Safety, General and Performance requirements of menstrual products

Convenor: Shri. S. Sivakumar, ssk@sitra.org.in

Project leader: To be decided later

Secretariat: Ms. Acaralp, Jenny (jenny.acaralp@sis.se)

ISO Technical programme manager: Mr Maho TAKAHASHI (takahashi@iso.org)

Active Work Items:

PWI 25130 - Menstrual Products: General and safety requirements

Report on the activities and current work item

WG 1 was established after the first ISO/TC 338 plenary meeting with the task to prepare a standard on General requirements of menstrual products. The committee is also intended to address the general and safety requirements of menstrual products meant for different applications, internal and external, single and multiple use. The WG1 has conducted 4 virtual meetings after the last plenary meeting on 8th December 2023 during which time the document was registered as a Preliminary Work Item (25130) in ISO portal. The working group 1 discussed on the working document titled “General and Safety requirements of Menstrual Products” and the following resolutions were made:

1) Title of PWI 25130 is finalised as “Menstrual Products: General and Safety Requirements”
2) Scope of the working document is finalised as given below:

This document specifies general and safety requirements for menstrual products and covers internally and externally used products intended for single and multiple use.

3) Outline of the document was finalised as follow:

Foreword
Introduction

1. Scope
2. Normative references
3. Terms and definitions

4. General / Classification
   4.1 Types of Menstrual products

5. General requirements
   5.1 Manufacturing practices
   5.2 Materials

6. Safety requirements
   6.1 General
   6.2 Physical Safety
   6.3 Exposure Based Risk Assessment (chemical and biological safety)
      6.3.1 Hazard Identification
      6.3.2 Exposure assessment
      6.3.3 Dose-response
      6.3.4 Quantitative risk assessment

6.4 Biological Safety
   6.4.1 Externally worn single use products
   6.4.2 Externally worn multiple use products
   6.4.3 Internally worn single use products
   6.4.4 Internally worn multiple use products

6.5 Microbiological requirements / Hygiene Testing Requirements

7. Packaging and labelling
8. User information
   8.1 General
   8.2 Marking
   8.3 Instructions of use, safety, handling, and storage
   8.4 Ingredient disclosure
   8.5 Cleaning and maintenance of multiple use products
   8.6 Instructions for disposal
   8.7 Shelf life of the product

9. Other requirements
   9.1 Biodegradability and Compostability (Optional)

10. Environmental safety
11. Risk Management – Informative annex

Bibliography

4. During the 3rd plenary meeting it was tentatively proposed that BIS will propose the NWIP by end of Feb'2024. However, during the subsequent meetings, it was noted that the working document was not matured enough to propose as an NWIP as there were divergent views from different members

on the technical content of a few clauses (such as chemical safety, biological safety and environmental safety) of the working document due to following reasons:

i. Varieties of menstrual products available in market across world
ii. Scientific data is not publicly available equally for all product categories
iii. Different regulatory frameworks and infrastructure
iv. Variation in Technical specifications established in different countries
v. Disposal and waste management guidelines
vi. Affordability, social and cultural issues

Hence, the WG1 has requested to conduct 2 to 3 meetings including the meeting alongside the plenary meeting in June 2024 before submitting the NWIP.

5. As the inputs from the members were divergent and varied according to the product category, it was decided to form 4 subgroups (each one for one product category). These subgroups were formed through the voting process. The details of the subgroups formed and their leaders are given below:

Subgroup / Details	**Subgroup 1 (SG 1)**	**Subgroup 2 (SG 2)**	**Subgroup 3 (SG 3)**	**Subgroup 3 (SG 3)**
Product category	Externally worn single use products	Externally worn multiple use products	Internally worn single use products	Internally worn multiple use products
Project Leader(s)	Mrs. Roocha Khedkar / Ms. Cai Hui	Ms. Shivani Swamy / Mr. Elijah Kiwanuka	Ms. Cai Hui	Ms. Elisabeth Mertl
Total no. of members	38	30	36	27
No. of meetings conducted so far	2 (31.05.24 & 12.06.24)	5 (23.05.24, 30.05.24, 06.06.24 13.06.24 & 20.06.24)	1 (07.06.24)	1 (07.05.2024 & 08.05.24)

6. These subgroups have started addressing the product specific inputs for the topics such as “Exposure based risk assessment”, “Biological safety” and other specific clauses.

7. The convenor of WG 1 presented the need for drafting of standards on menstrual products and the overview of this group’s activities during the Informational webinar organised by ISO/TC338 on 26th and 27th March 2024 at different time zones. About 30 participants from various countries have participated on both the sessions.

Further deliberations on the PWI - draft working document will be made during the next meeting of WG1 in Hybrid mode on 25th and 26th June 2024 planned alongside the plenary meeting of ISO/TC338.

Way forward:

The inputs from all the subgroups will be consolidated after consultation with the WG1 members and the NWIP will be proposed by BIS within 30 days after the plenary meeting.

Members

BIS, India
AFNOR, France
ASI, Austria
BSI, UK

DIN, Germany
DS, Denmark
GSA, USA
INDOCAL
IRAM, Argentina
JISC, Japan
KEBS, Kenya
NBN, Belgium
NSI, Namibia
SAC, China
SFS, Finland
SIS, Sweden
SLSI, Sri Lanka
UNBS, Uganda
UNE, Spain
UNI, Italy

Virtual Meetings held since last ISO/TC 338 plenary meeting

18th and 19th January 2024 (Fourth meeting)
15th and 16th February 2024 (Fifth meeting)
8th and 9th April 2024 (Sixth meeting)
15th and 16th May 2024 (Seventh meeting)

Meetings planned: 25th and 26th June 2024 in Hybrid mode (Eighth meeting)

Tentative timeline for prosing the NWIP: BIS will propose the NWIP titled “Menstrual

Products : General and Safety requirements” before the end of July 2024.

****

ISO/TC 338 **N 111**

ISO/TC 338 **"Menstrual products"**
Secretariat: SIS
Committee manager: **Acaralp Jenny Mrs**

ISO TC 338_AHG 1 - Update June 2024-2

Document type	Related content	Document date	Expected action
Meeting / Other	Meeting: København (Denmark) 25 Jun 2024	2024-06-23	

Replaces: N 102 ISO TC 338_AHG 1 - Update June 2024

ISO TC 338/AHG 1

Report for Plenary: 24 - 27th June 2024

Presented by: Tanya Mahajan, Member, BIS (India)

Objective

1. The task of this ad hoc group is to define terms related to menstrual (absorbent and menstrual fluid collecting) products

2. to discuss the scope of ISO/TC 338 based on the discussion of the meeting and provide a revised proposal, if necessary

The AHG 1 has focused its efforts on fulfilling objective 1 above.

Composition

- 33 members (+11 document monitors)
- 9 new members added in the last 6 months
- Convenor: Tanya Mahajan, BIS
- Convenor support: E. Santhini, BIS
- Secretariat support: Jenny Acaralp, SIS

Meetings

1	1 November 2022	Review scope of AHG 1 and develop process
2	13 December 2022	Detailed discussion on formative terms and resources including 'menstrual health and products' in workshop mode
3	14 February 2023	Developed document outline and sections and additional terms added
4	6, 10 March 2023	Finalization of terms for submission of document to plenary
Updates shared during plenary on 20-21st April 2023		
Terminology document shared with TC 338 for comments		
5	27 September 2023	Resolution of comments received on document
6	30 October 2023	Revise Terminology doc uploaded on Documents Workspace

Updates shared during plenary in December 2023		
7	15 April 2024	Resolution of comments on PWI
8	22 May 2024	Resolution of comments on PWI Revised proposal for document structure (not alphabetical)
9	24 June 2024	Update on meeting

Outcomes and resolutions - December 2023 plenary

Resolution 20: ISO/TC 338 requests AHG 1 to further investigate if maternity pads/post-partum pads should be included in the terminology document	After the discussion in plenary on whether maternity pads should be included in the scope of TC 338, it was decided that since there are no other relevant standards for the product, it is better to include than to exclude, even though the technical treatment may be different. To the same end, related terms will be included in the PWI, however, specific discussion on how, is included in theagenda for this week
Resolution 21: ISO/TC 338 agrees to register the terminology document as a Preliminary Work Item, and to appoint Tanya Mahajan (India) as project leader, as a consequence to maintain AHG 1 and to revise the terms of references accordingly.	PWI Terminology created and circulated for comments with the TC. Comments have been reviewed and addressed subsequently through 2 working meetings

For discussion – plenary

Key comments for review in plenary:

● Why are maternity pads included and the need to consider them separately for performance and safety

● Inclusion of GHP and GMHP as different from GMP

● Menorrhagia - menstrual disorder vs. concern

● Conversion of AHG1 to WG so that a NWIP can be proposed for the Terminology document

● Review proposal for revised structure

- Biology of menstruation
- Classification of menstrual products

- Types of menstrual products
- Raw material, manufacturing process and material safety
- Product performance
- Microbiological safety
- Material safety
- Labeling, packaging and consumer communication
- Product end of life

For discussion - refer to WG1

Key comments for review in WG1:

- Terms related to performance and safety to be cross-referenced with discussions in WG1 and sub-groups. What should be the process of cross-referencing?

- Approach for inclusion of maternity/post-partum pads in Terminology document - should be in line with the approach taken by WG1

- Medical devices - should we use this classification to guide which requirements are applicable to which product

- End of life scenarios

    - How are we dealing with end of life, from what perspective?
    - Re. the definition of incineration - should other methods of burning should be included and support needed to make the definitions contextually relevant

For discussion - refer to WG1

Key comments for review in WG1:

- Bleaching - Discuss comment ‘Make sure that there are not any other methods to increase whiteness than those with compounds that release chlorine or oxygen, to increase the whiteness of fibres and fabric’

- Which specific risks should be included as part of material safety?

- Antibacterial property: Comment ‘Suggest using the definition from BPR Article 3 - any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action’ - https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0528

ISO/TC 338 "**Menstrual products**"
Secretariat: SIS
Committee manager: **Acaralp Jenny Mrs**

Report from WG1 for the ISO TC 338 plenary meeting

Document type	Related content	Document date	Expected action
Meeting / WG report	Meeting: København (Denmark) 25 Jun 2024	2024-06-26	

STATUS REPORT AND ROADMAP

ISO/TC3 3 8 /WG1
Safety, Performance and General requirements of Menstrual Products

ISO/TC338/Working Group 1

Title of WG1**: Safety, Performance and General requirements of menstrual products**

Objectives

To bring out standards on menstrual products
Launch NP on “Menstrual products: General and Safety requirements”.

Ongoing project

ISO/ PWI 2513 0 Menstrual Products : General and safety requirements

WORK DONE SINCE LAST PLENARY MEETING

- Title of the group was approved as “Safety, Performance and General requirements of Menstrual Products”

- 4 virtual and 1 Hybrid meetings were conducted
- The document General and Safety requirements of menstrual products – registered as a PWI in Feb' 24 (ISO/PWI 25130)
- Later, the title of the document was revised to "Menstrual Products: General and Safety Requirements"

MEETINGS CONDUCTED SINCE LAST PLENARY MEETING

Meeting	Dates of meeting	Mode
4th meeting of the WG1	18th and 19th January 2024	Virtual
5th meeting of the WG1	15th and 16th February 2024	Virtual
6th meeting of the WG1	8th and 9th April 2024	Virtual
7th meeting of the WG1	15th and 16th May 2024	Virtual
8th meeting of the WG1	25th and 26th June 2024	Hybrid

Increased participation with new members joining the group almost every month.

Countries which Joined the WG1 since last plenary meeting: GSA – USA,

INDOCAL, NBN – Belgium, NSI – Namibia, SFS - Finland, SLSI - Sri Lanka, UNBS – Uganda, UNI – Italy

INFORMATIONAL WEBINAR ON 26th and 27th March 2024

- Webinar on different time zones
- 30 participants from various countries have participated on both the sessions.

Scope of PWI

This document specifies general and safety requirements for menstrual products and covers internally and externally used products intended for single and multiple use.

OUTLINE OF DOCUMENT FINALISED

Menstrual Products : General and safety requirements

CHALLENGES FACED

1. Varieties of menstrual products available in market across world

2. Scientific data is not publicly available equally for all product categories.

3. Different regulatory frameworks and infrastructure

4. Variation in Technical specifications established in different countries

5. Disposal and waste management guidelines

6. Affordability, social and cultural issues

FORMATION OF SUBGROUPS

Subgroup / Details	**Subgroup 1 (SG 1)**	**Subgroup 2 (SG 2)**	**Subgroup 3 (SG 3)**	**Subgroup 4 (SG 4)**
Product category	Externally worn single use products	Externally worn multiple use products	Internally worn single use products	Internally worn multiple use products
Project Leader(s)	Mrs. Rocha Khedekar / Ms. Cai Hui	Ms. Shivani Swamy / Mr. Elijah Kiwanuka	Ms. Cai Hui	Ms. Elisabeth Mert
Total no. of members	38	30	36	27
No. of meetings conducted so far	2 (31.05.24 & 12.06.24)	6 (23.05.24, 30.05.24, 06.06.24 13.06.24, 20.06.24 & 24.06.24)	1 (07.06.24)	1 (07.05.2024 & 08.05.24)

OPEN POINTS FOR DISCUSSION

- List of chemicals and allergens to be tested and their limit values for each type of Products

- Test methods and the list of analytes for the above

- Max. duration of use of the product based on the impact assessment
- Process flow for EBRA with an example
- Typical format for preparing a safety report of menstrual products
- Microbioligcal requirements – Limit value for microbiological count
- Sustainability Goals targeted by this document
- Flushability and Biodegradability of products and the test methods
- Environmental aspects
- Agreement on use of a common term for Shelf life

THE WAY FORWARD

- Consolidation of inputs from all the subgroups
- Submission of NWIP and the updated working document by the end of July 2024 by BIS, India
- Further process by ISO secretariat

ISO/TC 338 **N 113**

ISO/TC 338 "Menstrual products"
Secretariat: **SIS**
Committee manager: **Acaralp Jenny Mrs**

N113 Resolutions ISO TC 338 4th Plenary meeting Copenhagen June 2024

Document type	Related content	Document date	Expected action
Meeting/Other	Meeting: : København (Denmark) 25 Jun 2024	2024-06-27	

ISO/TC 338 N 113

Resolutions taken at the 4th plenary meeting of ISO/TC 338, 26-27 June 2024.

Resolution 24 - 2024

ISO/TC 338 agreed to adopt the draft agenda (N 108) with minor modifications.

Resolution 25 - 2024

ISO/TC 338 agrees that the secretariat of ISO/TC 338 together with Laurent Houillon (AFNOR), Carrie Eddings (ANSI), Tanya Mahajan (BIS) to be appointed to the resolutions drafting committee.

Resolution 26-2024

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

Resolution 27 – 2024

ISO/TC 338 agrees to disband ISO/TC 338 TG 1 Strategic Business plan and expresses thanks to the Convenor Dr E. Santhini for her great efforts.

Resolution 28 – 2024

ISO/TC 338 agrees to extend the task of AHG1 to propose an interim draft of the Terminology document within 30 days after WG 1 finalized its preliminary draft. Based on this proposal a NWIP ballot will be prepared and launched by the committee manager with the intention of developing the document as an international standard in a working group that is to be established if the NWIP is approved.

Resolution 29- 2024

ISO/TC 338 requests BIS to prepare a New Proposal Form 4 for ISO/PWI 25130 General and safety requirements of menstrual products latest by September 30, 2024.

If approved, this project will be allocated to WG1 – Safety, performance and general requirements of menstrual products.

Resolution 30- 2024

ISO/TC 338 agrees to establish a communication task group for disseminating the work of ISO/TC 338 to external stakeholders. ISO/TC 338 requests the committee manager to launch a Committee Internal Ballot (CIB) defining the terms of reference.

Resolution 31- 2024

ISO/TC 338 accepts the invitation from KEBS, Kenya to host the 6th ISO/TC 338 Plenary meeting in 2025.

Resolution 32 – 2024

ISO/TC 338 expresses their thanks to all participants for their valuable contribution and for attending the meeting and thanked Danish Standards and UNFPA for hosting the 4th ISO/TC 338 plenary and working group meetings.

ANNEX 12
(Item 7.*1*)

INTERNATIONAL ACTIVITIES

REPORT OF PANEL MEETING OF ADHOC GROUP (AHG 1) ON TERMINOLOGY HELD ON 24 JUNE 2024

Report for the 9th Meeting of ISO/TC 338 AHG1 – Terminology

Submitted by: Tanya Mahajan, Convenor, AHG1

Mode: Hybrid

Date: 24th June 2024

Time: 13:00 – 16:00 CET

Location: Danish Standards, Copenhagen and online

Attendees:

Tanya Mahajan, BIS
Shivani Swamy, BIS
Sivakumar, BIS
Dharmbeer, BIS (online)
Carrie Eddings, ANSI
Jenna Groves, ANSI
Marci Ruman, ANSI
Benjamin Sarbo, ANSI
Adele Stewart, ANSI
Francisca Frimpong, GSA
Jane Wamboi Wainaina, KeBS
Pramudi Perera, SLSI
Laurent Houillont, AFNOR
Elijah Kiwanuka, UNBS
Charlotte Persson, SIS
Louise Klintner, SIS
Gerda Larrson, SIS
Jenny Acaralp, SIS
Ulla Hildor, SIS
Nina Kjar, DS
Junjie Liu, SAC
Chen Gong, SAC
Jiajun Wang, SAC
Miao Tian, SAC
Hui Cai, SAC (online)
Orpa Rizapi Patuuomasa, NSI
Hermine Bertolini, NSI

Minutes of discussion

1. Opening of the meeting – The meeting was opened by the convener with a welcome to all participants for the in-person meeting and those attending virtually.

2. Adoption of the agenda – The agenda was adopted by all present without any changes.

3. Review of the work of AHG1 till date – The convenor presented an overview of the work done by the AHG1 till date, the presentation is uploaded as part of the meeting documents.

4. Review the proposal for the revised structure – The revised structure for the terminology document was shared with the AHG1 which is as per themes covered in the standard rather than alphabetically. This will allow users to better access the document as a standalone reference. The revised outline was accepted by the group.

5. Discuss coordination with WG1 – The AHG1 needs to coordinate with WG1 and any future working groups to ensure that all terms discussed about the themes e.g. material safety, are included. For this, it was decided that members of AHG1 who are also members of other groups will support in providing the requisite input. The following volunteers were identified for streamlining the terms for the general and safety requirements:

    a. WG1 – Dharmbeer,
    b. SG1 – Roocha, Chen
    c. SG2 - Shivani, Laurent
    d. SG3 – Chen
    e. SG4 – Tanya

6. Review language on the scope of the Terminology document – It was decided to add an introduction section after scope to provide additional context for the themes, scope and intended use of the document. The updated scope and introduction will be added to the Terminology document, all discussion points will be updated and the revised document will be shared with AHG1 for any further comments. Some points discussed for the Introduction are included below:
    a. Purpose - Common language/vocabulary for developing a shared understanding of menstrual products and their intended use and their performance, and safety
    b. For reference by those who are/are engaged with industry, end users, standard drafters, advocates and others.
    c. This terminology document includes terms related to maternity/post-partum pads.
    d. This terminology document does not include terms related to bladder incontinence products.

e. Menstrual products are classified as medical devices, quasi-drugs, consumer products (e.g., textile, hygiene products) or others depending on the regulations in a country or region and this classification varies significantly at the time of drafting this document. The general and safety requirements included in the standard can be referenced for assessing the regulatory classification of menstrual products in any country or region.
f. Structure of the document and language for each theme/sub-section e.g. *'The **classification of menstrual products** defines the mechanism of use of the products and is the basis of requirements included in the standard.'*

7. Terms related to maternity pads – The need for inclusion of maternity pads was discussed again and it was decided that this justification should be added to the introduction for clarification.

8. Proposed use of the document – as a standalone vocabulary document to guide policy and practice on menstrual health internationally and an integrated document that supports the work of WG1 and any future technical working groups. This was discussed and the group agreed on the value of the vocabulary/terminology as a standalone standard.

9. Any other business – Other outstanding technical points based on comments and editorial points based on the standards writing workshop conducted by ISO and SIS were also discussed. Some additions based on the same are as follows:

    a. Add SDG references in introduction
    b. Change notes to admitted terms where applicable
    c. Add cross-references to key terms
    d. Definitions for the phases of the menstrual cycle should be added
    e. Complete menstrual health definition as informative annex
    f. Terms related EBRA, antibacterial activity to be added
    g. Terminology document to be renamed as Vocabulary document in line with ISO documents

10. Resolutions for next steps
    a. The revised outline for the document was accepted by the group
    b. The updated scope and introduction will be added to the Terminology document, all discussion points will be updated and the revised document will be shared with AHG1 for any further comments.
    c. The following volunteers from AHG1 who are members of other groups will support in streamlining the terms for the general and safety requirements: WG1 – Dharmbeer, SG1 – Roocha, Chen, SG2 - Shivani, Laurent, SG3 – Chen, SG4 – Tanya

d. **AHG1 will finalize an interim draft of the Terminology document 30 days after WG1 finalizes its document on General and Safety requirements.** After this, an NWIP will be created for the Terminology document.
e. The following resolution was included to this effect as part of the plenary and accepted by the TC:

Resolution 28 - 2024: ISO/TC 338 agrees to extend the task of the AHG1 to propose an interim draft of the Terminology document within 30 days after WG1 has finalized its preliminary draft. Based on this proposal, a NWIP ballot will be prepared by the committee manager, launched with the intention of developing the document as an international standard in a working group that is to be established when the NWIP is approved.

11. Closure of the meeting – The meeting was closed with gratitude by the covenor.

ANNEX 13
(Item 7.*1*)
INTERNATIONAL ACTIVITIES

BRIEF REPORT ON OUTCOMES OF PLENARY MEETING HELD ON 26-27 JUNE 2024

The 4th plenary meeting of ISO/TC 338 'Menstrual Product' was held on 26-27 June 2024 at Copenhagen, Denmark in hybrid mode. Since the subject matter being dealt by ISO/TC 338 are important from India's perspective, critical and sensitive in nature so a strong representation at the plenary meeting was proposed to represent India during the meeting.

The following delegation of experts participated in the 4th plenary meeting in hybrid mode to represent India's point of view: -

1) Shri Dharmbeer, Sc-D, Textiles, Member Secretary TXD 36 **(Head of Delegation) (Virtual Mode)**
2) Shri S. Sivakumar, (Head, Medical Textiles), SITRA, Coimbatore **(Physical Mode)**
3) Smt. Tanya Mahajan, The Pad Project (NGO), India **(Physical Mode)**
4) Ms. Shivani Swamy, Livinguard Technologies Pvt. Ltd., Mumbai **(Physical Mode)**
5) Dr. E. Santhini, SITRA, Coimbatore **(Virtual Mode)**
6) Shri Nirav Mehta, Dima Products, Mumbai **(Virtual Mode)**
7) Ms. Roocha Khedkar, Kenvue, Mumbai **(Virtual Mode)**

Presentations on the progress report of the task group for Strategic Business Plan, WG 1 Safety, performance and general requirements of menstrual product and adhoc group for terminology were made by Dr. E. Santhini, Shri S. Sivakumar, SITRA and Ms. Tanya Mahajan respectively.

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

i)The progress reports presented by India on WG 1 Safety, performance and general requirements of menstrual product and adhoc group for terminology were accepted by the committee and leadership roles (Convenorship) of India have been continued in the Working Group 1 /Adhoc group AHG1.

ii) ISO/TC 338 agrees to disband ISO/TC 338 TG 1 Strategic Business plan and expresses thanks to the **Convenor Dr E. Santhini for her great efforts** for completion of the task.

iii) ISO/TC 338 agrees to extend the task of AHG1 to propose an interim draft of the Terminology document within 30 days after WG 1 finalized its preliminary draft. Based on this proposal a NWIP ballot will be prepared and launched by the committee manager with the intention of developing the document as an international standard in a working group that is to be established if the NWIP is approved.

iv) ISO/TC 338 requests BIS to prepare a New Proposal Form 4 for ISO/PWI 25130 General and safety requirements of menstrual products latest by September 30, 2024. If approved, this project will be allocated to WG1 – Safety, performance and general requirements of menstrual products.

ANNEX 14
(Item 7.*2*)

INTERNATIONAL ACTIVITIES

Ballot ISO/NP 25199 'Guidelines for Processing of Multiple-Use Healthcare Textiles'

The inputs from TXD on the ISO/NP 25199 'Guidelines for Processing of Multiple-Use Healthcare Textiles' are as follows :-

Questions and answers: -

No.	Questions	Possible Answers
1	1a. Do you approve, disapprove or abstain on this NWIP?	Approve
2	Please also select from one of the following options (note that if no option is selected, the default will be the first option):	Draft document can be registered as a Working Draft (WD - stage 20.00)
3	In case of disapproval, do you believe that further study and consultations are needed first among committee members on this proposal as a preliminary work item before this proposal can be formally accepted?	Not Applicable
4	1b. Did you consult with the range of relevant stakeholders identified in the proposal in the development of this voting position and related comments?	Yes
5	2. Standard(s), regulation(s), and other relevant documentation existing in our country, with any remarks concerning their application if necessary and consequences for global relevance, as well as copyright information on these documents, are attached:	Yes IS 18552 : 2024, Guidelines for Processing of Multiple-Use Healthcare Textiles
6	3. Do you wish to add any additional comments?	Yes* Proposed Project Leader (name and e-mail address) Dr. Sanjiiv Rehlan ceo@shalexmeditech.com;
7	4. We are committed to participating actively in the development of the project, at least by commenting on	Yes, we nominate below experts

No.	Questions	Possible Answers
	working drafts (P-members voting "Disapprove" in Qu. 1a may nevertheless nominate experts):	**Dr. Sanjiiv Rehlan, Project Leader** (ceo@shalexmeditech.com) Dr. Sidhartha Satpathy, (dr.sidharthasatpathy@gmail.com) Dr. Pankaj Arora (drpa1009@yahoo.co.in) Dr. Lallu Joseph (**lallujoseph@hotmail.com**) Dr. Sunil Khetarpal (drkhetarpal.ahpi@gmail.com) Dr. Vivek Kulkarni (vivekkulkarni27@gmail.com) Representative of NABH, New Delhi Head (Textiles) and Member Secretary (txd@bis.gov.in, htxd@bis.gov.in)
(*) A Comment is required for this answer value.		

ANNEX 15
(Item 7.*2*)

INTERNATIONAL ACTIVITIES

BALLOT ISO/NP 25199 'GUIDELINES FOR PROCESSING OF MULTIPLE-USE HEALTHCARE TEXTILES'

NEW WORK ITEM PROPOSAL FORM 4 AND THE WORKING DRAFT ON 'GUIDELINES FOR PROCESSING OF MULTIPLE-USE HEALTHCARE TEXTILES'

ISO Form 4
NEW WORK ITEM PROPOSAL (NP)

Circulation date: 2024-04-19 **Closing date for voting:** 2024-07-12	**Reference number:** ISO/NP 25199 ISO/TC 304 **N 437**
Proposer BIS	
Secretariat ANSI	

A proposal for a new work item within the scope of an existing committee shall be submitted to thesecretariat of that committee.

A proposal for a new project committee shall be submitted to the Central Secretariat, which will process the proposal in accordance with ISO/IEC Directives, Part 1, Clause 2.3.

Guidelines for proposing and justifying new work items or new fields of technical activity (ProjectCommittee) are given in ISO/IEC Directives, Part 1, Annex C.

IMPORTANT NOTE: Proposals without adequate justification and supporting information risk rejection orreferral to the originator.

☒ The proposer confirms that this proposal has been drafted in compliance with Annex C of ISO/IECDirectives, Part 1.

PROPOSAL

(to be completed by the proposer, following discussion with committee leadership if appropriate)

TITLE

English title:

GUIDELINES FOR PROCESSING OF MULTIPLE-USE HEALTHCARE TEXTILES

French title:

(In the case of an amendment, revision or a new part of an existing document, show the reference number and current title)

SCOPE

This document provides the general guidelines for processing of multiple - use (reusable) healthcare textiles being processed under hospital laundry whether in-house or outsourced laundry services. The processing guidelines are applicable to hospital laundry in the following areas:
i) Hospitals – private, public and any extended healthcare facilities
ii) Clinics
iii) Dental Services
iv) Nursing homes
v) Mental health institutions
vi) Diagnostics sector
vii) General healthcare centres etc.
1.2 This document generally covers reusable healthcare textiles for general ward linens and operating theatre textiles such as
i) General purpose linen — Patient care like curtains, drapes, table clothes and similar items commonly used in all parts of the hospital.
ii) Patient linen — Patient clothing such as pajamas, shirts, gowns, coats etc. worn by patients.
iii) Bed linen — Bed clothing such as bed sheets, pillow covers, blankets used by the patient.
iv) Operation theatre (OT), labour room, procedure room linen —Items such as pajamas, kurtas, gowns, coats, shirts, surgical gowns, caps, masks etc. worn by healthcare personnel and also trolley covers, towels required in operation theatre, labour room and procedure room.
1.3 This document does not cover the following: -
i) Design, specification or construction criteria for machine and equipment used to process reusable healthcare textiles;
ii) Criteria for staff qualification who handles the processing of healthcare textiles.
iii) Role of infection control committee in healthcare facility and the application of any sterilization technology or sterility assurance practices;
iv) Selection of reusable healthcare textiles;
v) Special laundry situations such as neonatal intensive, burn care, Hepatitis, HIV.
vi) Performance standards for reusable healthcare textiles
vii)Other laundry service purpose like commercial, hotel, industrial and institutional laundry, etc.

PURPOSE AND JUSTIFICATION

Multiple-use healthcare textiles offer clear environmental advantages, superior performance and protection, financial benefits, and more predictable availability. Multiple - use healthcare textiles are retaining market share due to increasing concerns about the environmental pollution caused by the disposal of single use healthcare textiles. With the rise in the demand of multiple-use healthcare textiles, it is more imperative than ever that these products be processed according to the highest standards of infection prevention, quality, and safety; and preferably in an accredited facility. Concern is rising about the risk of spreading infections from reusable healthcare textiles/linen used in healthcare setting (bed sheets and blankets, towels, personal clothing, patient apparel, uniforms, scrub suits, gowns, and drapes etc.) to patient, healthcare personnel, staff and the public, if not washed under a monitored environment.

Sustainable Development Goals (SDGs)

Goal 3: Good Health and Well-Being for People
Goal 8: Decent Work and Economic Growth
Goal 14: Life Below Water

Preparatory work

☒ A draft is attached ☐ An outline is attached ☐ An existing document serving as the initial basis is attached

The proposer is prepared to undertake the preparatory workrequired:

☒ Yes ☐ No

If a draft is attached to this proposal:

Please select from one of the following options:

☒ The draft document can be registered at Preparatory stage (WD – stage 20.00)
☐ The draft document can be registered at Committee stage (CD – stage 30.00)
☐ The draft document can be registered at enquiry stage (DIS – stage 40.00)

If the attached document is copyrighted or includes copyrighted content:

☐ The proposer confirms that copyright permission has been granted for ISO to use this content in compliance with the ISO/IEC Directives, Part 1 (see also the Declaration on copyright).

Is this proposal for an ISO management System Standard (MSS)?

☐ Yes ☒ No

Note: If yes, this proposal must have an accompanying justification study. Please see the Consolidated Supplement to the ISO/IEC Directives, Part 1, Annex SL or Annex JG

Indication of the preferred type to be developed

☒ International Standard ☐ Technical Specification

☐ Publicly Available Specification *

* While a formal NP ballot is not required to start developing a PAS (no eForm04), the NP form may provide useful information for the committee P-members to consider when deciding to initiate a Publicly Available Specification.

Proposed Standard Development Track (SDT – to be discussed by the proposer with the committee manager or ISO/CS)

☐ 18 months ☐ 24 months ☒ 36 months

Draft project plan (as discussed with committee leadership)Proposed

date for first meeting: 2024-08-23

Dates for key milestones: Circulation of 1st Working Draft (if any) to experts: 2024-08-18

Committee Draft consultation (if any): 2025-07-11

DIS submission*: 2026-07-10

Publication*: 2027-07-09

* Target Dates for DIS submission and Publication should be set a few weeks ahead of the limit dates automatically determined when selecting the SDT.

NOTE: ISO/Meetings and ISO/Projects allow you to register and continuously update the meeting dates and project target dates during the development of the project.

Known patented items (see ISO/IEC Directives, Part 1 for important guidance)

☐ Yes ☒ No

If "Yes", provide full information as annex

Co-ordination of work: To the best of your knowledge, has this or a similar proposal been submitted to another standards development organization?

☐ Yes ☒ No

If "Yes", please specify which one(s):

Listing of relevant documents (such as standards and regulations) at international, regional and national level

Identification and description of relevant affected stakeholder categories (Please see ISO CONNECT)

	Benefits/Impacts/Examples
Industry and commerce - large industry	Promote global harmonisation of the essential Guidelines for processing of healthcare textiles. Better protection of patients and healthcare Professional.
Industry and commerce - SMEs	Promote global harmonisation of the essential Guidelines for processing of healthcare textiles. Better protection of patients and healthcare Professional.
Government	The guidelines will be helpful for implementation of government schemes and infection prevention in Hospital environment.
Consumers	Lower the risk of spreading infections from reusable healthcare textiles/linen used in healthcare setting (bed sheets and blankets, towels, personal clothing, patient apparel, uniforms, scrub suits, gowns, and drapes etc.) to patient, healthcare personnel, staff and the public
Labour	Better protection of patients and healthcare Professional.
Academic and research bodies	The guidelines may be useful to hospitals/users in evaluating the capabilities of facilities being considered for the processing of reusable surgical textiles
Standards application businesses	The products be processed according to the highest standards of infection prevention, quality, and safety; and preferably in an accredited facility
Non-governmental organizations	
Other (please specify)	

Liaisons: A listing of relevant external international organizations or internal parties (other ISO and/or IEC committees) to be engaged as liaisons in the development of the deliverable. AAMI, BSI	**Joint/parallel work:** **Possible joint/parallel work with:** ☐ IEC (please specify committee ID) ☐ CEN (please specify committee ID) ☐ Other (please specify)

A listing of relevant countries which are not already P-members of the committee.

Note: The Committee Manager shall distribute this NP to the ISO members of the countries listed above to ask if they wish to participate in this work

Proposed Project Leader (name and e-mail address)	**Name of the Proposer** (include contact information)
Shri S. Siva Kumar ssk@sitra.org.in	Shri S. Siva Kumar ssk@sitra.org.in

This proposal will be developed by:

☐ An existing Working Group:

☒ A new Working Group: (title: WG 9 Healthcare Textiles)

(Note: establishment of a new Working Group requires approval by the parent committee)

☐ The TC/SC directly

☐ To be determined:

Supplementary information relating to the proposal ☒ This proposal relates to a new ISO document ☐ This proposal relates to the adoption as an active project of an item currently registered as a Preliminary Work Item ☐ This proposal relates to the re-establishment of a cancelled project as an active projectOther:
Maintenance agencies (MA) and registration authorities (RA) ☐ This proposal requires the designation of a maintenance agency. If so, please identify the potential candidate: ☐ This proposal requires the designation of a registration authority. If so, please identify the potential candidate: NOTE: Selection and appointment of the MA or RA are subject to the procedure outlined in ISO/IEC Directives, Part 1, Annex G and Annex H.
☒ Annex(es) are included with this proposal (provide details)
Additional information/question(s)

Working draft for New Item Proposal for

Guidelines for Processing of Multiple Use Healthcare Textiles

FOREWORD

With the rise in the demand of reusable (multiple use) healthcare textiles, it is more imperative than ever that these products are to be processed according to the highest standards of infection prevention, quality, and safety.

Concern is rising about the risk of spreading infections from reusable healthcare textiles/linen used in healthcare setting (bed sheets, blankets, towels, personal clothing, patient apparel, uniforms, scrub suits, gowns, and drapes etc.) to patient, healthcare personnel, staff and the public, if not

washed under a monitored environment. Reusable textiles used in healthcare settings can be a component in the chain of infection transmission.

The risk is greater in such cases because contaminated garments have to be handled properly. Such garments can be a source of microbes, if the laundry process fails to eliminate contamination, it can spread to the other items in the laundry load. For example, if laundry is left damp, this encourages microbial survival and residual microorganisms could grow. A healthcare facility can avert this risk by having these garments professionally laundered by a hygienically clean healthcare certified linen & uniform service. Thus, laundering is a very necessary process in the life cycle of reusable textiles.

However, this process consumes large amounts of water and consequently produces the same amount of wastewater. And, even if the resulting wastewater is fully treated and recycled to reduce detrimental effects to the environment, there is still the problem of energy consumption during the laundry operation. From a material life cycle perspective, however, reusable textiles (woven or knitted) have the advantage of a longer lifetime, capable of surviving up to 50 or more hospital laundry cycles and thereby offering an additional saving to users and the environment.

This recommended practice is intended to provide guidelines that will help material managers, laundry managers, central service managers, and other health care professionals implement effective quality assurance systems for the processing of reusable healthcare textiles. The guidelines provided may also be useful to hospitals/users in evaluating the capabilities of facilities being considered for the processing of reusable healthcare textiles.

1 SCOPE

1.1 This standard provides the general guidelines for processing of multiple – use (reusable) healthcare textiles under hospital laundry whether in-house or outsourced laundry services. The processing guidelines are applicable to hospital laundry in the following areas:

i) Hospitals – private, public and any extended healthcare facilities
ii) Clinics
iii) Dental Services
iv) Nursing homes
v) Mental health institutions
vi) Diagnostics sector
vii) General healthcare centres etc.

1.2 This standard generally covers reusable healthcare textiles for general ward linens and operating theatre textiles such as

i) General purpose linen — Patient care like curtains, drapes, table clothes and similar items commonly used in all parts of the hospital.
ii) Patient linen — Patient clothing such as pyjamas, shirts, gowns, coats etc. worn by patients.
iii) Bed linen — Bed clothing such as bed sheets, pillow covers, blankets used by the patient.
iv) Operation theatre (OT), labour room, procedure room linen —Items such as pyjamas, kurtas, gowns, coats, shirts, surgical gowns, caps, masks etc. worn by healthcare personnel and also trolley covers, towels required in operation theatre, labour room and procedure room.

1.3 This standard does not cover the following: -

i) Design, specification or construction criteria for machine and equipment used to processing of reusable healthcare textiles;
ii) Criteria for staff qualification who handles the processing of healthcare textiles.
iii) Role of infection control committee in healthcare facility and the application of any sterilization technology or sterility assurance practices;
iv) Selection of reusable healthcare textiles;
v) Performance standards for reusable healthcare textiles.
vi) Special laundry situations such as neonatal intensive, burn care, HIV, Hepatitis (B, C) etc.
vii) Other laundry service purpose like commercial, hotel, industrial and institutional laundry, etc.

2 REFERENCES

The standards listed below 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 indicated below.

LIST OF REFERRED INDIAN STANDARDS

IS/Other Publication	*Title*
IS 201 : 2022	Quality tolerances for water for textile industry (*third revision*)
IS 1390 : 2022/ ISO 3071 : 2020	Textiles — Determination of pH of aqueous extract (*third revision*)
IS/ISO 10993-7 : 2008	Biological evaluation of medical devices Part 7 Ethylene oxide sterilization residuals
IS/ISO 11137-1: 2006	Sterilization of health care products — Radiation: Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices
IS/ISO 11137-2: 2013	Sterilization of health care products — Radiation: Part 2 Establishing the sterilization dose
IS/ISO 11135: 2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization processfor medical devices
IS/ISO 11607-1: 2006	Packaging for terminally sterilized medical devices: Part 1 Requirements for materials, sterile barrier systems and packaging systems

IS/ISO 11607-2: 2006 Packaging for terminally sterilized medical devices: Part 2 Validation requirements for forming, sealing and assembly processes

ISO 11138-7: 2019 Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results

ISO 11737-1 : 2018 Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products

ISO 17665-1 : 2006 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

3 TERMS AND DEFINITIONS

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

3.1 Barrier Properties — Ability of a protective material to resist the penetration of liquids and resistance to airborne and liquid borne microorganisms, blood, and OPIM.

3.2 Bio-hazardous bags — Bags used to collect, compile, pack, and dispose the harmful and infectious wastes that are generated by the clinical laboratories, healthcare facilities, and pharmacy industries.

3.3 Bleaching — Use of an oxidizing agent (usually sodium hypochlorite or hydrogen peroxide) within a laundry formula to decompose some types of stains and/or disinfect contaminated textiles

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

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

3.6 Calendaring — Calendaring is a finishing process used on cloth in which fabric is passed between rollers at high temperatures and pressures.

3.7 Centrifuging — Excess water from the washed clothes are spin-out of fabric which facilitates faster drying.

3.8 Cleaning — The process to physically remove contamination by foreign material, e.g. dust, soil. It will also remove organic material, such as blood, secretions, excretions and microorganisms, to prepare a healthcare textiles for disinfection or sterilization.

3.9 Cleanliness–microbial — Freedom from population of viable microorganism on a product and/ or a package.

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

3.11 Colony Forming Unit (CFU) — Unit by which culturable number of microorganisms is expressed.

3.12 Contaminated — State of having been actually or potentially in contact with microorganisms.

3.13 Contamination — The soiling of inanimate objects or living material with harmful, potentially infectious or unwanted matter.

3.14 Decontamination — The use of physical or chemical means to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

3.15 Detergent — A cleaning agent that increases the ability of water to penetrate organic material and break down greases and dirt. Detergents are needed to allow effective cleaning to take place.

3.16 Disinfection — Process that kills pathogenic and other microorganisms by physical or chemical means.

3.17 Doffing — Removal or take off of protective materials such as gloves, aprons, and so on.

3.18 Effluent — Effluent is wastewater from sewers or industrial outfalls that flows directly into surface waters either untreated or after being treated at a facility.

3.19 EPA — Environmental Protection Agency.

3.20 Extraction — Use of physical forces (usually centrifugal or strike/impact) to remove excess water from a wash load prior to drying.

3.21 Germicide — a substance or other agent which destroys harmful microorganisms.

3.22 Health Care Facility — means a place where diagnosis, treatment or immunization of human

beings is provided irrespective of type and size of health treatment system, and research activity pertaining thereto. Health care facilities includes District Hospitals, Sub Divisional Hospitals, Community Health Centres, Primary Health Centres and Sub centres.

3.23 Healthcare Personnel (HCP) — Refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (for example blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP may include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the health care facility, and persons (for example clerical, dietary, environmental services, laundry, security, maintenance, engineering and facilities management, administrative, billing, and volunteer personnel) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted among from HCP and patients.

3.24 Healthcare Textiles — Healthcare textiles materials are mainly used for protection from infections in hospital environment. They are used either in the operation theatre or in the hospital wards for safety of healthcare personnel/staff, doctor and patients. For example, bed sheets, blankets, towels, patient apparel, uniforms, scrub suits, coverall, mask, cap, gowns, and drapes etc.

3.25 Hospital Acquired Infections (HAI) — The hospital-acquired infection (HAI) also referred to as healthcare-associated infections or nosocomial infections is defined as the infections that develops in patient within 48 to 72 hours of admission to a hospital for treatment, these infections were neither present nor in incubation period at the time of admission.

3.26 Hospital Linen — Refers to all textiles used in the hospital including mattress, pillow covers, blankets, bed sheets, towels, screens, curtains, doctors' coats, theatre cloth and table cloths etc.

3.27 Hydro-extraction — It is a process of extracting water from the textiles usually done after laundry.

3.28 Infected textiles — Textiles which holds pathogenic disease-causing bacteria or virus.

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

3.30 Invasive Surgical Procedure — Surgical procedure penetrating skin or mucosa.

3.31 Laundry Processes — Activities that encompass the handling, washing, and drying of soiled textiles.

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

3.33 Manufacturer — Natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in the emergence of a new product having a distinct name, character and use.

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

3.35 Microorganism — Entity, encompassing bacteria, fungi, protozoa, and viruses, of microscopic size.

3.36 OT — Operation Theatre.

3.37 Other Potentially Infectious Materials (OPIM) — Any materials, other than blood or body fluids, containing blood-borne pathogens or materials that have been linked with the potential transmission of infectious disease.

3.38 Personal Protective Equipment — Commonly referred to as "PPE", is specialized clothing or equipment worn to minimize exposure to hazards that cause serious workplace injuries and illnesses. These injuries and illnesses may result from contact with chemical, radiological, physical, electrical, mechanical, or other workplace hazards.

3.39 pH — A measure of how acidic or basic a substance or solution is.

3.40 Processing Area — Area of the laundry containing the processing equipment used to decontaminate and clean soiled textiles.

3.41 Protective Textiles — Used to prevent or minimize exposure to hazards biological hazards.

3.42 Processing — All steps that are necessary to make a contaminated reusable healthcare textile ready for its intended use. These steps may include cleaning, functional testing, packaging, labelling, disinfection and sterilization.

3.43 Reusable/Multiple Use Product — Product intended by the manufacturer to be reprocessed and reused.

3.44 Rinsing — An operation designed to remove all suspended soils, soaps, detergents and bleach from the textiles being laundered.

3.45 Scrub suits — Loose-fitting, usually two-piece garment, worn by surgeons and assisting personnel in an operating room.

3.46 Single-use /Disposable Product — Product intended by the manufacturer to be used only once.

3.47 Sluicing — It is the process of freeing potentially harmful or infectious substances from laundry and flushing it away prior to the main washing cycle.

3.48 Soiled (Contaminated) Textiles — Textiles that have had potential contact with blood, body fluids, or OPIM.

3.49 Soil-Sort Area — Area of a laundry facility designated for receiving, retention, handling, and sorting of soiled textiles.

3.50 Soil Sorting — Process of sorting soiled items into defined or established categories so that they can be laundered together.

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

3.52 Sterilization — Sterilization is defined as a process of complete elimination or destruction of all forms of microbial life (i.e., both vegetative and spore forms), which is carried out by various physical and chemical methods.

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

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

3.55 Validation — Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently disinfect and sterilize instruments and other medical devices.

4 GENERAL REQUIREMENT FOR LAUNDRY SERVICES MANAGMENT

4.1 Laundry service in a hospital is one of the major components which directly affects the patient and hospital staff's health and hygiene. It is accountable for supplying clean and adequate linen to the hospital. It includes collecting, sorting, storage and transportation of dirty linen from hospital and washing, disinfection, extracting, drying, ironing, folding, transportation of clean linen from laundry service; back to the hospital and storage of clean linen in the hospital.

4.2 The laundry service shall establish, document, implement and maintain a quality policy for laundry infection control which includes risk management and maintain its effectiveness. The purpose of this policy is the prevention of infection or injury in service users and laundry staff involved in the use, handling or laundering of healthcare textiles. Policies and procedures shall be framed to provide a clear framework for ensuring that all individuals involved in the handling, processing, and transport of used/ soiled healthcare textiles understand their roles and responsibilities for preventing contamination.

4.3 The supervisors/managers and laundry staff shall be fully trained about the laundry procedure, handing of equipment, machine operation etc. Regular training shall be provided to supervisor and laundry staff about potential infectious hazards and techniques to prevent the spread of micro-organisms in the environment to finished healthcare textiles/linen. The role and responsibility of the supervisors/managers and laundry staff shall be defined by the laundry service provider.

5 LAUNDRY LAYOUT AND DESIGN – GENERAL REQUIREMENT

5.1 The laundry facility in a health-care setting shall be designed for efficiency in providing hygienically clean textiles, fabrics, and apparel for healthcare personnel and patient. The laundry facility shall comply with all the relevant regulatory requirements (amended from time to time) by Govt. of India for facilities and equipment. Maintaining hygiene and clean environment at laundry facility is essential for ensuring products that are appropriate for consumers use. Following are recommended guidelines for ensuring adequate infrastructure, hygiene and clean environment at laundry facilities:

i) Location of laundry facility should be free from objectionable odours, smoke, dust and other contaminants.
ii) The building shall be of adequate size to hold the required equipment, services and systems, and afford comfort to and protection of staff, equipment and goods.
iii) The laundry facility shall be designed to have a physical barrier or functional separation between areas in which soiled textiles are received and processed and areas in which clean textiles are handled and stored for distribution to the pack assembly area. This is done to prevent cross- contamination and maintain hygiene standards.

iv) A laundry facility is usually partitioned into two separate areas - a “dirty” area for receiving and handling the soiled laundry and a “clean” area for processing the washed items.

v) If healthcare textiles are processed outside the building (off site laundry), provisions shall be made for a service entrance, protected from inclement weather, for loading and unloading of healthcare textiles; an area for pick-up and receiving.

vi) Machine, equipment and systems shall be designed to reduce the risk of injury to operators/staff and to provide safe working conditions particularly with respect to odours, noise, lighting, heating, cooling, standing, sitting, stretching, bending and lifting.

vii) Work area design should allow adequate space for all functions and should promote efficiency by minimizing distances between related areas.

viii) 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.

ix) Appropriate lighting and proper ventilation of the facility shall be ensured.

x) Separate areas shall be demarcated for sorting/collection, handling, segregation of soiled and cleaned products. Dedicated areas for washing, disinfection, sterilization and packing of cleaned healthcare textiles shall be provided.

xi) Separate area shall be demarcated for storing personal effects and personal protective equipment of unit workers to minimize risk of contamination.

xii) All personnel involved in the collection, transport, sorting, and washing of soiled linen shall be adequately trained and wear appropriate personnel protective equipment (PPE).

xiii) The standard operating procedures (SOPs) should be developed and implemented to ensure that all the employees/staff shall follow the same procedures for handling contaminated materials and minimizing exposure to bloodborne pathogens.

xiv) To minimize the potential for re-contaminating cleaned laundry with aerosolized contaminated lint, areas receiving contaminated textiles should be at negative air pressure relative to the clean areas.

xv) Toilet and hand-washing station shall be provisioned away from cleaning and storage area.

xvi) There should be an eyewash station located near the equipment(s) where staff/workers are handling chemicals or other hazardous materials.

xvii) Provision of 70 percent isopropyl alcohol (IPA) solution or equivalent or soap for hand sanitization inside the production facility. Hand hygiene shall be practiced before packing of cleaned products.

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

xix) Regular pest control measures and fly screen shall be put in place.

xx) Drain outlets carrying effluent from washing machines should be sealed (close piped) into the disposal system. If a washing machine drains into an open sump, this should, where practicable, be covered to prevent the spread of organisms by aerosol when the water is dumped from the machine and also to minimize the potential chemical hazard from splashing.

xxi) The humidity should not exceed 65 percent and the temperature should be in a controlled condition from 20°C to 27°C. If the laundry facility is in the basement, adequate ventilation will be provided through proper installation and management of heating, ventilation, and air conditioning (HVAC), fresh air blowers and exhaust lines.

xxii) The environment should be made as comfortable as possible, which can generally be accomplished by proper ventilation in the work area.

xxiii) The exhaust in the laundry section should be provided with the necessary filters to capture the dust and lint.

5.2 The laundry service layout and process flow are given in FIG 1 and FIG 2 for guidance only.

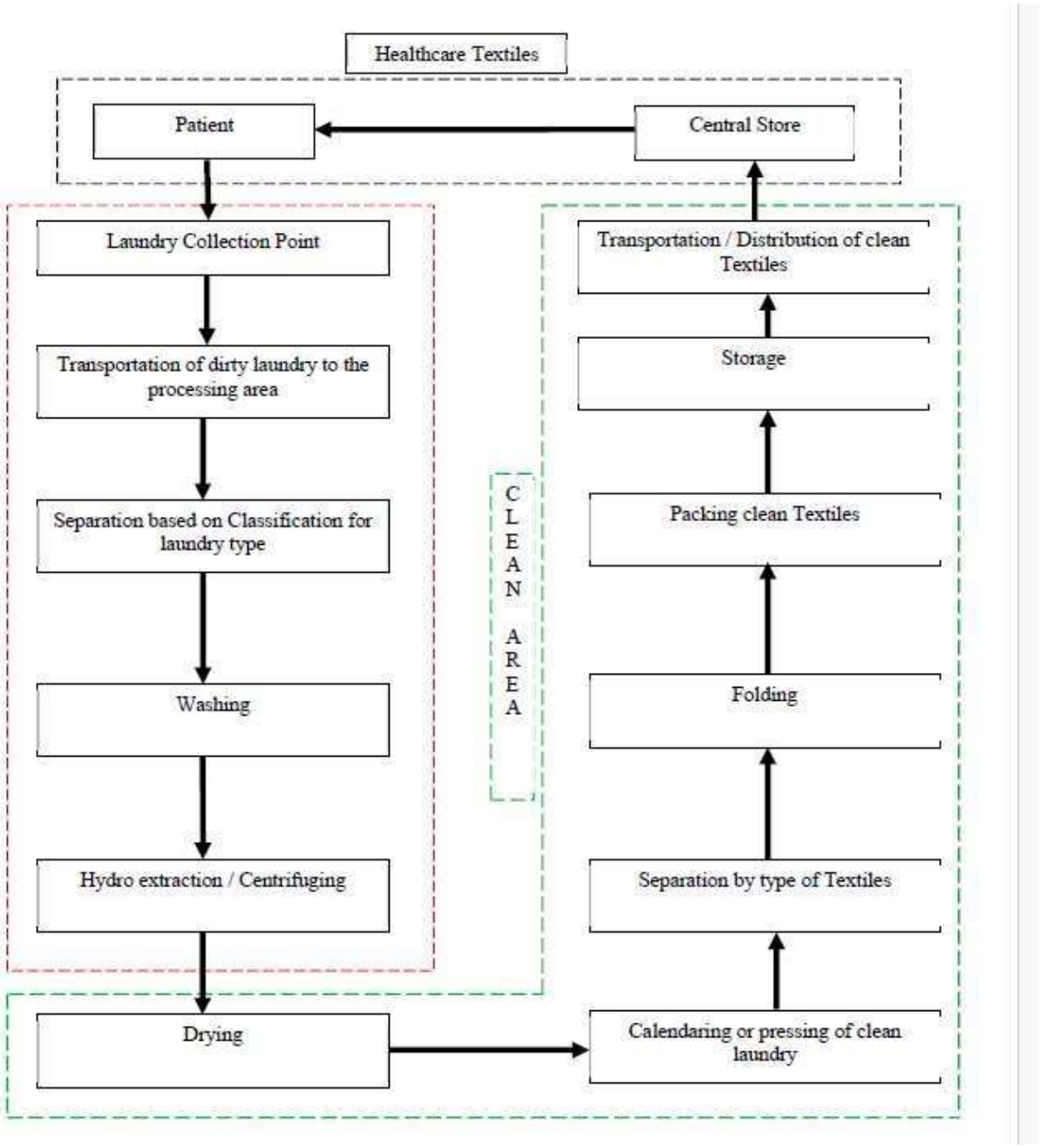


FIG 1 LAUNDRY LAYOUT

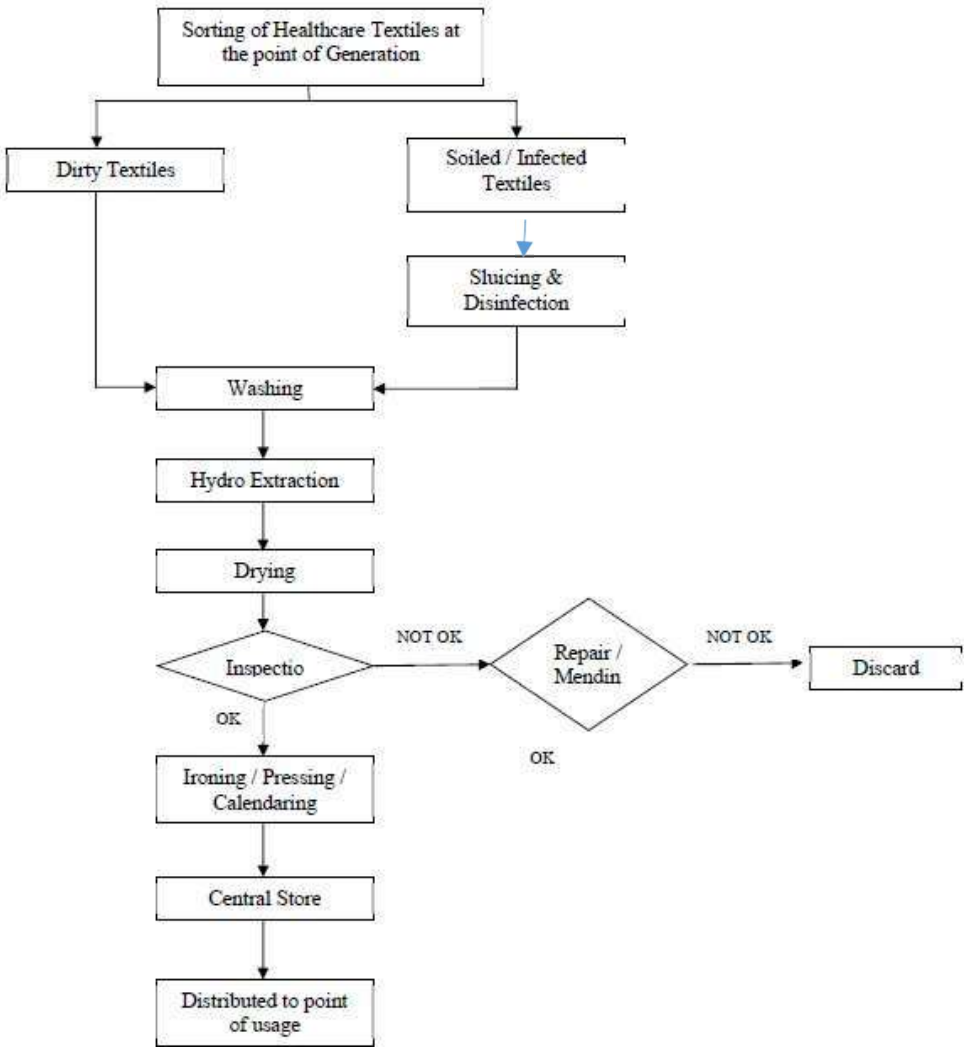


FIG 2 LAUNDRY PROCESS FLOW

6 COLLECTION AND SEGREGATION OF SOILED MATERIAL

6.1 The soiled/contaminated healthcare textiles are collected from the patient wards, patient-care areas, surgical areas, operation theatres and clinical laboratories in bio-hazardous bags. The soiled healthcare textiles may be sorted out in two ways - pre-sort systems and post-sort systems. Pre-sort systems involve sorting soiled healthcare textiles at the point of use, before they aretransported to the laundry soil-sort area. Post-sort systems involve sorting soiled healthcare textiles in the laundry soil-sort area, after they have been transported from the point of use.

6.2 Sorting must be performed carefully as the textiles from operating room or other procedure areas may often contain sharps (suture needles, razor blades, scalpel blades etc.) and the bedding

from patient's rooms may contain soiled dressings or bloodstains, as well as other body fluids. Such materials should be handled cautiously by wearing gloves, goggles, apron of high protection and disposed after sorting.

6.3 Disposable gloves and personnel protective equipment shall be used during collection and the person should not touch his/her personnel before doffing. The bags and gloves should be leak proof and possess for optimum tensile strength and high thickness. The contamination levels of the collected healthcare textiles are identified by the colour codes or labelling the bags.

6.4 The textiles with soil stain and dirt to be segregated in one cluster and the material with blood stains and infected textiles from operation theatre are to be grouped separately based on the hazardous rate, nature and depth of the stain. Segregation reduces the exposure of laundry workers to the infected material. It protects the textile and processing machinery from hard objects such as needles, syringe and sharp objects from patients.

6.5 The soiled textile materials are removed carefully by folding and rolling to avoid unnecessary agitation and directly placed into the appropriate bags. Separate areas should be used for the processing of soiled textiles from those used for folding clean healthcare textile, patient wards and food preparation areas. The areas for clean and soiled healthcare textiles should be adequately ventilated and separated by physical hindrance.

6.6 The following instruction and information should also be monitored at collection and segregation area in laundry service in healthcare facility: -

i) Hospital should have organize a daily schedule for the collection of healthcare textiles.
ii) Extra care should be taken before collection to ensure that there is no non-textile items namely syringes, needles etc. are presented.
iii) Reusable healthcare textiles from operation theatre, procedure areas and patient wards should be changed on daily basis and the healthcare material of hospital staffs should be replaced weekly.
iv) Whenever any reusable healthcare textile material is visibly dirty or soiled in the hospital, it should be changed.
v) Hand hygiene should be followed strictly before and after handling of the healthcare textiles. In case of any skin lesions, it should be covered properly.
vi) Infected textiles must be collected only in bags and should not be placed in any other surfaces. It should be stored only in the designated area.
vii) Different colour codes or labels should be followed for distinguishing the textiles collected from different areas.
viii) The supervisor/in-charge of the area should update the daily records every time when the soiled or infected textile is collected from the area. It includes the type and number of

items collected from the particular area. The record of soiled/infected healthcare textiles should be maintained for different areas for the same.

7 TRANSPORT OF CONTAMINATED HEALTHCARE MATERIALS TO RECEIVING AREA OF LAUNDRY

7.1 Soiled healthcare textiles collected from various areas of the hospital should be transported in different trolleys, bins, bags or other transport means. Transportation of soiled healthcare textiles is an important aspect of the overall process of handling these materials. Proper transportation procedures help to minimize the risk of infection transmission and ensure that textiles are effectively cleaned and disinfected.

7.2 Healthcare textiles collected through chutes should have proper design, and maintained periodically as the piston-like action of a laundry bag traveling in the chute can propel airborne microbial contaminants throughout the facility. It should be maintained in negative air pressure to avoid the transmission of microbes from floor to floor. Laundry personnel who receives the reusable healthcare textiles must enter the details in the receiving and distribution register which includes the type and quantity of item received, department that receives the material, date and time of receiving.

7.3 The following the key steps involved during transportation of contaminated healthcare textiles to receiving area of laundry service: -

i) Soiled materials should be transported in separate trolleys, bins, bags or other transport means.
ii) The containers for transportation shall be selected based on their ability to contain the materials being transported, as well as their durability and ability to prevent leaks or spills.
iii) Dedicated trolley/container should be used for transportation and the trolleys used for any other purposes should not be used.
iv) While transportation, it is to be ensured that that the collection bags are leak-proof and tied firmly.
v) In case of any leakage of infected textile materials during transport, it needs to be placed securely in the trolley and the spilled surface should be cleaned as per the spill management protocol of the hospital.
vi) Loose and contaminated pieces of healthcare textiles should not be placed in transport media to prevent the contents from falling out.
vii) The hospital must keep records for laundry management of healthcare textiles to ensure quality.

8 PRE-TREATMENT/DISINFECTION BEFORE WASHING

8.1 Heavily soiled textiles may sometime require additional pre-treatment, such as soaking in chemical/disinfectant/spot cleaning, before laundering to ensure that all soil is removed. Healthcare textiles used during radiotherapy also require special handling and washing to ensure they are properly disinfected and free of any radioactive particles.

8.2 The laundry service in healthcare facility shall decide the suitable and effective processing and disinfection method depending upon fibre content of fabric, manufacturing process, design, level of contamination, anticipated risk, type of coating etc. The most common method used for disinfection of soiled healthcare textiles is by using sodium hypochlorite solution. Hydrogen peroxide is also used as disinfectant for soiled healthcare textiles.

8.3 Disinfecting the contaminated textile material is the first step for processing. Soiled healthcare textiles should be stripped from the bed with care taken not to shake the textiles during this action. It should be soaked in 1:50 hypochlorite solution for 30 min for white textiles and the coloured materials to be processed as per hospital policy where a suitable high-level disinfectant to be used.

8.4 It is then rinsed in water until the residual bleach is removed and handed over for washing. If the laundry services are outsourced, it is the responsibility of the hospital to disinfect and sluice the soiled textile material within the facility itself before handing over the same to the outsourced agency or personnel for further processing.

9 WASHING

9.1 The laundry service in healthcare facility should follow the instruction of manufacturer of the finished healthcare textile product before deciding the washing and drying procedures to be followed. The laundry service shall have ongoing programs that record and monitor all key laundry processes. The programs shall include clear procedures for-

i) Achieving and maintaining effective washing, disinfection, drying, finishing as well as appropriate product life; and

ii) Preventative maintenance systems that ensure correct and safe operation of all plant and equipment including appropriate calibration of all key equipment such as water level controls, agitation level, temperature controls and other process timer controls that ensures compliance and process stability.

iii) The effectiveness of the washing/laundering process depends on many factors like time and temperature, mechanical action, water quality (pH, hardness), volume of the load, extent of soiling, model/availability of commercial washers and dryers.

iv) Bleach/detergent acts as a chemical germicide to kill the microbes present in the contaminated textiles. Chlorine bleach is safer and provide colour safety and better anti-microbial activity. Oxygen-based bleach or detergent registered under Environmental Protection Agency (EPA) or concerned regulatory authority authorities may also be used as an alternative for chlorine bleach.

9.2 Textiles contaminated with blood and body fluids collected in a leak-proof bag should be immersed in compatible disinfectant. Washing of the contaminated textile material should be performed immediately after the removal. During washing soiled healthcare textiles, the washing person should be given PPE.

9.3 The soiled healthcare textiles may be re-processed with hand wash or machine wash at laundry facility as per the agreement between the user and laundry service provider.

9.3.1 Hand Wash

Heavily soiled or contaminated healthcare textiles should be separated from the non-soiled material. The whole material is washed in water with liquid soap to remove the dirt, soil and spillages. The material is pre-soaked only for the soiled or infected textiles. The usage of warm water for washing is preferred based on availability. Add 30 – 60 ml of a 5% chlorine solution (bleach) for cleaning the soiled material and to assist the microbial removal. Add sour (mild acid) for neutralizing and to avoid textile materials from yellowing. Evaluate the final material for its cleanliness (wash again if it is dirty) Rinse the item with clean water.

9.3.2 Machine Wash

Soiled textile material is separated from non-soiled and washed heavily. When the wash cycle is complete, check the material for cleanliness. Rewash if it is dirty or stained. (Heavily soiled may require two wash cycles). Dirty healthcare textile is to be washed in the first batch, with plain water and detergent. The commercial hospital laundry detergent as agreed between the buyer and seller may be used. After sluicing, the infected textile is treated with hot water and detergent.

9.4 Process Parameter

The washing process consists of a combination of mechanical action, water flow, water temperature, time, and chemicals to clean/decontaminate soiled textiles. These individual processes can be adjusted in one washing machines to optimize the productivity of the operation and the performance and durability of the textiles being processed. The parameter for guidance are provided as follows: -

i) The water used for washing should meet the requirement specified in IS 201.
ii) Hot water with temperature > 71°C is recommended.
iii) Bleaching should be performed at 22°C to 25°C for heat sensitive fabrics.
iv) 50 mg/L to 150mg/L of chlorine bleach should be used in rinsing cycles after disinfection.
v) Wash cycle – 30 min.

9.5 Hydro-Extraction and Drying

Washed and clean healthcare textiles should be put in the mechanized hydro-extractor for extraction of water from the processed textiles. If the hospital does not have hydro extracting facility then the healthcare textiles can be air dried in a direct sunlight. During the process of drying of the healthcare textiles it is to be ensured that the material is kept off the ground and away from dust exposure.

9.6 Repair

All the healthcare textile material is checked for any damage, wear and tear. In case of any damage like minor hole or tear observed, it should be sent for repair and mending. The reusable healthcare textiles with crack, hole, tears and stains that cannot be removed should be incinerated. If the textile material is severely damaged and cannot be repaired, the same can be discarded or condemned as per the hospital condemnation policy, by the laundry supervisor.

9.7 Calendaring and Iron

Hospital should have a provision for a calendaring machine for calendaring the heavy reusable textile materials. If the hospital does not have the facility of calendaring machines, the textile material needs to be ironed using flat work iron and should be folded properly.

10 STERILIZATION AND PACKING

10.1 Need of Sterilization

Critical area of healthcare textiles are needed to be sterilized after every wash. Most of the textiles at healthcare facilities which includes surgical drapes and reusable gowns must be sterilized before use and therefore require steam autoclaving after laundering.

10.2 Sterilization Methods

Healthcare textiles that have contact with sterile body tissues or fluids are considered critical items. These items should be sterile when used because any microbial contamination could result in disease transmission. If healthcare textiles are heat resistant, the recommended sterilization process is steam sterilization, because it has the largest margin of safety due to its reliability, consistency, and lethality. However, processing of healthcare textiles which are heat- and moisture-sensitive requires use of a low- temperature sterilization technology like ethylene oxide. The other type of sterilization process may also be used if agreed between the user and laundry service provider.

10.3 Validation of sterilization

For packaging and sterilization, the Medical Device Rule, 2017 shall be followed. Sterilization and validation of sterilization process shall be done as per IS/ISO 11135, IS/ISO 11137-1 and 2, ISO 11138-7, IS/ISO 10993-7 and ISO 17665-1 standards.

10.4 Packing

The sterile healthcare textiles shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. The details of the packing shall be legibly made to provide necessary information for usage including sterilization date, identification, lot details, list of pack contents, etc. Packaging of the product shall be such as to maintain the integrityof the product throughout its shelf life. For packaging of the products, requirements as per IS/ISO11607-1 and 2 should be followed.

11 SPECIAL LAUNDRY/OTHER RE-PROCESS CONSIDERATIONS

For processing and disinfection, the manufacturer of the healthcare textiles is required to select and recommend a suitable method/technology for their product. One of the following methods or their combinations as suggested by the manufacturer (complete and detailed protocol for processing, disinfection and quality control has to be prepared by manufacturer) based on the scientific experimentations, specific to their product and agreed by the user may be used:

1) Washing with detergent;
2) Sodium hypochlorite and/or soap solution;
3) Ultraviolet (UV) irradiation;
4) Gamma and electron beam irradiation;
5) Ethylene oxide sterilization;
6) Vapourised hydrogen peroxide or hydrogen peroxide or gas plasma sterilization; and
7) Steam (autoclaving).

12 STORAGE AND DELIVERY

12.1 General Guidelines

The processed textile is transported in clean covered trolley to the central store. It is to be ensured that the storage of clean healthcare textiles before distribution is separate from dirty material. From the central store the clean textiles is issued to respective departments based on the indent generated from the departments. The clean and hygiene healthcare textile materials is supplied from the central store to respective departments in the clean and closed trolleys. Record of issued healthcare textiles needs to be updated in the central store room while the respective departments need to update the transaction register with the details of textile material received in the department.

12.2 The following instruction shall be followed for storage area in laundry service at healthcare facility: -

i) The trolleys used for transporting clean textiles should be washed routinely. It should be washed in a washing station after use and clean trolleys should be separated.
ii) Good ventilation systems to prevent the accumulation of soil, dirt and micro dusts.
iii) Sewage apertures or water pipers should not be present near the storage area.
iv) The shelves for storage placed should be 15-20 cm above the floor, 2.5-5 cm away from the walls and 25 cm below ceiling.
v) The storage shelves should be used only for storing clean reusable healthcare textile materials and the door of the storage shelf should be always closed.
vi) The sterile storage area should be a limited access area with a controlled temperature (may be as high as 75°F) and relative humidity (30-60%) in all works areas except sterile storage, where the relative humidity should not exceed 70%.
vii) The floors and walls should be constructed of materials capable of withstanding chemical agents used for cleaning or disinfecting. Ceilings and wall surfaces should be constructed of non-shedding materials.

13 RESPONSIBILITIES OF PERSONNEL IN HOSPITAL LAUNDRY SERVICE

13.1 Nursing In-charge

i) Manage the process of collecting and transporting used textiles from the health care facilities.
ii) Ensure that the central laundry documentation reflects infection control requirements.
iii) Observe and monitoring the infection control requirements in the outsourced laundry service with a documented book.
iv) Engaging and assisting in the renovation of the laundry department.

v) Infection control basics should be taught annually and prior to starting any new contracts.

13.2 Laundry supervisor

i) Ensure these guidelines are implemented, monitored and supervised.
ii) Establish an open communication channel between the laundry department and the users.
iii) Provide training on these guidelines to all employees in the laundry.
iv) Inspect linen for correct and safe handling.
v) Maintenance and calibration of laundry equipment.

13.3 Laundry Workers

i) Collecting used linen from wards or operation theatre and transporting it to laundry facilities.
ii) The used linen must be sorted, handled by wearing impermeable aprons, gloves and using standard measures.
iii) The safe transportation of clean textiles to departments using closed carts.

Table 1 Responsibilities of Personnel in Hospital Laundry Service

(*Clause* 13)

Sl No.	Steps involved	Personal Responsible
(1)	(2)	(3)
i)	Change of linen	Staff nurse/ward attendant
ii)	Sorting and storing of used linen	Ward attendant/housekeeping staff
iii)	Disinfection of soiled/infected linen	Housekeeping/laundry staff
iv)	Collection of used/soiled linen	Laundry staff
v)	Counting of collected linen	Laundry staff/nursing in-charge
vi)	Transporting dirty linen	Laundry staff
vii)	Washing, drying and ironing	Laundry staff
viii)	Receipt of washed linen in departments	Nursing in-charge
ix)	Storage and issue of washed linen	Nursing in-charge

14 QUALITY INSPECTION

There are inspection methods which can be done on laundered healthcare textiles to indicate the effectiveness of laundry process performance. Such process performance measures include the results of visual inspection pH tests, residual chlorine spot tests, and cleanliness / microbial load

on cleaned healthcare textiles. The user may randomly check the performance requirement of a specific healthcare textiles product as per the Indian Standard published by Bureau of Indian Standard.

14.1 Visual Inspection

14.1.1 Before each reuse, all healthcare textile products should be visually inspected against written quality standards. These standards should be developed by individuals responsible for product inspection, in consultation with end users, and should be based on the functional requirements and the identified important related attributes, which may vary depending on product classification, design, construction, and intended end use. After each laundering, the critical zones of healthcare textiles like gowns, drapes, table covers, and sterilization wraps should be visually inspected with the assistance of a light table to determine if

i) Stain or residue removal is necessary;
ii) Physical defects, such as holes and missing components, need to be repaired;
iii) Chemical or thermal damage needs to be repaired;
iv) Foreign debris (e.g., lint, hair) needs to be removed;
v) Appropriate labels are in place; and
vi) The tracking system is intact.

14.1.2 The written quality standards should define the acceptance and rejection criteria for each product type and explain how rejected items should be handled. Depending on the functional requirements, there may be different limitations for different items or even for different areas within the same item.

14.1.3 The results of quality control inspections can provide valuable feedback regarding the performance of the process. Increased levels of lint, colour loss or transfer, ineffective removal of tape, and the development of holes can provide an indication that the process can be improved upon or is out of alignment. Colour transfer on healthcare textiles occurs when hospital greens, blues, and whites are laundered together (i.e., textile classifications have been incorrectly combined in laundering). Colours transfer from coloured to white fabrics, tinting the white fabrics. This tinting is permanent because polyester does not release colour. Although dyed polyester fibres are fast to laundering, the migration of loose dye contained in new fabrics is sufficient to produce this tinting effect.

14.2 Acceptable Stains/Damages/Defects

The acceptability of healthcare textile products for use in surgery may be influenced by their appearance and the user's perception of cleanliness. Discolorations that do not interfere with the

functional performance of a textile are acceptable, and every effort should be made to allow for their continued use. However, discolorations caused by certain types of residual soils might have to be removed before the item can continue in service, because they could affect the functional performance of the product, potentially introduce particulate matter into the surgical site, and potentially prevent effective sterilization.

Table 2 An Example of Inspection Criteria for Stains

(*Clause* 12.2)

Sl No.	Stain	Accept	Reject
(1)	(2)	(3)	(4)
i)	Dye transfer from product identification labels	×	
ii)	Medicinal stains (e.g., iodine, scarlet red, methyl blue)[1]	×	
iii)	Colour lift/change from closure tape (e.g., autoclave tape on wrappers)	×	
iv)	Dark brown or rust-coloured stains resembling blood		×
v)	Light or dull discoloration	×	
vi)	Bright or dark discoloration covering a total area that is smaller than a 6-inchsquare (36 square inches), with the exception of medicinal stains (e.g., iodine, scarlet red, methyl blue) caused by the user/customer[2])	×	
vii)	Tactile stain (e.g., sticky residue, foreign matter)		×
viii)	Residue; raised (e.g., tape, casting material)[3]		×
ix)	Elastic band marks (on wrappers)	×	
x)	Colourless oil stain[4]		×
xi)	Dye/colour fade because of repeated laundering	×	

xii)	Yellow tie-dyed effect on wrappers, mayos, table covers	×	
xiii)	Scorched, burned, or melted fabric		×
xiv)	Ink or marker stains[5]	×	
xv)	Heavy ends (thick threads or additional threads in the fill)	×	

xvi)	Slubs (knots or nubs)	×	

NOTES -

1) Medicinal stains typically do not affect the performance of healthcare textiles; however, they may present an aesthetic issue for some users. Continued use of products with such stains should be discussed with and agreed to by the end user.
2) Continued use of healthcare textiles with bright or dark discoloration in primary areas should be discussed with and agreed to by the end user.
3) ltems with raised residues may be acceptable for an alternative use, such as a decontamination gown. If acceptable for an alternative use, the items should be appropriately marked to ensure that they are not used inadvertently in clinical applications.
4) An item with a colourless oil stain may continue to be used if it can be demonstrated that the oil does not affect the performance of the item.
5) Legible writing should be rendered illegible to prevent potential misinterpretation in subsequent uses.

14.3 Tests to Ensure the Effectiveness and Safety of Clean Laundered Materials

14.3.1 The functional properties of all the healthcare textiles are expected to meet the quality compliance as per manufacturer's declaration. However, to ensure the effectiveness of the laundering process and to have an evidence that the laundry process has not left the healthcare textiles harm to use after chemical exposures, the following two tests at the healthcare settings are recommended after every batch laundering on sampling basis. To ensure the effectiveness and safety of clean laundered materials, the following test may be carried out:

i) pH test - 6 to 8 when tested as per IS 1390
ii) Chlorine spot test – absent when tested as per clause **14.3.1.2.**
iii) Microbial load / cleanliness ≤ 300 CFU/ 100cm^2 when tested as per ISO 11737 (Part 1)

14.3.1.1 pH Spot Test

The pH of a finished product can indicate whether it has been appropriately rinsed and soured. Depending on the product type and end use of the product, the final pH of the finished product can vary. However, all textiles should be soured to a pH in the range of 6.0 to 8.0 to be compatible with human skin and to maximize their durability. The pH of a finished product can be measured by means of a "universal" or "sour" tester. In these qualitative tests, a pH indicator is dropped on the product and gives a visual indication of the product's pH by the resulting colour change of the indicator. The indicator is usually placed on a white portion of the textile after extraction but before drying.

14.3.1.2 Spot Chlorine Test

The presence or absence of residual chlorine indicates whether chlorine was appropriately used in the laundry process and rinsed from the product. Residual chlorine can reduce the life expectancy of textiles and is also a potential skin irritant. The presence of residual chlorine can be detected by

means of orthotolidine, which turns yellow in the presence of chlorine; the darker the yellow, themore chlorine is present.

14.3.1.2 Cleanliness / Microbial Load on the Laundered Material

Healthcare textile products should be clean and possess an inherent bio burden low enough to allow for safe handling and effective sterilization. Commercially available test methods can be used to assess bio burden levels during process qualification, process validation, or ongoing process monitoring. ISO 11737-1 provides guidance on the selection and use of these methods; this standard should be referenced for all bio burden assessments for industrial or other commercialapplications. Typically, these methods involve extraction of the item and then enumeration of aerobic and spore- forming organisms, reported as colony-forming units (CFU).

15 **Maintenance of Records**:

The following record of files and registers should be maintained for processing of healthcare textiles management in the hospital: -

i) Linen stock register at the central store
ii) Area wise daily transaction register
iii) Laundry and linen receiving register and distribution register at the laundry
iv) Any other record as per the policy and procedure of hospital or laundry service provider.

16 GENERAL GUIDELINES FOR ENVIRONMENT PROTECTION

16.1 Laundry service in hospitals have critical roles in society and their operations have major social and environmental risk. The factors including high consumption of water, high energy consumption, smoke emission by boilers, generation of bio medical waste and liquid waste, and processing and disposal of water with chemicals used in decontamination and sterilizationprocesses will lead to environmental risks. It is imperative to be that the hospitals or laundry service provider should be concerned about the environmental risks of the laundry process. The laundry facility for healthcare textiles shall follow the applicable requirement of the concerned State/Central Pollution Control Board as per the provisions of Water (Prevention and Control of Pollution) Act, 1974 and Air (Preventions and Control of Pollution) Act, 1981 under the Environment (Products) Act, 1986 and the rules made thereunder.

16.2 Treatment, Disposal and Re-use of Waste Water:

The following steps should be taken for treatment and disposal of waste water to minimize or avoid those environmental risks due to processing of healthcare textiles: -

i) Chemical disinfection is to be performed by 1-2% hypochlorite solution or equivalent disinfectant like aldehydes, lime, ammonium salts, phenolic compounds etc. Chemical disinfection performed must meet the standard of chemical disinfection as listed inSchedule II of Bio Medical Waste Management (BMWM) Rules, 2016 or other rules/regulation issued by the concerned regularity authority.

ii) Effluent Treatment Plant (ETP) shall be necessary if discharge from laundry service inHealth Care Facility (HCF) is connected with city's/town's public sewerage network not having any terminal sewage treatment plant or if the HCF is not connected to public sewerage network. Treated wastewater from healthcare facility should conform to the standards of liquid waste as listed in Schedule II of BMW Rules, 2016.

iii) Wastewater generated from the laundry service in healthcare facilities is treated in theETP and shall be disposed into drain / sewer or may be reused in: flushing, horticulture, and scrubber. The effluent from the laundry facility, after treatment in an ETP shall meet the general standards for discharge of environmental pollutant and common effluent treatment plants emission as stipulated in The Environment (Protection) Rules, 1986 (as amended from time to time).

ANNEX 16
(Item 8.1)

COMMENTS ON PUBLISHED STANDARDS

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

a) Dr. E. Santhini, SITRA

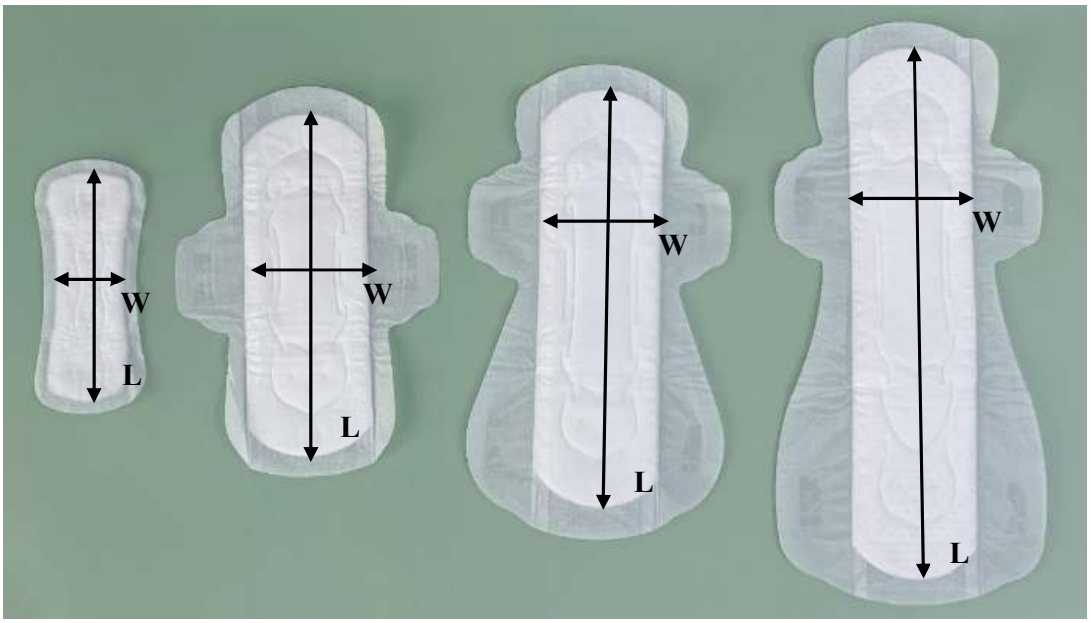
Subject: clarification on queries on IS 5405 received from stack holder - Reg
Dear sir,

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

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

SITRA Response:

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



L – Length; W – Width

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

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

SITRA Response:

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

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

SITRA Response:

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

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

SITRA Response:

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

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

SITRA Response:

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

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

SITRA Response:

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

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

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

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

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

b) Shri Nirav Mehta, Dima Products, Mumbai

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

Currently Panty liners and maternity napkins are not covered under IS 5045 and can be included with different size and performance requirements.
For panty Liners the general sizes vary from 145mm to 200mm. The main difference will be in the width and absorption capacity.
For maternity napkins, the absorption capacity should be higher as compared to the current napkins
This topic should be referred to the separate committee to come up with size and performance parameters.

- Is it possible in practical to manufacturer 100 % flushable sanitary napkin and/or 100 % biodegradable sanitary napkin. Whether we need to include these additional

requirements in the existing standard. What could be the procedure, requirement, and test method.

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

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

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

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Specific Proposal (Draft clause to be add/amended)	Remarks	Technical References and justification on which (2), (3), (4) are based
(1)	(2)	(3)	(4)	(5)
6. Manufacture, Workmanship and Finish The wood Pulp or other absorbent filler shall be arranged and neatly cut to the required size and shape of the napkin without any wrinkles and distortion. The absorbent material is deposited onto a pre-glued cover in such a way that it does not cause lump formation with the effect of sudden pressure. The covering fabric should cover the filler completely and shall extend beyond the width for wing	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 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.	**1) Sanitary Napkin tab-less**  **2) Sanitary Napkin with tab**

formation or beyond the length of the filler to form tabs or loops at each end. The absorbent along with the cover is then fed to the embossing unit, if any pattern is required to be embossed. Finally, a pre-glued barrier is applied on the other side of absorbent filler, forming a complete napkin structure. A napkin is then sealed using heat and pressure along the periphery or alternatively, it can be stitched or glued, depending upon the type of material used. In case of tab-less napkins, an adhesive system or other suitable methods may be introduced for holding the napkins securely in position. The barrier is applied with adhesive with release paper to fix the napkin to the undergarment, for the tab-less napkins.		the effect of sudden pressure. The covering fabric should cover the filler completely and shall extend beyond the width ***~~for wing formation~~ of the filler*** or beyond the length of the filler to form tabs or loops at each end. The absorbent along with the cover is then fed to the embossing unit, if any pattern is required to be embossed. Finally, a pre-glued barrier is applied on the other side of absorbent filler, forming a complete napkin structure. A napkin is then sealed using heat and pressure ***or other methods*** along the periphery or alternatively, it can be stitched or glued, depending upon the type of material used. In case of tab-less napkins, an adhesive system or other suitable methods may be		 **3) Napkin without wings** 

		introduced for holding the napkins securely in position. The barrier ***or cover*** is applied with adhesive with release paper to fix the napkin to the undergarment, for the tab-less napkins.		

c) Smt. Monika Sathe, Kenvue, Mumbai

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

1. Addition of a new product type-Panty liners needs detailed evaluation of requirements, testing needs and lab infrastructure for meeting BIS expectations.
2. Assessment of raw materials : Raw materials used in panty liner products need to be evaluated through suppliers and their awareness, technical discussions and implementation would take time.
3. BIS compliance at manufacturing sites : These products are manufactured within India and also imported, hence review of current controls and changes required in processes/documentation to meet BIS compliance.
4. Awareness and training : Since such products are also imported, the understanding of BIS requirements and inspection readiness for certification of these sites outside India needs various preparedness activities-e.g., training, testing capabilities, resources, etc.

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

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

FORMAT FOR SENDING COMMENTS ON BIS DOCUMENTS

(Please use A4 size sheet of paper only and type within fields indicated. Comments on each clause/sub clause/table/fig etc. be started on a fresh box. Information in column 3 should include reasons for the comments and suggestions for modified working of the clauses when the existing text is found not acceptable. Adherence to this format facilitates Secretariat's work)

Please e-mail your comments to textiles.bis@gmail.com or txd@bis.gov.in or faxed on 011-23231282.

NAME OF THE COMMENTATOR/ORGANIZATION:

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

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

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Specific Proposal (Draft clause to be add/amended)	Remarks	Technical References and justification on which (2), (3), (4) are based
(1)	(2)	(3)	(4)	(5)
Specification title Sanitary Napkins	Include Panty Liners	Sanitary Napkins including Panty Liners	N/A	N/A
Foreword Sanitary napkin is an absorbent material used to absorb fluid discharged during menstruation. As compared to cloth and other materials (husks, ashes, etc.) used during menstruation, it provides better hygiene and protection against leakage	Add use of Panty liner	Panty Liner is an absorbent material used to absorb small quantity of fluid discharged from vagina, like daily vaginal discharge, menstrual fluid, or urinary incontinence.	N/A	N/A

Section I SCOPE This standard covers the requirements for disposable (non-reusable) sanitary napkins for external use	Include panty liner in scope	This standard covers the requirements for disposable (non-reusable) absorbent hygiene products like sanitary napkins, Panty Liners for external use.	**N/A**	**N/A**
Section 3 **Materials** All types of sanitary napkins basically consist of three major components:	**N/A**	All kinds of Sanitary pad and Panty Liner consist of three major components**.**	**N/A**	**N/A**
Section 3.3 Barrier or Bottom Sheet The barrier shall be made of suitable leak proof material so that it meets the requirement specified in 7.2	**N/A**	The barrier shall be made of suitable leak proof material of films or non-woven material so that it meets the requirement of ability to withstand pressure.	**N/A**	**N/A**
Section 4.1 The sanitary napkin shall be of following types: a) thick napkins; and b) thin napkins	**N/A**	Include c) Panty Liners	**N/A**	**N/A**

Section 5 **SIZES** Size of sanitary napkins shall be as agreed to between the purchaser and the supplier. Sizes of sanitary napkins shall be variable depending on the absorbent capacity, purchaser's needs and wing features	Include information related to Panty Liner	Size of Panty Liner should be as agreed to between the purchaser and the supplier. Sizes of Panty Liner should be variable depending on the absorbent capacity and purchaser's needs.	N/A	N/A
Section 6 MANUFACTURE, WORKMANSHIP AND FINISH	N/A	Refer attachment 3 for manufacturing process	**N/A**	**N/A**
Section 7.1 pH Value Amendment 4 'The pH of sanitary napkin (top and absorbent core) shall be from 3.5 to 7.5 when tested by the method given in IS 1390: 2022/ISO 3071: 2020	Applicable for Panty liner	'The pH of Absorbent Hygiene product (top and absorbent core) shall be from 3.5 to 7.5 when tested by the method given in IS 1390: 2022/ISO 3071: 2020	**N/A**	**N/A**
Section 7.2 Ability to Withstand Pressure after Absorption	Include same method with modification to suit Panty liner	The Panty Liner shall absorb **5 ml of coloured distilled water** and it shall not show leakage at the bottom or sides of the Panty liner when tested according to method given in Annex () Lay the Panty Liner on a flat level transparent surface, so that underside of panty liner can be observed. Drip at the rate of 1 ml per minute, 5 ml of coloured distilled	Suitable to absorb a sudden gush or low menstrual flow	Patient education: Vaginal discharge in adult women (Beyond the Basics) - UpToDate Estimation of menstrual blood loss volume based on menstrual diary and laboratory data Ulrike Schumacher1,2*, Jens Schumacher3 , Uwe Mellinger4 , Christoph

		water maintained at temperature of 27°C ± 2°C on to the centre of the liner from a height of 1-2 mm. After the liner has absorbed full amount of coloured distilled water, keep a standard weight of 1 kg for 1 min on the portion where coloured distilled water was absorbed. Observe the bottom and sides of sanitary napkin for any leak through. Test sample passes if liquid does not leak through and fails if liquid leak through.		Gerlinger4 , Andreas Wienke5 and Jan Endrikat
Section 7.3 Hygiene Testing Requirement	No change	N/A	N/A	**N/A**
Section 7.4 Biocompatibility Evaluation Cytotoxicity, Irritation and Skin Sensitization **Amendment 1 & 2**	No change	N/A	N/A	**N/A**
Section 7.5 Biodegradability (Optional)	No change	N/A	N/A	**N/A**

Section 8.1 **8.1 Lot** All the sanitary napkin of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot. **8.1.1** Each lot shall be tested separately for ascertaining the conformity of the lot. **8.1.2** The number of sanitary napkin to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, column 3 and column 5 of Table 1.	N/A	Refer Attachment 2 for suggestions for sampling plan	N/A	**N/A**
Section 8.2 Number of Tests and Criteria for Conformity 8.2.1, 8.2.2, 8.2.3,	N/A	Refer Attachment 2	N/A	**N/A**

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

DOCUMENT NO: IS 5405: 2019 Sanitary Napkins — Specification

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)
Section 6.1 of MANUFACTURE, WORKMANSHIP AND FINISH	The process is defined with very specific steps in manufacturing tab and tab less napkins and does not allow any changes depending on different product construct and manufacturing capability.	The manufacturing process for tab and tab less napkin should be as per agreement between buyer & seller.	Different manufacturers of tab and tab-less napkin may use raw materials and follow related manufacturing process depending on their operational capability. The testing labs follow the section 6.1 as written in IS5405 and share report basis compliance to process mentioned here.	
Section 6.2 of MANUFACTURE, WORKMANSHIP AND FINISH The sanitary napkins shall	The standards allow to use of cotton as absorbent core. Considering that material from natural source is permissible to use the clarification of	The sanitary napkins shall have a soft feel and when worn shall not chafe or give any uncomfortable feeling. They		

have a soft feel and when worn shall not chafe or give any uncomfortable feeling. They shall be free from all sorts of foreign matter	foreign matter is practical.	shall be free from all sorts of foreign matter **(un-intended foreign matter that can cause injury or discomfort)**		
Section 3.2 Absorbent Core An absorbent core forming the middle layer(s) shall consist of filler materials, such as cellulose pulp, cellulose wadding, tissue, cotton, wood pulp, other absorbent and super absorbent materials or combination of these materials, etc. It shall be free from lumps, oil spots, dirt or foreign material	The standards allow to use of cotton as absorbent core. Considering that material from natural source is permissible to use the clarification of foreign matter is practical.	Section 3.2 Absorbent Core An absorbent core forming the middle layer(s) shall consist of filler materials, such as cellulose pulp, cellulose wadding, tissue, cotton, wood pulp, other absorbent and super absorbent materials or combination of these materials, etc. It shall be free from lumps, oil spots, dirt or foreign material **(un-intended foreign matter that can cause injury or discomfort)**		

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

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

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

e) Shri Prashant Jadhav, Procter & Gamble, India

Sr. No.	Topic (Inputs requested by BIS)	P&G Position
1	Whether disposable pantyliner and maternity pad are covered in IS 5405 or not. If not, what are the different requirements/variety other than given in IS 5405 :2019. Please share inputs on additional size/dimension, variety, performance requirement and test method.	**1. Period Panty/Maternity Pants** Design aspects are different to the conventional sanitary napkin. P&G is of opinion NOT TO include Period Panty in the existing Sanitary napkin standard. In case the BIS feels the need to standardize period panty P&G is ok to collaborate with BIS & Industry to develop new standard for the period panty. P&G would like to have more clarity on terminology (Period Panty Vs Maternity pad as intended use is different). **2. Panty Liners** Panty Liners are not the menstrual product. They are intended for the daily usage (to manage non-menstrual vaginal discharge). Due to the different usage scenario, liners are smaller than menstrual pads and typically have less fluid absorption capacity (starting from 1 ml).
2	Is it possible in practical to manufacturer 100 % flushable	P&G is of opinion to deliberate this topic in the committee & move forward accordingly.

	sanitary napkin and/or 100 % biodegradable sanitary napkin. Whether we need to include these additional requirements in the existing standard. What could be the procedure, requirement, and test method.	
3	Whether dioxin and furan chemical substances traces are found/relevant in disposable sanitary pad. What could be the possible requirement and test method.	• Dioxins and Furan chemical substances are not found (or below detection limits) and not relevant in disposable sanitary napkins • The identification of Chemical impurities should be based on the type of raw materials & their origin. • Random inclusion of such impurities is unscientific. In the manufacturing of AHPs, certain raw materials like cotton, cellulose pulp, and viscose undergo a bleaching process. In the past, elemental chlorine gas was used, but it has been phased out in favour of more environmentally friendly practices. The industry standards now adopts the Elemental Chlorine-Free (ECF) bleaching method, which significantly reduces the presence of Dioxin/Furan. It's also important to note that the bleaching process is not carried out on the finished products themselves. *Trace amounts of Dioxin/Furan that may be present in AHPs are typically due to the ubiquitous nature of these compounds in the environment.*

f) Ms Paridhi, Soothe Healthcare,

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

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

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

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

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

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

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

g) Shri Mithun A. Shah, Anabio Technologies

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

Response:

Pantyliners, primarily used for daily discharge and light spotting, and maternity pads, designed for postnatal use to manage heavier bleeding after childbirth, can sometimes fall under the broader category of sanitary napkins due to their similar usage in maintaining hygiene.

In the IS 5405:2019 standard, which specifies requirements for disposable (non-reusable) sanitary napkins, the scope and materials sections clearly state that the standard covers products consisting of three major components:

Cover or top sheet: The layer in contact with the skin.

Absorbent core: The middle layer responsible for absorbing and retaining fluid.

Barrier or bottom sheet: The layer that prevents fluid from leaking out of the napkin.
Given this definition, any sanitary product incorporating these three components would be covered within the scope of IS 5405:2019. The size/dimension, performance requirement and test method for pantyliner (primarily used for daily discharge and light spotting) and maternity pads (designed for postnatal use to manage heavier bleeding after childbirth) has to be specified separately.

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

Response:

Flushable Sanitary Napkins:

Yes, it is possible and practical to manufacture flushable sanitary napkins.

Biodegradable Sanitary Napkins:

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

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

Requirements:

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

Test Methods:

For Biodegradability:

ISO 14855-1:2012: Determination of the ultimate aerobic biodegradability of plastic materials under controlled composting conditions.

ASTM D6400: Standard specification for labeling of plastics designed to be aerobically composted in municipal or industrial facilities.
ISO 17088:2008: Specifications for compostable plastics, which can be adapted for other biodegradable materials.

For Flushability:

INDA/EDANA Flushability Guidelines (followed in US & Europe): Testing for toilet and drainline clearance, disintegration, and biodegradation.

UK Water Industry (followed in UK): Testing for toilet and drainline clearance, disintegration, snagging, settling and biodegradation by chemical & biological methods.

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

ANNEX 17
(Item 8.2)

COMMENTS ON PUBLISHED STANDARDS

IS 17787 : 2021, Medical Textiles — Nonwoven Wipes — Specification and IS 17788 : 2021 Medical Textiles — Nonwoven Fabric for Wipes — Specification

a) Shri Pronab Nandi, Ginni Filaments Limited

Suggestions/Comments for Modification in requirements in IS 17788:2021 and IS 17787:2021

1. As per IS 17788:2021 (Clause 6.1), **IS 15891 (Part 18**) is mentioned for strength testing. But, **IS 15891 (Part 18)** is Grab Tensile Test method and it is not suitable for Nonwoven fabric.

For Nonwoven fabric, **IS 15891 (Part 3**) which is a Strip Tensile test method and it is widely used for Nonwoven fabric and it is equivalent to **ISO 9073-3:2023**, **EDANA202-89.** So, we would request you to please remove IS 15891 (Part 18) from IS 17788:2021 (Clause 6.1) and please replace with **IS 15891 (Part 3)**.

2. As per IS 17787:2021 (Clause 6.1), the requirement of length and width (mm) is mentioned as agreed to between the buyer and seller with a tolerance of ± 1 mm. As Nonwoven spunlace fabric is highly stretchable, it is not possible to maintain it with a tolerance of ± 1 mm. Hence, we recommend the tolerance of ± 5 mm.

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

DOCUMENT NO: IS 17788: 2021 Medical Textiles — Nonwoven Fiber for Wipes — Specification.

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)

Table 1 Performance Requirement for Nonwoven Fabric (Clause 6.1) i) Fabric identification	For the requirement of "at least 20 percent of cotton or/and viscose fibre", the test method mentioned is IS 667. IS 667 "Identification of Textile Fibres" is qualitative method.	Meets the requirements for cotton or/and viscose fibre. For percent content, check the requirement through manufacturing process records.	IS 667 "Identification of Textile Fibres" is qualitative method and not quantitative hence percent content of cotton or/and viscose fibre cannot be verified.	

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

DOCUMENT NO: IS 17787: 2021 Medical Textiles — Nonwoven Wipes — Specification.

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)
Table 1 Performance Requirement for Nonwoven Wipes (Clause 6.1) ii) Length and width, mm	The tolerance limit to be modified from ± 1 mm	As agreed to between the buyer and the seller with a tolerance of ± 5 mm	The wipes are made of spun lace fabric which has elongation properties, therefore gets stretched during manufacturing.	
ii) pH	Revise the limit	3.5 – 7.5		OEKO-TEX® STANDARD 100: New regulations 2023 Wet wipes The pH-footnote was added to the OEKO-TEX ® STANDARD 100 to allow an exception

				in the pH range for wet wipes. The new accepted pH range for wet wipes is 3.5 - 7.5.
8 MARKING Section l) Anti-bacterial if claimed; and	Section 1.1 mentions - This standard does not cover wet wipes impregnated/coated with alcohol and other wipes with germicidal claim (numerical germ kill, disinfection etc.).	Modify as below: Anti-bacterial if claimed (other than bactericidal mode of action)		

c) Shri Rohit Srivastava, Unicharm India

IS 17787:2021

Medical Textiles Nonwoven Wipes –Specification

6.1 i) Tolerance ±1mm - Request to changeNeed change to ± 10mm

Reason for Change

There are 2 process which are involved in dimensions of Wipes.

Process 1) Mother Roll Slitting - Spunlace Mother roll is slitted as per requiredSlit Width for the Wet wipes machine.

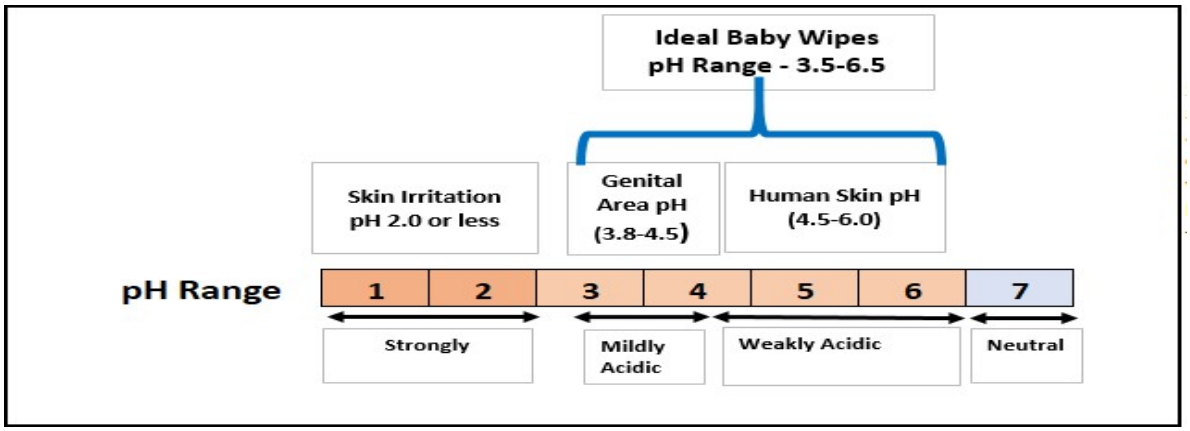
The tolerance is ± 5mm

Process 2) Machine In line Slit of Finished Goods - Once Spunlace desired Slitted roll is kept on wet wipes machine the machine itself cuts the fabric intodesired length. The tolerance is ± 5mm needed as material is moving during production time.

Hence Considering Condition of Process 1 and Process 2 Overall Toleranceshould be considered ± 10mm.

6.1 ii) pH 4.5-7.5 Request to change

Need change to pH 3.5 - 6.5



1) The skin's natural part like hand, foot and other body has pH slightly acidic,ranging from 4.5 to 6.0.

2) The genital area like pubic/vaginal area has pH 3.8-4.5.

3) Below pH 2 or less is consider as Skin corrosive/irritation pH.

4) Wipes especially baby wipes are used to clean urine and stool which covers delicate area and also used to clean other body parts like hand, foot and otherbody part. Our main target is to have hygiene around genital area hence considering all factors we have considered the mildly acidic range with 3.5-6.5.

Conclusion - Our Wipes are designed to match the actual baby wipespH range 3.5-6.5.

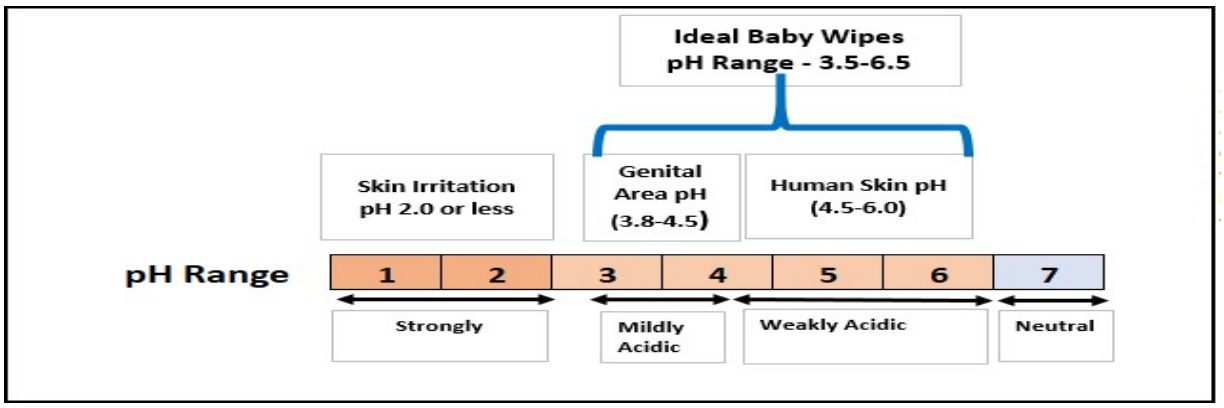
IS 17788:2021, Medical Textiles Nonwoven Fabric for Wipes – Specification

4 Material; Cotton or Viscose Fiber at least 20% or more Request to Change Need change to No Design limitation

Reason for Change

Currently based on Standard shared Unicharm wipes could meet the standard but we shouldn't limit wipes to minimum 20% viscose/cotton as Wipes design spec depends on Consumer requirement and demand of Stiffness in fabric and fluffiness requirement. Hence, we shouldn't restrict wipes specification as we limiting product design.

6.1 vi) pH 5.5-8.0 Request to change Need change PH 3.5- 6.5



1) The skin's natural part like hand, foot and other body has pH slightly acidic, ranging from 4.5 to 6.0.

2) The genital Area like pubic area has pH 3.8-4.5

3) Below pH 2 or less is consider as Skin corrosive/irritation pH.

4) Wipes especially baby wipes are used to clean urine and stool which covers delicate area and also used to clean other body parts like hand, foot and other body part. Our main target is to have hygiene around genital area hence considering all factors we have considered the mildly acidic range with 3.5-6.5.

Conclusion - Hence Wipes are designed to match the actual baby pH range 3.5-6.5.

ANNEX 18
(Item 9.*1*)

DUE FOR REVIEW

List of Standards Due for Review

S.No.	IS Number	IS Title	Allotted to committee members/experts to review/comments
1	IS 10829 : 1993	X-Ray detectable gauze swabs and laparotomy sponges – Specification (first revision)	Dr. Manish Sabharwal, Dr. Sabharwal Wound Care
2	IS 14944 : 2020	Surgical Dressings — Methods of Test (First Revision)	-do-
3	IS 1681 : 1998	Textiles – Hospital blankets, woollen, dyed – Specification (third revision)	Dr. Sanjiiv Rehlan, FICCI (Shalex Medtech)
4	IS 4717 : 2020	Medical Textiles - Zinc Oxide Self-Adhesive Plaster - Specification (Second Revision)	Dr. Manish Sabharwal, Dr. Sabharwal Wound Care
5	IS 4738 : 2020	Medical Textiles - Bandage, Plaster of Paris - Specification (Third Revision)	-do-
6	IS/ISO 20645 : 2004	Textile fabrics – Determination of antibacterial activity - Agar diffusing plate test	Member Secretary TXD 36
7	IS 16288 : 2014	Medical textiles - Method for evaluation of the bacterial filtration efficiency of surgical face masks	Shri D. Veerasubramaniam, SITRA
8	IS 16289 : 2014	Medical textiles - Surgical face masks - Specification	Shri Mahesh Kudhav, VENUS Safety & Health Pvt Ltd. Shri Anand Singh,

			Thea - Tex Healthcare (India) Private Limited Representative of Magnum Health and Safety Pvt. Ltd.
9	IS 16290 : 2014	Medical textiles - Knitted viscose primary dressings - Specification	Shri D. Veerasubramaniam, SITRA Shri T. Balaji, KOB Medical Textiles Pvt Ltd, Dr. Manish Sabharwal, Dr. Sabharwal Wound Care
10	IS 16291 : 2014	Medical textiles - Paraffin gauze dressings - Specification	-do-
11	IS 16302 : 2020	Medical Textiles — Orthopedic Stockinet — Specification (First Revision)	-do-
12	IS 16303 : 2014	Medical textiles - Cast padding for orthopaedic plaster - Specification	-do-
13	IS 16466 : 2020	Medical Textiles - Povidone Iodine Ointment Based Knitted Dressing - Specification (First Revision)	-do-
14	IS 16549 : 2020/ISO 22610 : 2018	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment – Test method to determine the resistance to wet bacterial penetration (first revision)	Member Secretary TXD 36
15	IS 16671 : 2020	Medical Textiles — Belladonna Adhesive Plaster — Specification (First Revision)	Shri D. Veerasubramaniam, SITRA Dr. Manish Sabharwal, Dr.

			Sabharwal Wound Care
16	IS 17349 : 2020	Medical textiles – Shoe covers – Specification	Shri Anand Singh, Thea - Tex Healthcare (India) Private Limited Representative of Magnum Health and Safety Pvt. Ltd. Shri Sumit Marwah, Dispoline India Private Limited
17	IS 17348 : 2020	Medical textiles – Adhesive incise drape – Specification	Dr. Prabha Hegde, 3 M India Shri Sumit Marwah, Dispoline India Private Limited Dr. Sanjiiv Rehlan, FICCI (Shalex Medtech)
18	IS 17350 : 2020	Medical textiles – Abdominal binder – Specification	Dr. Manish Sabharwal, Dr. Sabharwal Wound Care
19	IS 17351 : 2020	Medical textiles – Dressing, shell compressed – Specification	Dr. Manish Sabharwal, Dr. Sabharwal Wound Care
20	IS 17352 : 2020	Medical textiles – Foam dressing – Specification	Dr. Prabha Hegde, 3 M India
21	IS 17353 : 2020	Medical textiles – Pressure garment – Specification	Shri D. Veerasubramaniam, SITRA

			Shri T. Balaji, KOB Medical Textiles Pvt Ltd, Dr. Manish Sabharwal, Dr. Sabharwal Wound Care
22	IS 17354 : 2020	Medical textiles – Dental bib/Napkins – Specification	Shri Sumit Marwah, Dispoline India Private Limited Dr. Sanjiiv Rehlan, FICCI (Shalex Medtech)
23	IS 17359 : 2020	Medical textiles – Anti-embolic stocking for Post op use upto thigh medium – Specification	Shri D. Veerasubramaniam, SITRA Shri T. Balaji, KOB Medical Textiles Pvt Ltd, Dr. Manish Sabharwal, Dr. Sabharwal Wound Care
24	IS 17333 (Part 1) : 2020ISO 13629-1:2012	Textiles – Determination of antifungal activity of textile products Part 1 Luminescence method	Member Secretary TXD 36
25	IS 17333 (Part 2) : 2020ISO 13629-2 : 2014	Textiles – Determination of antifungal activity of textile products Part 2 Plate count method	-do-
26	IS 17347 : 2020ISO 18184 : 2019	Textiles – Determination of antiviral activity of textile products	-do-
27	IS 17506 : 2020	Medical Textiles - Hydrocolloid Dressing - Specification	Dr. Prabha Hegde, 3 M India
28	IS 17507 : 2020	Medical Textiles - Cellulose Wading - Specification	Dr. Manish Sabharwal, Dr. Sabharwal Wound Care

29	IS 17508 : 2020	Disposable Adult Incontinence Diaper - Specification	Dr. E. Santhini, SITRA Shri Kamal Jauhari, Nobel Hygiene
30	IS 4605 : 2020	Crepe Bandage - Specification (Second Revision)	Shri D. Veerasubramaniam, SITRA Shri T. Balaji, KOB Medical Textiles Pvt Ltd, Dr. Manish Sabharwal, Dr. Sabharwal Wound Care

ANNEX 19
(Item 9.*1*)

LIST OF PRE-2000 STANDARDS

Sl No.	IS Number	IS Title	Allotted to committee members/experts to review/comments
1	IS 10829 : 1993	X-Ray detectable gauze swabs and laparotomy sponges – Specification (first revision)	Dr. Manish Sabharwal, Dr Sabharwal Medicals Pvt Ltd, Chandigarh
2	IS 11046 : 1984	Specification for towel, operating	-do-
3	IS 12839 : 1989	Wool/polyamide blended flannel, hospital, grey - Specification	Dr. Sanjiiv, FICCI (Shalex Medtech)
4	IS 14316 : 1995	Swabs, small, in bag of 50 - Specification	Dr. Manish Sabharwal, Dr Sabharwal Medicals Pvt Ltd, Chandigarh
5	IS 1681 : 1998	Textiles – Hospital blankets, woollen, dyed – Specification (third revision)	Dr. Sanjiiv, FICCI/PWMAI
6	IS 6237 : 1971	Specification for handloom cotton cloth for plaster of Paris bandages and cut bandages	**Representative of M/s Bella Premier Happy Hygiene Care Pvt. Ltd.**
7	IS 757 : 1971	Specification for handloom cotton lint, absorbent, bleached, non-sterilized (first revision)	Dr. Manish Sabharwal, Dr Sabharwal Medicals Pvt Ltd, Chandigarh