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BUREAU OF INDIAN STANDARDS

AGENDA

Technical Textiles for Medtech Applications Sectional Committee, TXD 36 **22nd Meeting**

Date	Time	Venue
09 June 2023 (Friday)	1100 h	Video Conference through CISCO Webex

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

MEMBER SECRETARY: **Shri Dharmbeer, Scientist D, '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 21st meeting of the TXD 36 committee held on 27 March 2023 through CISCO Webex Videoconferencing were circulated vide our reference TXD 36/A 2.21 email dated 06 April 2023.

No comments were received.

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

Item 2 SCOPE AND COMPOSITION OF TXD 36

2.1 The present scope and composition of the committee is given in **Annex 1 (Pages 10-12).**

2.1.1 The Committee may **REVIEW**.

Item 3 ISSUES ARISING OUT OF PREVIOUS MEETING OF TXD 36

3.1 Summary of actions taken on the various decisions of the 21st meeting is given in **Annex 2 (Pages 13-15).**

3.1.1 The Committee may **NOTE**.

Item 4 DRAFT STANDARD FOR FINALIZATION

4.1 As decided by the committee in last meeting, the following draft standard was issued in wide circulation for two months for eliciting comments from stake holders vide our letter reference no. TXD 36/22151 dated 23-03-2023: -

1) Textiles — Determination of Antibacterial Activity of Textile Products [(First revision of IS/ISO 20743) (Doc : TXD 36 (22151)]

The last date for comments was 23-05-2023.

The draft standards as issued under wide circulation are given at **Annex 3 (Pages 16-18).**

No comments were received.

4.1.1 The Committee may **DECIDE.**

Item 5 DRAFT AMENDMENT FOR WIDE CIRCULATION

5.1 IS 19022: 2023, Medical Textiles — Barrier Face Covering — Specification

BIS has received All India First Application for grant of license as per IS 19022 : 2023. CMD-II of BIS vide email 22 May 2023 provided their comments on issues related to implementation of the standard: -

The comments received from CMD-II of BIS are given at **Annex 4 (Pages 19-21).**

The suggestion received from SITRA are given at **Annex 5 (Pages 22-25).**

The proposed amendment 1 to IS 19022 : 2023 is given at **Annex 6 (Page 26).**

5.1.1 The Committee may **DECIDE.**

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

In the last meeting, the committee decided that an amendment to IS 17354 : 2020 incorporating the following changes shall be issued:-

i) [(Page 1, Table 1, Sl no. (iv), a)] — Substitute 'Liquid absorbency time' for 'Sinking time'.
ii) [(Page 1, Table 1, Sl no. (iv), b)] — Substitute 'Liquid absorptive capacity' for 'water holding capacity'.
iii) The information on test liquid to be used was not available, the committee requested SITRA to suggest the suitable test liquid for dental bib.
iv) (Page 2, Clause 7.1) — Insert the following information at the end:-
f) Declared shelf-life of the product

The suggestion received from SITRA on suitable liquid for testing of dental bib is given at **Annex 7 (Page 27).**

5.2.1 The Committee may **DECIDE.**

Item 6 PRELIMINARY DRAFT FOR APPROVAL FOR WIDE CIRCULATION

6.1 Medical Textiles – Nonwoven Gauze (Sterile and Non-Sterile) - Specification

In the last meeting, the committee decided that M/s Ginni Filaments, M/s Welspun India and M/s Alpha Foam Pvt. Ltd. shall share their inhouse test report for non-woven gauze on performance parameter mentioned in table 1 including the tensile strength [IS 15891 (Part 3) : 2011/ISO 9073-3:1989] and breaking strength [IS 15891 (Part 18) : 2017/ISO 9073-18:2007] for dry and wet condition in machine and cross-direction to decide the final value.

The performance table for non-woven gauze swab and the test report received from M/s Ginni filament is given at **Annex 8 (Pages 28-37).**

The test report/results from M/s Welspun India and M/s Alpha Foam Pvt. Ltd. are yet to be received.

6.1.1 The Committee may **DECIDE.**

Item 7 NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD

7.1 In the last meeting of TXD 36, the committee decided that the following committee members/stakeholders shall provide their technical inputs on new subjects/new areas/gap areas identified for Medical Textiles under SNAP 2022-27: -

Sl No.	Field	Subjects	Stakeholder Identified
1	Medtech	Medical wipes	Dr. Manish Sabharwal, Dr. Sabharwals Manufacturing Labs Pvt Ltd Shri Prashant Jadhav, P & G
2	Medtech	Non-woven gauze swab	Shri Gurmeet Singh, M/s Ginni Filaments, Noida. Shri Rajiv Ranka, M/s Alpha Foam Pvt. Ltd., Pune Shri Sunil Kumar Rathi, M/s Welspun India
3	Medtech	Dental floss	Shri Prashant Jadhav, P & G Representative of Colgate Palmolive
4	Medtech	Scrub suit/patients clothing	Dr. Sanjiiv, PWMAI Ms. Shivani Swamy, Livinguard Mr. Apurva Ranka/Mr. Rajiv Ranka, Alpha Foam Ltd Shri Khalil Khan, Surya Textech, Shri Sumit Marwah, Dispoline India Pvt. Ltd.

			Representative of Arvind Mills
5	Medtech	Sutures (Absorbable & Non-absorbable)	Shri Aditya Vats/Shri Mehul Tyagi, Johnson and Johnson Shri R. Krishnakumar, Cologenesis Healthcare Private Limited Dr. Anmol Kumar Ray, B. Braun India
6	Medtech	Sterilization wrap	Shri D. Veerasubramanian, SITRA Shri Dhaval Ghuge/Shri Anthony D'costa, Medline Healthcare Industries Pvt. Ltd Shri Sumit Marwah, Dispoline India Pvt. Ltd.
7	Medtech	Tampons	Ms. Roocha Khedkar, Johnson and Ms. Tanya Mahajan, The Pad Project India Shri Rahesh Shah/Representative, Feminine and Infant Hygiene Association
8	Medtech	Maternity napkins/pads	Shri Nirav Mehta, Dima Products Ms. Tanya Mahajan, MHAI/The Pad Project Shri Rahesh Shah/Representative, Feminine and Infant Hygiene Association Ms. Roocha Khedkar, Johnson and Johnson Ms. Shivani Swamy, Livinguard Shri Kamal Johari, Nobel Hygiene
9	Medtech	Antistatic Healthcare Textiles	SHI Medicare Shri Khalil Khan, Surya Textech,
10	Medtech	Advanced wound dressings - Hydrogel, film and foam-based dressings, multilayer, tissue engineer based wound dressings etc.	Dr. Prabha Hegde, 3 M India Shri T. Balaji, KOB Medical Textiles Dr. Manish Sabharwal, Dr. Sabharwals Manufacturing Labs Pvt Ltd Shri R. Krishnakumar, Cologenesis Healthcare Private Limited

11	Medtech	Burn sheet, Hemostatic dressing, IV dressings (Film/Non-woven/Woven), Multi-layer Compression bandaging (2 layer / 4 layer), Undercast padding	Dr. Prabha Hegde, 3 M India Shri T. Balaji, KOB Medical Textiles Dr. Manish Sabharwal, Dr. Sabharwals Manufacturing Labs Pvt Ltd Shri R. Krishnakumar, Cologenesis Healthcare Private Limited
12	Medtech	Synthetic orthopaedic cast / sling / splint, Mopping Pad, Leukodepletion filter or textiles used for blood purification, Hernia mesh, Umbilical tape	Shri R. Krishnakumar, Cologenesis Healthcare Private Limited Shri Aditya Vats/Shri Mehul Tyagi, Johnson and Johnson

The technical inputs received from Dr. Sabharwal Wound care on new subject - IV Dressings (Film/Non-Woven), Synthetic Orthopaedic Cast Badnage, Synthetic Orthopaedic Cast Splint, Burn Sheet, Medical Wipes are given at **Annex 9 (Pages 38-40).**

The technical inputs on other subjects are yet to be received.

7.1.1 The Committee may **DECIDE.**

Item 8 COMMENTS ON PUBLISHED STANDARDS

8.1 IS 5405 : 2019, Sanitary Napkins — Specification (Second Revision) and IS 17514 : 2021, Reusable Sanitary Pad / Sanitary Napkin / Period Panties — Specification

In the last meeting of TXD 36, the committee requested Smt. Meeta Singala, Testtex, and Smt. Sharadha Dongre, SASMIRA to share the suitable test method for Volatile Organic Method for sanitary pad/reusable cloth.

The working draft for test method of Volatile Organic Compounds received from Smt. Meeta Singala, Testtex India Laboratory Pvt. Limited is given at **Annex 10 (Pages 41-47).**

The working draft was sent vide our email dated 16 May, 2023 for the comments of panel members/experts. The comments received from Shri Padmanaban KS, SGS, Chennai are given at **Annex 11 (Page 48).**

8.1.1 The committee may **DELIBERATE** and **DECIDE**.

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

In, the last meeting of TXD 36, the committee decided to constituted a panel for preparation of revised draft of IS 17334 under **convenorship of Dr. E. Santhini, Senior Scientific Officer, SITRA.**

The panel meeting was convened on 18 May 2023 through virtual mode. The agenda and minutes of panel meeting are given at **Annex 12 (Pages 49-77).**

The panel was further requested to discuss the following aspects/comments and provide their recommendation: -

i) The remaining comments of SITRA on test procedure and reporting (Hydrostatic resistance, Particle release test and Biocompatibility test), requirement of dry and wet microbial penetration.
ii) Any other aspects.

8.2.1 The Committee may **DISCUSS AND DECIDE.**

Item 9 INTERNATIONAL ACTIVITIES

9.1 The second plenary meeting of ISO/TC 338 'Menstrual Product' was held on 20-21 April, 2023 in Stockholm, Sweden in hybrid mode.

The following delegation of experts participated in the plenary meeting to represent India' point of view-

1) Shri J.K. Gupta, Scientist E & Head, Textiles (Head of Delegation) (Physical mode)
2) Shri S. Sivakumar, (Head, Medical Textiles), SITRA, Coimbatore (Physical mode)
3) Shri Dharmbeer, Scientist C, Textiles, Member Secretary TXD 36 (Physical mode)
4) Dr. E. Santhini, SITRA, Coimbatore (Virtual Mode)
5) Ms. Shivani Swamy, Livinguard Technology Pvt. Ltd., Mumbai (Virtual Mode)
6) Smt. Tanya Mahajan, The Pad Project (NGO), India (Virtual Mode)

The agenda of plenary meeting, briefing meeting of Indian delegates and resolution and report of ISO/TC 338 are given at **Annex 13 (Pages 78-91).**

The report of the Indian delegation on outcomes of plenary meeting is given at **Annex 14 (Pages 92-96).**

The panel meeting of working group WG 1 'general requirement' and Strategic business plan (TG 1) were held on 29-30 May 2023 and 01 June 2023 through virtual mode.

The agenda of the panel meeting for working group WG 1 'general requirement' is given at **Annex 15 (Pages 97-105).**

The agenda of the panel meeting for Strategic business plan (TG 1) is given at **Annex 16 (Pages 116-119).**

The minutes of working group WG 1 'general requirement' and Strategic business plan (TG 1) are yet to be received.

9.1.1 The Committee may **NOTE.**

9.2 Committee Internal Ballot (CIB) - ISO TC 338 N 38 Menstrual Products — Terminology

In the 2nd plenary meeting of ISO/TC 338 held on 20-21 April 2023 at Stockholm Sweden, it was decided that the committee manager will launch a Committee Internal Ballot (CIB) for 4 months to call for comments on document ISO TC 338 N 38 Menstrual Products — Terminology prepared by AHG1 Terminology under Convenorship of Ms. Tanya Mahajan/Dr. E. Santhini.

ISO/TC 338 secretariat issued a Committee Internal Ballot (CIB) for comments of member countries. The document is given at **Annex 17 (Pages 120-127).**

The committee members are requested to go through the document and provide their comments as per the ISO template only so that the India's vote is cast before the last date.

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

Item 10 REVIEW OF PUBLISHED STANDARDS

10.1 As per procedure of BIS, standards which were published/reaffirmed five years ago or earlier are required to be reviewed to assess adequacy of the requirements specified. Review is carried out keeping in view the changes in technology, current industrial practices and the needs/expectations of the consumers/users so as to decide regarding further reaffirmation/revision/withdrawal/amendment of the standards under review.

The committee decided that following Indian Standards shall be reviewed by expert members for their comments and suggestion: -

Sl No	IS No.	Title	Allotted To/Review Status	Due Date
1	IS 16111 : 2013	Elastic bandage	Shri T. Balaji, KOB Medical Textiles Pvt Ltd, Coimbatore Comments and the latest draft received from KOB is given at **Annex 18 (Pages 128-136)**	July, 2023
2	IS 5405 : 2019	Sanitary napkins – Specification (second revision)	Under review by Panel	March, 2024
3	IS 6237 : 1971	Specification for handloom cotton cloth for plaster of Paris bandages and cut bandages	Allotted to Dr. Manish Sabharwal, Dr Sabharwal Medicals Pvt Ltd, Chandigarh	July, 2023

			& Shri D. Veerasubramaniam, SITRA Coimbatore Comments are yet to be received	
4	IS 757 : 1971	Specification for handloom cotton lint, absorbent, bleached, non-sterilized (first revision)	-do-	July, 2023
5	IS 17243 : 2019	Medical textiles – Test methods for compresses for wound management and surgical procedures	To be allotted	March, 2024
6	IS 17334 : 2019	Medical textiles – Surgical gowns and surgical drapes – Specification	Under review by Panel	March, 2024

The committee requested following experts/committee member to send their comments and suggestion for pre-2000 standards.

Sl No	IS No.	Title	Allotted To/Review
1	IS 10829 : 1993	X-Ray detectable gauze swabs and laparotomy sponges – Specification (first revision)	Dr. Manish Sabharwal, Dr Sabharwal 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/PWMAI

4	IS 14274 : 1995	Bandage, T - Shaped, calico - Specification	Dr. Manish Sabharwal, Dr Sabharwal Medicals Pvt Ltd, Chandigarh
5	IS 14306 : 1995	Bandage, triangular, calico – Specification	-do-
6	IS 14316 : 1995	Swabs, small, in bag of 50 - Specification	-do-
7	IS 1681 : 1998	Textiles – Hospital blankets, woollen, dyed – Specification (third revision)	Dr. Sanjiiv, FICCI/PWMAI

The technical inputs/comments are yet to be received.

10.1.1 The Committee may **DECIDE.**

Item 11 NEW INITIATIVES IN STANDARDIZATION

11.1 With a view to facilitate effective implementation of the SNAP 2022-27, streamline the functioning of the standardization activity and with an aim to make BIS a future-ready organization, following process reforms have been instituted by the competent authority:

i) Rolling Annual Action Plan for the year 2023-24

ii) Annual calendar of Technical Committee meetings

iii) List of National and International events to be participated

iv) Scientific journals and periodicals to be subscribed

v) Identification of eminent scientists/public figures

vi) Efficient Working of TCs

vii) Creation of pool of experts etc....

The draft rolling plan/annual action plan is given at **Annex 19 (Pages 137-144).**

A brief presentation on the Process Reforms proposed for effective functioning of standardization activity is given at **Annex 20 (Pages 145-150).**

Item 12 DATE AND PLACE OF NEXT MEETING

Item 13 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 such as healthcare and hygiene textile products, implantable and non-implantable and extra corporeal textile products.

Meeting(s) held	**Date & Place**
19th Meeting	24 August 2022 (Through VC)
20th Meeting	14 December 2022 (Through VC)
21st Meeting	27 March 2023 (Through VC)

SL NO.	ORGANIZATION REPRESENTED	NAME OF THE REPRESENTATIVE PRINCIPAL/ (ALTERNATE)	ATTENDANCE
1.	**Director, SITRA**	**Dr. Prakash Vasudevan (Chairman)**	3/3
2.	3 M India Limited New Delhi	Shri Kulveen Singh Bali (Smt. Prabha Hegde)	2/3
3.	Alpha Foam Ltd., Pune	Shri Rajiv Ranka (Shri Apurva Ranka)	1/1
4.	Association of Indian Medical Device Industry (AiMeD), New Delhi	Dr. G.D. Agrawal (Shri Jitendra Sachchade)	2/3
5.	All Indian Institute of Medical Sciences New Delhi	Dr. Vijaydeep Siddharth (Dr. Anoop Daga)	2/3
6.	Business Coordination House New Delhi	Shri Sameer Gupta (Smt. Ritika Gupta)	2/3
7.	Cologenesis Healthcare Pvt Ltd, Salem	Shri R Krishnakumar Shri K. Ramprasad	3/3
8.	Defence Research & Development Establishment (DRDE), Gwalior	Dr. Vikas B. Thakre (Shri Suraj Bharati)	0/3
9.	DGAFMS, Ministry of Defence, New Delhi.	Surg Capt S.S. Dalawayi (Surg Lt Cdr Kotian V. Gopal)	2/3
10.	DGQA (Ministry of Defence), New Delhi	Shri Senthil Kumar (Shri Arnab Das)	3/3

SL NO.	ORGANIZATION REPRESENTED	NAME OF THE REPRESENTATIVE PRINCIPAL/(ALTERNATE)	ATTENDANCE
11.	Dima Products, Mumbai	Shri Nirav Mehta	3/3
12.	Director General of Health Services New Delhi	Dr. Naresh Panchal (Dr. B.S. Charan)	3/3
13.	Dispoline India Private Limited ,Bangalore	Shri Sumit Marwah	3/3
14.	DMSRDE, Kanpur	Dr. Mukesh Kumar Sinha	1/1
15.	Dr. Sabharwals Manufacturing Labs Pvt Ltd Panchkula	Shri Manish Sabharwal (Shri Dhruv Sabharwal)	3/3
16.	Federation of Indian Chambers of Commerce & Industry, New Delhi	Dr. Sanjiiv Rehlan (Ms Tulsi)	3/3
17.	Ginni Filaments Limited NOIDA	Shri Pramod Sharma	3/3
18.	Govt. Medical College & ESI Hospital Coimbatore	Dr. N. Tamilselven (Dr. K. Kulendaivelu)	1/3
19.	Indian Council of Medical Research New Delhi	Dr. Sadhana Srivastav	2/3
20.	Indian Institute of Technology, New Delhi	Prof Ashwini Agarwal (Prof Bipin Kumar)	0/3
21.	Indian Technical Textile Association, Mumbai	Dr. Anup Rakshit (Shri Mahesh Kudav)	3/3
22.	Johnson & Johnson Ltd. Mumbai	Ms. Roocha Khedkar	3/3
23.	KOB Medical Textiles Pvt Ltd, Palladam	Shri Arun Buchade (Shri T. Balaji)	3/3
24.	Kovai Medical Center and Hospital, (KMCH), Coimbatore	Dr J. Jayalakshmi	1/1
25.	Livinguard Technologies Pvt. Ltd. Mumbai	Ms. Shivani Swamy (Shri Virendra Madiyar)	3/3

SL NO.	ORGANIZATION REPRESENTED	NAME OF THE REPRESENTATIVE PRINCIPAL/(ALTERNATE)	ATTENDANCE
26.	Maulana Azad Medical College, New Delhi	Dr. Pawanindra Lal (Dr. Bharti Wadhwa)	2/3
27.	Medline Healthcare Industries Pvt. Ltd, Pune	Mr. Anthony D'Costa (Shri Dhaval Ghuge)	3/3
28.	Ministry of Textiles (NTTM) , New Delhi	Nomination awaited	1/2
29.	National Physical Laboratory, New Delhi	Dr. Suraj Khanna	1/3
30.	Nobel Hygiene, Mumbai	Shri Kamal Johari (Mr. Joy Devassy)	2/3
31.	Office of the Drug Controller (CDSCO), Delhi	Dr. Ravikant Sharma (Mr. Arvind Hiwale)	3/3
32.	Office of the Textile Commissioner Mumbai	Shri Sivakumar S. (Shri Narottam Kumar)	1/3
33.	PGIMER, Chandigarh	Dr. Pankaj Arora (Dr. Vijay Tadia)	3/3
34.	Procter and Gamble Co., Mumbai	Shri Prashant Jadhav (Shri Girish Parhate)	3/3
35.	South India Textile Research Association Coimbatore – 641 014	Shri S. Sivakumar (Dr. E. Santhini) (Smt. Udhaya Asokan -YP)	3/3
36.	Surya Textech, Chandigarh	Shri Khalil Khan (Shri Yogesh Yadav)	1/1
37.	Textiles Committee Mumbai	Shri Kartikeyan Dhanda (Dr. P. Ravichandran)	3/3
38.	The Bombay Textile Research Association Mumbai – 400 086	Mrs Aruna Apte	3/3
39.	The Pad Project (NGO), India	Smt. Tanya Mahajan	2/3
40.	The Synthetics & Art Silk Mills Research Association, Mumbai	Dr Manisha Mathur (Mrs. S.S. Dongre)	3/3

ANNEX 2
(Item 3.1)

SUMMARY OF ACTIONS TAKEN ON THE MINUTES OF 21st 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 FINALIZATION** **4.1** 1) TXD 36 (21300), Medical Textiles — Absorbent cotton gauze — Specification (*fifth revision* of IS 758) 2) TXD 36 (21301), Medical Textiles — Cotton bandage cloth— Specification (*third revision* of IS 863) 3) TXD 36 (21299), Medical Textiles — Grey, hospital flannel — Specification (*fourth revision* of IS 674) The committee decided that the above draft standards as given in agenda are FINALIZED for publication as Indian Standard.	Under Publication
4.2	**DRAFT STANDARD FOR FINALIZATION** **4.2** 1) TXD 36 (21302), Medical Textiles — Zinc oxide elastic adhesive bandage — Specification (*second revision* of IS 4739) 2) TXD 36 (21303), Medical Textiles — Bandage, suspensory — Specification (*first revision* of IS 9751) The committee decided that the above draft standards as given in agenda are FINALIZED for publication as Indian Standard.	Under Publication
5.1	**NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD** **Medical Textiles – Nonwoven Gauze (Sterile and Non-Sterile) - Specification**	

	The committee decided that M/s Ginni Filaments, M/s Welspun India and M/s Alpha Foam Pvt. Ltd. shall share their inhouse test report for non-woven gauze on above parameter including the tensile strength [IS 15891 (Part 3) : 2011/ISO 9073-3:1989] and breaking strength [IS 15891 (Part 18) : 2017/ISO 9073-18:2007] for dry and wet condition in machine and cross-direction to decide the final value.	Coming up for discussion under agenda **Item 6.1**
5.2	**NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD** The committee requested stakeholder to provide technical inputs/working draft on New Subject Identified under Standards National Action Plan (SNAP) 2022-2027. The technical Inputs on New subjects has been received from Dr. Sabharwal Lab Pvt. Limited.	Coming up for discussion under agenda **Item 7.1.**
6.1	**COMMENTS ON PUBLISHED STANDARDS** **IS 5405 : 2019, Sanitary Napkins — Specification (Second Revision) and IS 17514 : 2021, Reusable Sanitary Pad / Sanitary Napkin / Period Panties — Specification** The committee further decided that the test method for Volatile Organic Compounds shall be taken up with Chemical Methods of Test Sectional Committee, TXD 05 on top priority.	Coming up for discussion under agenda **Item 8.1.**
6.2	**COMMENTS ON PUBLISHED STANDARDS** **IS 17334 : 2019, Medical Textiles — Surgical Gowns and Surgical Drapes — Specification** The committee decided to constituted a panel for preparation of revised draft of IS 17334.	Coming up for discussion under agenda **Item 8.2.**
6.3	**COMMENTS ON PUBLISHED STANDARDS** **IS 17354 : 2020, Medical Textiles — Dental Bib / Napkins — Specification** The committee decided that based on comments from CMD-II an amendment shall be issued.	Coming up for discussion under agenda **Item 5.2.**

7.1	**INTERNATIONAL ACTIVITIES** The committee decided that the Convenor and the nominated experts shall have pre-meeting to decide the India's point of view and build consensus on critical matters before attending/convening the meeting of any working groups of ISO/TC 338. The committee also decided that additional experts (if required) shall be nominated from India in Adhoc Group/ WG 1 General requirements/ WG-Strategic Business Plan for participation in the meeting of working group/panel/planerary meeting of ISO/TC 338	Coming up for discussion under agenda item **9.1 and 9.2.**
8.1	**REVIEW OF PUBLISHED STANDARDS** The committee decided that the Indian Standards shall be reviewed by expert members for their comments and suggestion/changes required in the standard.	Coming up for discussion under agenda item **10.1 and 10.2**

ANNEX 3
(Item 4.*1*)

DRAFT STANDARD FOR FINALIZATION

[Doc: TXD 36 (22151)]

Draft ***Indian Standard***

Textiles — Determination of Antibacterial Activity of Textile Products
[(First revision of IS/ISO 20743)

Technical Textiles for Medtech Application Sectional Committee, TXD 36

NATIONAL FOREWORD

(Formal clauses will be added later)

This Indian Standard intended to be adopted is identical with ISO 20743 : 2021 'Textiles – Determination of antibacterial activity of textiles products' issued by the International Organization for Standardization (ISO).

This standard was originally published in 2014 which was identical with ISO 20743: 2013. The first revision of this standard has been undertaken to align it with the latest version of ISO 20743 : 2021.

The text of ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appears referring to this standard, they should be read as `Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standard which is to be substituted in its place, is listed below along with its degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 6330, Textiles – Domestic washing and drying procedures for textile testing	Doc: TXD 05 (22094)] Textiles — Domestic washing and drying procedures for textile testing [second revision of IS 15370]	Identical with ISO 6330 : 2021

In reporting the result of a test or analysis made in accordance with this standard, if the final value; observed or calculated, is to be rounded off, it shall be done in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (*second revision*).’

_____

1) Since revised in 2021.

Brief of IS/ISO 20743 : 2021, Textiles — Determination of Antibacterial Activity of Textile Products

This third edition cancels and replaces the second edition (ISO 20743:2013), which has been technically revised.
The main changes compared to the previous edition are as follows:

- — Clause 2 has been updated;
- — some NOTEs have been changed to regular text;
- — Annex F has been updated.

Introduction
Specialty products of antibacterial-treated textiles have been introduced in the market and are expanding year by year in various applications. These textiles meet the consumer's requirement to seek prevention of, and protection from, the negative effects caused by bacteria, which in turn secures the quality of life.

This established a substantial need for an International Standard which covers test methods to determine the antibacterial activity for antibacterial textile products.
A qualitative test method for antibacterial activity was developed as ISO 20645. At the time, there were no testing standards for the quantitative method which gives more objective information for the antibacterial activity of the textile products.

Although there are 6 ways for the combination of inoculation methods and quantitative measurements to execute this test, the choice of the ways depends on the user's availability and consensus between the concerned parties.

1 Scope

This document specifies quantitative test methods to determine the antibacterial activity of all antibacterial textile products including nonwovens.

This document is applicable to all textile products, including cloth, wadding, thread and material for clothing, bedclothes, home furnishings and miscellaneous goods, regardless of the type of antibacterial agent used (organic, inorganic, natural or man-made) or the method of application (built-in, after-treatment or grafting).

This document covers three inoculation methods for the determination of antibacterial activity:

- a) absorption method (an evaluation method in which the test bacterial suspension is inoculated directly onto specimens);
- b) transfer method (an evaluation method in which test bacteria are placed on an agar plate and transferred onto specimens);
- c) printing method (an evaluation method in which test bacteria are placed on a filter and printed onto specimens).

NOTE Based on the intended application and on the environment in which the textile product is to be used, and also on the surface properties of the textile properties, the user can select the most suitable inoculation method.

This document also specifies the colony plate count method and the adenosine triphosphate (ATP) luminescence method for measuring the enumeration of bacteria.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- ISO 6330, *Textiles — Domestic washing and drying procedures for textile testing*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.
ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- — ISO Online browsing platform: available at https://www.iso.org/obp
- — IEC Electropedia: available at http://www.electropedia.org/

3.1
control fabric
fabric used to validate the growth condition of test bacteria and validate the test
Note 1 to entry: The same fabric as the fabric to be tested but without antibacterial treatment or a 100 % cotton fabric without fluorescent brighteners or other finish can be used.

3.2
antibacterial agent
product designed to prevent or mitigate the growth of bacteria, to reduce the number of bacteria or to kill bacteria

3.3
antibacterial finish
treatment designed to prevent or mitigate the growth of bacteria, to reduce the number of bacteria or to kill bacteria

3.4
antibacterial activity
activity of an **antibacterial finish** (3.3) used to prevent or mitigate the growth of bacteria, to reduce the number of bacteria or to kill bacteria

3.5
plate count method
method in which the number of bacteria present after incubation is calculated by counting the number of colonies according to a ten-time dilution method
Note 1 to entry: The results are expressed in “CFU (Colony Forming Unit)”.

3.6
luminescence method
method in which the amount of ATP contained in bacterial cells is measured
Note 1 to entry: The results are expressed in “moles of ATP”.

3.7
neutralizer
chemical agents used to inactivate, neutralize or quench the antibacterial properties of **antibacterial agents** (3.2)

ANNEX 4
(Item 5.*1*)

DRAFT AMENDMENT FOR WIDE CIRCULATION

COMMENTS ON IS 19022:2023 FROM CMD-II OF BIS

CLAUSE	CHANGES PROPOSED	JUSTIFICATION
6 WASHING, DRYING AND HANDLING INSTRUCTION	Clause 6, 2nd sentence may be changed to "Reusable barrier face coverings shall withstand at least 5 washing and drying cycles when tested using **Reference washing machine Type A using Reference detergent 2 as per wash procedure no. 4N, and any drying procedure specified** in IS 15370"	Cl. 6 states that Reusable barrier face coverings shall withstand at least 5 washing and drying cycles when tested at 40 °C using a normal wash procedure as specified in IS 15370. However, IS 15370 specifies different types of washing procedure based on the type of washing machine used. As such it is not clear which specific washing procedure is being referred here although 4N of type A seems to be closest. The drying procedure to be followed or reference detergent to be used is also not specified.
7.1, Table 1, Sl No iv) Dimensional Stability to washing	In Table 1 Col (4), Sl No (iv) – Method of test for dimensional stability to washing, the following may be added after Annex C of IS 16394: Where dimensional stability to washing shall be measured after 5 washing and drying cycles when tested using **Reference washing machine Type A using Reference detergent 2 as per wash procedure no. 4N, and any drying procedure specified** in IS 15370	As per Table 1 to IS 19022:2023, Dimensional stability to washing is to be tested as per Annex C of IS 16394. In Annex C of IS 16394 it is stated that subject the specimens to washing using the reference detergent specified in 4.1.2 of IS 15370. However, in IS 15370:2020 there is no Cl. 4.1.2 and reference detergents are mentioned in Cl. 6.1. (it may be a reference to 6.1.2 i.e. Reference Detergent 2). It is also not mentioned which Type of washing machine and washing, drying methods are to be used and how many washing and drying cycles to be done. This also needs to be aligned with the requirement of Cl. 6.
8 Fastening Mechanism	The third sentence in the clause may be changed to "The laces, elastic strips, fabric tie etc. used as fastening mechanism shall withstand a force of 10 N (for single use face covering) or 50 N (for reusable face covering) when subjected to a tensile force for 10s with the face covering mounted on a dummy head."	The current test method given in Table 2 is IS 1969 (Part 2):2018 which is applicable for fabrics. Further, testing strength of attachments using CRE type tensile testing machine may not be an appropriate simulation of the type of loading to which the attachments to the face covering will be subjected to in a real-world scenario.

9.1 Table 2 S. No. (iii) Tie and Attachment Strength	Delete	To avoid overlap/duplication with Cl. 8 as above
9.1 Table 2 S. No. (i) Annex B Determination of Breathability (Differential Pressure)	Change B-2 as follows Suitable Breathing resistance test apparatus for measurement of pressure differential equipped with flow meter, pressure gauges etc. (such as the Apparatus given in Fig. 1). ***Note: Equivalent automated instruments validated against the test method prescribed may also be used .***	There are mechanised/automated instruments available which operate on the same principle and on the same test parameters which can also be used for this test, which should be permitted (in line with provisions in IS 9473:2002)
9.1 Table 2 S. No. (ii), Annex C – Determination of Particulate Filtration Efficiency	1. Substitute "polyester latex" for "latex" wherever it appears. 2. Add the following Note under C-1 Instead of aerosol containing suspended polyester latex (PSL) spheres, NaCl aerosol may also be used 3. Add the following note under C-2 ***Equivalent automated instruments validated against the test method prescribed may also be used.***	1. Only aerosol containing suspended latex spheres is permitted in the standard. The type of latex to be used e.g. Polyester Latex (PSL) or otherwise is also not clear 2. Further, in other standards where filtration efficiency for this product is specified, NaCl aerosol is permitted (e.g. ASTM F3502 – Standard Specification for Barrier Face Coverings). 3. The standard prescribed optical particle counters (OPC) but deployment of an aerosol test system incorporating a laser photometer instead of OPCs was observed which allows direct determination of penetration % and thereby filtration efficiency without the need to determine particle count and then calculate filtration efficiency. It bears mention that the International Standard ISO 14644-3 which sets out test methods that may be used for the purpose of characterizing a cleanroom, permit the use of both discrete particle counters and aerosol based photometers for testing of filter system leakage (essentially the same as filtration efficiency). Firm also informed that they are doing the test as per the method prescribed in ASTM standard F3502-21 (Standard

		Specification for Barrier Face Coverings) Therefore, it is felt that equivalent automated instruments validated against the test method prescribed should be permitted (in line with provisions in IS 9473:2002)

ANNEX 5

DRAFT AMENDMENT FOR WIDE CIRCULATION
(Item *5.1*)

SUGGESTION RECEIVED FROM SITRA ON IS 19022 : 2023

SITRA's response to the changes proposed by the CMD-II of BIS is given below for your kind reference. Please be informed that as per the scope of IS 19022:223, the Barrier Face Coverings are intended for use by the general public,mainly to minimize the transmission of aerosol mediated disease in epidemic or pandemic situations. It should not be used by healthcare personnel and other people showing symptoms of viral or bacterial infection. Therefore, the product could not be treated as either personnel protective equipment or industrial (N95 category) respirator. Further, most of the points given in the comments from CMD-II of BIS have already been deliberated during the panel meetings and TxD 36 committee meetings held and finalised by consensus of participants. Hence, these points may be deliberated in detail with the stake holders during the upcoming meetings of the committee and the decision may be arrived.

However, we give below our point of view through our comments in the below table for your kind consideration:

COMMENTS ON IS 19022:2023

CLAUSE	CHANGES PROPOSED	JUSTIFICATION	SITRA comments
6 WASHING, DRYING AND HANDLING INSTRUCTION	Clause 6, 2nd sentence may be changed to "Reusable barrier facecoverings shall withstand at least 5 washing and drying cycles when tested using **Reference washing machine Type A using Reference detergent 2as per wash procedure no. 4N, and any drying procedure specified** in IS 15370"	Cl. 6 states that Reusable barrier face coverings shall withstand at least 5 washing and drying cycles when tested at 40 °C using a normal wash procedure as specified in IS 15370. However, IS 15370 specifies different types of washing procedure based on the type of washing machine used. As such it is not clear which specific washing procedure is being referred here although 4N of type A seems to be closest. The drying procedure to be followed or reference detergent to be used is also not specified.	We are of the opinion that the standard should allow the use of any washing machine (Type A or Type B) as is the case with IS 15370 or ISO 6330. As an option, when the user wants to use Type B washing machine, Standard washing machine parameters can be fixed at Normal cycle, Warm temperature (41 +/- 3 deg C) and any drying procedure may be allowed.
7.1, Table 1, Sl No iv) Dimensional Stability to washing	In Table 1 Col (4), Sl No (iv) – Method of test for dimensional stability to washing, the following may be added after Annex C of IS 16394: Where dimensional stability to washing shall be measured after 5 washing and drying cycles when tested using	As per Table 1 to IS 19022:2023, Dimensional stability to washing is to be tested as per Annex C of IS 16394. In Annex C of IS 16394 it is stated that subject the specimens to washing using the reference detergent specified in 4.1.2 of IS 15370. However, in IS 15370:2020 there is no Cl. 4.1.2 and reference detergents	We are of the opinion that the standard should allow the use of any washing machine (Type A or Type B) as is the case with IS 15370 or ISO 6330. As an option, when the user wants to use Type B washing machine, Standard washing machine

	Reference washing machine Type A using Reference detergent 2 as per wash procedure no. 4N, and any drying procedure specified in IS 15370	are mentioned in Cl. 6.1. (it may be a reference to 6.1.2 i.e. Reference Detergent 2). It is also not mentioned which Type of washing machine and washing, drying methods are to be used and how many washing and drying cycles to be done. This also needs to be aligned with the requirement of Cl. 6.	parameters can be fixed at Normal cycle, Warm temperature (41 +/- 3 deg C and any drying procedure may be allowed.
8 Fastening Mechanism	The third sentence in the clause may be changed to "The laces, elastic strips, fabric tie etc. used as fastening mechanism shall withstand a force of 10 N (for single use face covering) or 50 N (for reusable face covering) when subjected to a tensile force for 10s with the face covering mounted on a dummy head."	The current test method given in Table 2 is IS 1969 (Part 2):2018 which is applicable for fabrics. Further, testing strength of attachments using CRE type tensile testing machine may not be an appropriate simulation of the type of loading to which the attachments to the face covering will be subjected to in a real-world scenario.	Internationally there seem to be no separate standard available for Tie / Attachment strength of facemasks. In AATCC M 014 standard for Barrier face coverings, ASTMD D5034 is referred. Also, BSI flex 5555 standard refers BS EN ISO 13934-2 to perform the tie-attachment strength. Both the test methods are based on CRE principle only. Hence, the IS 1969 (Part 2) Method is the best available standard for performing this test.
9.1 Table 2 S. No. (iii) Tie and Attachment Strength	Delete	To avoid overlap/duplication with Cl. 8 as above	Not required. In clause 8, the details such as recommended material used for fastening mechanism and adjustment set-up for tie attachment was given. Further, it is also referring to Table 2 only.
9.1 Table 2 S. No. (i) Annex B Determination of Breathability (Differential Pressure)	Change B-2 as follows Suitable Breathing resistance test apparatus for measurement of pressure differential equipped with flow meter, pressure gauges etc. (such as the Apparatus given in Fig. 1).	There are mechanised/automated instruments available which operate on the same principle and on the same test parameters which can also be used for this test, which should be permitted (in line with provisions in IS 9473:2002)	IS 9473 test method is suitable for evaluating the quality of N95 mask which is used for industrial and laboratory use. Whereas barrier face coverings used by public during pandemic to minimize the transmission of

	Note: Equivalent automated instruments validated against the test methodprescribed may also be used .		aerosol containing disease. Based on the application, the existing test method more opt to evaluate the breathability of barrier face coverings. Further, the flow rate as per Annex B of IS 19022 is 8 LPM. However, the flow rate as per IS 9473 is 30 LPM, 95 LPM (inhalation) and 160 LPM (exhalation). Hence, these 2 methods are not equal and cannot be used interchangeably. Moreover, the digital versions of Differential pressure tester are available in the market already and are perhaps less costly compared to the ones required for IS 9473.
9.1 Table 2 S. No. (ii), Annex C – Determination of Particulate Filtration Efficiency	1. Substitute "polyester latex" for "latex" wherever it appears. 2. Add the following Note under C-1 Instead of aerosol containing suspended polyester latex (PSL) spheres, NaCl aerosol may also be used 3. Add the following note under C-2 ***Equivalent automated instruments validated against the test method prescribed may also be used.***	1. Only aerosol containing suspended latex spheres is permitted in the standard. The type of latex to be used e.g. Polyester Latex (PSL) or otherwise is also not clear 2. Further, in other standards where filtration efficiency for this product is specified, NaCl aerosol is permitted (e.g. ASTM F3502 – Standard Specification for Barrier Face Coverings). 3. The standard prescribed optical particle counters (OPC) but deployment of an aerosol test system incorporating a laser photometer instead of OPCs was observed which allows direct determination of penetration % and thereby	1. The standard Annex C of IS 19022 permits the use of latex spheres. As such Polyester latex spheres are not available. May be, we can mention "Polystyrene latex spheres" to be specific. 2. NaCl aerosols are used for testing of Tight fit N95. N99 respirator masks. Most of the barrier face coverings are not of tight fit and their structure, in most cases, are

		filtration efficiency without the need to determine particle count and then calculate filtration efficiency. It bears mention that the International Standard ISO 14644-3 which sets out test methods that may be used for the purpose of characterizing a cleanroom, permit the use of both discrete particle counters and aerosol basedphotometers for testing of filter system leakage (essentially the same as filtration efficiency). Firm also informed that they are doing the test as per the method prescribed in ASTM standard F3502-21 (Standard Specification for Barrier Face Coverings) Therefore, it is felt thatequivalent automated instruments validated against the test method prescribed should be permitted (in line with provisions in IS 9473:2002)	similar to surgical facemasks. Hence, the opt method would be Annex C of IS 19022 only. Further, the flow rate as per Annex C of IS 19022 is 28.3 LPM. However, the flow rate as per IS 9473 is 95 LPM suitable for industrial applications. Hence, these 2 methods are not equal and cannot be used interchangeably. 3. The values recommended for PFE in IS 19022 Table 2 are based on this Annex C method only. Hence, IS 9473 standard cannot be referred / used for this application. 4. Digital versions of instruments as per Annex C are available in the market already and are perhaps less costly compared to the ones required for IS 9473.

ANNEX 6

DRAFT AMENDMENT FOR WIDE CIRCULATION

(Item *5.1*)

Doc: TXD 36 (xxxxx)

PROPOSED DRAFT AMENDMENT NO. 1 TO IS 19022 : 2023, MEDICAL TEXTILES — BARRIER FACE COVERING — SPECIFICATION

(*Page* 2, *Clause* 6, *second line*) — Substitute the following for the existing:

'Reusable barrier face coverings shall withstand at least 5 washing and drying cycles when tested using reference washing machine Type A using reference detergent 2 as per wash procedure no. 4 N and drying procedure (as per care instruction) as specified in IS 15370.'

(*Page* 2, *Clause* 8 *third line*) — Substitute the following for the existing:

'The laces, elastic strips, fabric tie etc. used as fastening mechanism shall withstand a minimum force of 10 N (for single use face covering) or 50 N (for reusable face covering) when subjected to a tensile force for 10s with the face covering mounted on a dummy head.'

[*Page* 3, *Clause* 7.1, *Table* 1, *Sl no* (*iv*)] — Insert the following note at the end:

'NOTE —Reusable barrier face coverings shall withstand at least 5 washing and drying cycles when tested using reference washing machine Type A using reference detergent 2 as per wash procedure no. 4 N and drying procedure (as per care instruction) as specified in IS 15370.'

[*Page* 6, *Clause* 9.1, *Table* 2, *Sl no* (*i*), **B-2**] — Substitute the following for the existing:

'Suitable breathing resistance test apparatus for measurement of pressure differential equipped with flow meter, pressure gauges etc. (such as the apparatus given in Fig. 1).

NOTE — Equivalent automated instruments validated against the test method prescribed may also be used.'

[*Page* 7, *Clause* 9.1, *Table* 2, *Sl no* (*ii*), Annex C] — Substitute 'polystyrene latex' for 'latex'.

[*Page* 7, *Clause* 9.1, *Table* 2, *Sl no* (*ii*), **C-**1] — Insert the following note at the end:

'NOTE — Instead of aerosol containing suspended polystyrene latex (PSL) spheres, NaCl aerosol may also be used.'

[*Page* 7, *Clause* 9.1, *Table* 2, *Sl no* (*ii*), **C-**2] — Insert the following note at the end:

'NOTE — Equivalent automated instruments validated against the test method prescribed may also be used.'

[*Page* 7, *Clause* 9.1, *Table* 2, *Sl no* (*iii*)] — Delete.

ANNEX 7

DRAFT AMENDMENT FOR WIDE CIRCULATION

(Item 5.2)

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

COMMENTS OF SITRA ON IS 17354 – SUITABLE LIQUID FOR TESTING OF DENTAL BIB

It is understood that the purpose of the Dental Bib is to clean and protect the user against a mixture of water, saliva and debris. Hence, ideally the liquid required for the testing of Dental bib should be a combination of these items. However, in practice no such liquid is reported to be available. Hence, we are of the opinion that artificial saliva may be used as the liquid for testing of the said parameters (i.e) Liquid absorbency time and Liquid absorptive capacity. Composition and preparation procedure of artificial saliva is given below with reference to the standard in DIN 53160-1:2010.**

Reagents	Mass fraction (g/l)
Magnesium chloride	0.17
Calcium chloride	0.15
Dipotassium hydrogen phosphate	0.76
Potassium carbonate	0.53
Sodium chloride	0.33
Potassium chloride	0.75
1% (m/m) Hydrochloric acid	To be added until a pH value of 6.8 ± 0.1 is achieved.

Preparation of the artificial saliva

Dissolve the potassium and sodium salts in about 900 ml of water. Then add calcium chloride and magnesium chloride and stir until the complete dissolution of all the reagents added. Calibrate the pH meter in accordance with the manufacturer's instructions using buffer solution. Immerse the pH electrode in the solution, stir slightly, and add hydrochloric acid until a stable pH value of 6.8 ± 0.1 is achieved. Transfer the solution to a 1000 ml one-mark volumetric flask and make upto the mark with water. Protect from light and make sure before use that the pH value of the artificial saliva is in the range of 6.8 ± 0.1.

If the artificial saliva is to be stable longer than 2 weeks, it recommended to use water that has been heated to boiling for ten minutes.

** It may be deliberated during the meeting.

ANNEX 8

PRELIMINARY DRAFT FOR APPROVAL FOR WIDE CIRCULATION
(Item *6.1*)

PERFORMANCE TABLE FOR NON-WOVEN GAUZE SWAB AND THE TEST REPORT RECEIVED FROM M/S GINNI FILAMENT

Table 1 Performance Requirements for Nonwoven Gauze

(*Clause* 5)

Sl. No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Fibre identification	At least 20 percent of cotton or/and viscose /absorbent fibres	IS 667
ii)	Weight per square metre, g/m^2, *Min*	30	IS 15891 (Part 1)
iii)	Absorbency a) Liquid absorption time, s, *Max* b) Liquid absorptive capacity, percent, *Min*	 10 400	IS 15891 (Part 6)
iv)	Tensile strength in machine direction (Dry) in N/5cm, *Min*	20 (To be reviewed)	IS 15891 (Part 3)
v)	Tensile strength in machine direction (Wet) in N/5cm, *Min*	20 (To be reviewed)	IS 15891 (Part 3))
vi)	Total viable count (cfu/g), *Max* (Non-sterile)	100	ISO 11737 Part 1
vii)	pH value of aqueous extract	6.5 to 8.5	IS 1390
viii)	Water soluble substance, percentage, *Max*	1	IS 14944
ix)	Ether soluble substance percentage, *Max*	1	IS 14944
x)	Particle release [log10 (lint count)]	≤ 4.0	IS 15891 (Part 10)
viii)	Freedom from optical whitener	No fluorescence or not more than occasional point of fluorescence visible’	Viewing under ultra-violet light

		when viewed under the ultra-violet (UV) light of wavelength 365 nm	
xi)	Cytotoxicity	Non-Toxic (Reactivity as none)	IS/ISO 10993-5

TEST REPORT

Test Repot No.	: **C2300145**	Date	**: 17-05-2023**
Our Ref No	;**V/ 3 /E / 121187/23**	No of Sample	**: 2**
Your Ref No	; **20.4.23**	Received on	:**09-05-2023**

To
Ginni Filaments Ltd
Plot No.205-207,GIDC Industrial Estate,
Panoli,Ankleshwar,
Bharuch,Gujarat ,India Pincode : 394116
Contact No(s) : 8929312993

Date (s)of Test Performance :17-05-2023

Dear Sir /Madam,

We are pleased to give our results (enclosed) on your above samples.

Authorised by,
(Kumaran.M)

Test Repot No. : C2300145
Ginni Filaments Ltd

Report Date : 17-05-2023
Reference :20-04-2023

Samples Tested at : R.H. 65% ± 2% and Temp. 21 Degree C ± 1 Degree C

Fabric - Tensile Strength (Zwick/Roell)	C2300145-2 RAW WHITE. GSM-30. PV3070A2030 30% POLY.70% VISCOSE, APERTURE U MESH REF-GNW/200423-01. WET	C2300145-3 RAW WHITE, GSM-30, 30% POLY,70% VISCOS REF-GNW200423-0,DRY
Machine Direction Strength (N)	31.3	36.9
Machine Direction Elongation (%)	24.1	19.2
Cross Direction Strength (N)	8.79	9.67
Cross Direction Elongation (%)	84.6	88.0

Note : Rate of traverse 100 mm/min, Specimen Size: 20x 500mm

TEST REPORT

XXVII/P/E/ 22937/23

ULR: TC694423600008445F
Inward / Report No. : P2300127

To,
Ginni Filaments Ltd
Plot No.205-207,GIDC Industrial Estate,
Panoli, Ankleshwar,
Bharuch, Gujarat ,India
Pincode : 394116
Contact No(s) : 8929312993
Email: gurmeet@ginnifilaments.com

Inward Date :06-05-2023
Tested on :**08-05-2023**
Report Date **:08-05-2023**

Dear Sir /Madam,

This has reference to the sample(s) submitted by you for testing vide your letter reference no : **Mail Dt.05.05.2023**.

The results pertaining to your sample(s) are enclosed herewith.

Authorised by,

(D.Veerasubramanian)

Ginni Fliaments Lid, Ref : Mail Dt.05.05.2023 **ULR: TC694423600008445F**

(Sample Tested at: R.H 65% +/- 2% and Temp. 21 Degree C +/- 1 Degree C)

Liquid Absorption Time **IS 15891 (Part 6) : 2012 Reaffirmed 2020**	P2300127-1 Described by the Customer : **30 GSM Product Code:PV3070A2030, Blend-30%Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW1200423-01,Colour-Raw White**
Type of test liquid used	Distilled water
Average liquid absorbency time in sec	1.57
Standard deviation	0.21

Liquid Absorptive Capacity **S 15891 (Part 6) : 2012 Reaffirmed 2020**	P2300127-1 Described by the Customer **: 30 GSM Product Code:PV3070A2030, Blend-30%Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No; GNW/200423-01,Colour-Raw White**
Type of test liquid used	Distilled water
Average liquid absorbency capacity in %	1114.46
Standard deviation	20.75

TEST REPORT

XXVII/P/E/ 22936/23 **ULR: TC694423600008444F**
Inward / Report No. : P2300128

To,
Ginni Filaments Ltd
Plot No.205-207,GIDC Industrial Estate,
Panoli, Ankleshwar,
Bharuch, Gujarat ,India
Pincode : 394116
Contact No(s) : 8929312993

Inward Date : 06-05-2023
Tested on : **08-05-2023**
Report Date **: 08-05-2023**

Email: gurmeet@ginnifilaments.com

Dear Sir /Madam,

This has reference to the sample(s) submitted by you for testing vide your letter reference no : **Mail Dt.05.05.2023**.

The results pertaining to your sample(s) are enclosed herewith.

Authorised by,
(D.Veerasubramanian)

Ginni Fliaments Lid, Ref : Mail Dt.05.05.2023 **ULR: TC694423600008444F**

(Sample Tested at: R.H 65% +/- 2% and Temp. 21 Degree C +/- 1 Degree C)

Mass per Unit Area **IS 15891-1:2011 Reaffirmed 2019**	**P2300128-1** Described by the Customer : **30 GSM Product Code:PV3070A2030, Blend-30%Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW1200423-01,Colour-Raw White**
Test result of Specimen 1 in g/m^2	34.43
Test result of Specimen 2 in g/m^2	35.37
Test result of Specimen 3 in g/m^2	34.73
Mean value in g/m^2	34.84
Co-officiant of Variation in %	1.38
The conditioning atmosphere used	Teprature:20+/- 2 deg.C and RH:65+/-4

XXVII/P/E/ 22941/23

Report No**. : P2300132**
ULR: TC694423600008449F

To,
Ginni Filaments Ltd
Plot No.205-207,GIDC Industrial Estate,
Panoli, Ankleshwar,
Bharuch, Gujarat ,India
Pincode : 394116
Contact No(s) : 8929312993
Email: gurmeet@ginnifilaments.com

Sample Received on **:08-05-2023**
Inward Date : **08-05-2023**
Tested on **: 09-05-2023**
Report Date **: 09-05-2023**

Dear Sir /Madam,

This has reference to the sample(s) (details given below) submitted by you for testing vide your letter reference no : **Mail Dt.05.05.2023**.

Sample Code	Your Reference
P2300132-1	30 GSM product Code: PV3070, Blend-30% Polyester +70% Viscose. Type : Aperture 16 mesh, Ginni Ref No : GNW/200423-01, Colour-Raw White

The results pertaining to your sample(s) are enclosed herewith.

Authorised by,
(D.Veerasubramanian)

Ginni Filaments Ltd

TEST RESULTS - P2300132 Report Date : 09-05-2023 Ref: Mail Dt.05.5.202

TOTAL LINTING – IS 15891-10

A SIDE

	3.0 Micron	5.0 Micron	10.0 Micron	25.0 Micron	Total
A1	192	146	190	41	569

A2	163	159	166	31	519
A3	262	201	245	72	780
A4	310	299	319	94	1022
A5	292	283	325	87	987
AVG	244	218	249	65	775
C0	0	0	0	0	0
AVG-CO	244	218	249	65	775

B SIDE

	3.0 Micron	5.0 Micron	10.0 Micron	25.0 Micron	Total
B1	408	298	379	81	1166
B2	284	268	290	57	899
B3	157	141	185	110	593
B4	415	380	387	119	1301
B5	501	541	683	132	1857
AVG	353	326	385	100	1163
C0	0	0	0	0	0
AVG-CO	353	326	385	100	1163

	A SIDE	**B SIDE**	**C SIDE**
Total Particles	775	1163	969
Log 10(Lint Count)	2.89	3.07	2.99

TEST REPORT

Test Repot No.: **M2300115**	**URL: TC694423700002196F**	Report Date **: 22-05-2023**
SITRA Ref No: **XXVII/M/E/23058/23**		No of Sample **: 1**
Customer Ref No.: Mail Dt.05-05-2023		Received on : **25-04-2023**

To
Ginni Filaments Ltd
Plot No.205-207, GIDC Industrial Estate,
Panoli, Ankleshwar,
Bharuch, Gujarat ,India
Pincode : 394116
Contact No(s) : 8929312993

Dear Sir / Madam,

This has reference to the sample(s) submitted by you for testing vide your Letter reference no : ***Mail*** **Dt.5.5.23**.

The results pertaining to your sample(s) are enclosed herewith.

Authorised by,
(Dr. R. Radhai)

Test Repot No**.: M2300115** **URL: TC694423700002196F** Report Date : **22-05-2023**
Ginni Filaments Ltd Ref : Mail Dt.**05-05-2023**

Test Name : ISO 11737 -Part -1 -2018 Bio burden testing
Test Condition:

Sample size/ Volume : 1 g
Media used : Nutrient agar, Sabourauds dextrose agar with chloramphenicol
Eluent used : 0.85% Saline with 0.1 % tween 80
Diluent used : 0.85% Saline
Method used to remove Microorganisms : Mechanical shaking
Method of plating : Pour plate method
Inoculum / plate : 1 mL
Incubation conditions : 37°C for 24 h and 25°C for 7 days

Test Parameter	**M2300115-1** Described by the customer : **Nonwoven; 30 GSM Product Code:PV3010A2030, Blend-30% Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW/200423-01,Colour-Raw White**
Total bacterial count	2.1×10^6 CFUL/g
Total fungal count	2.2×10^6 CFUL/g
Result: The samples tested for their bioburden analysis showed 2.1×10^6 CFU/g bacterial growth after 24 h of incubation and 2.2×106 CFU/g fungal growth after 7 days of incubation when tested according to ISO 11737- Part1. The microbial load of the lab environment was within the limit during the test.	

XXVII/PO/E/ 23089/23 **Inward / Report No. : S2300106**

To,
Ginni Filaments Ltd
Plot No.205-207,GIDC Industrial Estate,
Panoli, Ankleshwar,
Bharuch, Gujarat ,India
Pincode : 394116
Contact No(s) : 8929312993
Email: gurmeet@ginnifilaments.com

Inward Date **: 06-05-2023**
Report Date : **23-05-2023**

Dear Sir /Madam,

This has reference to the sample(s) submitted by you for testing vide your letter reference no : **Mail Dt.05.05.2023**.

The results pertaining to your sample(s) are enclosed herewith.

Authorized by.
(L. Amaporpaya Mary)

Ginni Filaments Ltd.	Ref. : Mail Dt. 05-05-2023
pH Values	**S2300106-1** Described by the customer : **30 GSM Product Code:PV3010A2030, Blend-30% Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW/200423-01,Colour-Raw White**
pH	6.40

Water Soluble Substances British Pharmacopocia	**S2300106-1** Described by the customer : **30 GSM Product Code:PV3010A2030, Blend-30% Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW/200423-01,Colour-Raw White**
Percentage	0.17

Ether Soluble Substances EN 14079:2003	**S2300106-1** Described by the customer : **30 GSM Product Code:PV3010A2030, Blend-30% Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW/200423-01,Colour-Raw White**
Percentage	0.11

Fluorescence British Pharmacopocia	**S2300106-1** Described by the customer : **30 GSM Product Code:PV3010A2030, Blend-30% Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW/200423-01,Colour-Raw White**
Result (Percentage /Absent)	Absent

Fibre Identification	**S2300106-1** Described by the customer : **30 GSM Product Code:PV3010A2030, Blend-30% Polyester +70% Viscose, Type: Aperture 16Mesh,Ginni Ref No: GNW/200423-01,Colour-Raw White**
Fibre Identification	Polyester

EN 14079 : 2003, IS 667 : 1981 RA 2013

ANNEX 9

(Item *7.1*)

NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD

TECHNICAL INPUTS RECEIVED FROM DR. SABHARWAL WOUND CARE ON NEW SUBJECT - IV DRESSINGS (FILM/NON-WOVEN), SYNTHETIC ORTHOPAEDIC CAST BADNAGE, SYNTHETIC ORTHOPAEDIC CAST SPLINT, BURN SHEET, MEDICAL WIPES

DRAFT BIS SPECIFICATION FOR IV DRESSINGS (FILM/NON-WOVEN)

PARAMETERS	SPECIFICATION LIMIT	
	Film Based	**Non-Woven Based**
General Characteristics	It is a breathable P.U. film coated with Adhesive & covered with release liner. It can also be a combination of P.U. Film and Non-woven fabric. It may contain an absorbent pad. It may contain a slit/keyhole slot for ease of application over cannula.	It is a breathable non-woven fabric coated with Adhesive & covered with release liner. It can also be a combination of P.U. Film and Non-woven fabric. It may contain an absorbent pad. It may contain a slit/keyhole slot for ease of application over cannula.
Size	± 5% of label claim	± 5% of label claim
Weight of film per unit area	Not less than 17 g/m^2	Not less than 28 g/m^2
Weight of Adhesive per unit area	Not less than 17 g/m^2	Not less than 17 g/m^2
Primary Packing	It is packed in airtight package – non-permeable	It is packed in airtight package – non-permeable
Sterility (Gamma Sterile)	Should pass the sterility Test	Should pass the sterility Test

DRAFT BIS SPECIFICATION FOR SYNTHETIC ORTHOPAEDIC CAST BADNAGE

PARAMETERS	SPECIFICATION LIMIT
General Characteristics	Polyurethane Casting Bandage consists of light weight porous fabric base which has been coated with polyurethane polymer, which sets after exposure to moisture. It should be confirmable to the body both in width and length.
Colour	As per label claim
Dimensions: **Width** **Stretched Length**	 NLT 98% of label claim NLT 95 % of label claim

Weight of Bandage per unit area	NLT 200 g/m^2
Setting Time	NMT 8 minutes

DRAFT BIS SPECIFICATION FOR SYNTHETIC ORTHOPAEDIC CAST SPLINT

PARAMETERS	SPECIFICATION LIMIT
General Characteristics	Polyurethane Casting Splint consists of light weight porous fabric base which has been coated with polyurethane polymer, which sets after exposure to moisture. It should be confirmable to the body both in width and length. It consists of synthetic cast of 5 or more layers sealed inside 2 nonwoven cast padding layers and sealed in moisture-proof packaging.
Colour	As per label claim
Dimensions: **Width** **Stretched Length**	 NLT 98% of label claim NLT 95 % of label claim
Weight of Bandage per unit area	NLT 200 g/m^2 of each layer
No. of Layers	At least 5
Setting Time	NMT 10 minutes

DRAFT BIS SPECIFICATION FOR BURN SHEET

PARAMETERS	SPECIFICATION LIMIT
General Characteristics	Burn gel dressing consists of absorbent foam/nonwoven substrate impregnated with water based burn gel unmedicated. The dressing has been prepared by cutting to the required size packed into a peelable pouch and completely impregnated with a sufficient quantity of water based burn gel.
Weight of Substrate per m^2	Should NLT 25 g/m^2 for Foam base Should NLT 50 g/m^2 for Non-woven base
Weight of Gel for 10cm x 10cm	Should NLT 20g
Sterility (Gamma Sterile)	Should pass the sterility Test

DRAFT BIS SPECIFICATION FOR MEDICAL WIPES

PARAMETERS	SPECIFICATION LIMIT
General Characteristics	It is preinjection swab consisting of absorbent non-woven fabric saturated with 70% v/v Isopropyl Alcohol
Weight of Non-Woven Pad per unit area	NLT 30 g/m^2
Weight of Solution per Pouch	NLT 0.2g per pouch
Percentage of IPA in Solution	70% v/v ± 5%

ANNEX 10

(Item 8.1)

COMMENTS ON PUBLISHED STANDARDS - IS 5405 : 2019, SANITARY NAPKINS — SPECIFICATION (SECOND REVISION) AND IS 17514 : 2021, REUSABLE SANITARY PAD / SANITARY NAPKIN / PERIOD PANTIES — SPECIFICATION

WORKING DRAFT FOR TEST METHOD OF VOLATILE ORGANIC COMPOUNDS

DETERMINATION OF VOLATILE ORGANIC COMPOUND IN TEXTILE PRODUCT: Head-space gas chromatographic method

1 Scope

The method described is applicable to the determination of benzene & its derivates, methylbenzene (toluene), dimethylbenzenes (xylenes), acetone, methanol & methylene chloride in textile product.

A number of further derivatives and nonpolar compounds with similar physical properties may also be determined by this method. The applicability of the method should be verified.

2 Principle

A defined weight of test sample with solution of matrix modifier and dimethyl sulfoxide (DMSO) is heated in a gas-tight septum-covered vial. After establishment of equilibrium between the gaseous and liquid phases, an aliquot of the gaseous phase is transferred to a gas chromatograph. Separation of benzene and its derivatives is carried out by injection on capillary column.

3 Interferences

Loss of VOC's may occur during sampling, transport storage and preparation of samples due to evaporation and stripping. Volatile organic compounds in the ambient air may contaminate samples and solvent -used for blank tests, leading to high limits of detection and high blank values, respectively.

Specific problems in the gas chromatographic system shall be handled according to the manufacturers instruction

Solvents can modify the normal equilibrium with the gaseous phase.
The determination may be hindered by superposition of other hydrocarbons, for instance mineral oil constituents, which may also result in column overload.

4 Apparatus

Keep all precleaned bottles and vials in an upside-down position for 1 h at 150 °C in a ventilated drying oven before use. After this procedure, protect them from pollution, for instance by covering them with aluminum foil while they cool and closing them as soon as they are cool.

4.1 Me c h an i c al Shaker or Rotor

4.2 Micropipette, capacity e.g., 0.1 ml, 1 ml, 5 ml.

4.3 Volumetric flasks, capacity 10ml, 50 ml, 1 000 ml.

4.4 Crimp-top sampling vials with PTFE or aluminum-coated septum and filler cap, suited to the automatic head-space dosing system used.

4.5 Automatic head-space system with thermos stating facility or heatable gas-tight injection syringe, nominal capacity 2,5 ml or 5 ml.

The correct choice of the syringe is essential to minimize the injection error.

4.6 Crimp-top vials with PTFE septum and filler cap, capacity 10 ml, for the stock solutions.
4.7 Gas chromatograph with Head Space supplied with gases as specified by the manufacturer.
4.8 Capillary columns for gas chromatography (see annex A).
4.9 Injection syringes, capacity 50 µI and 100 µI.

5 Reagents
Use only reagents of recognized analytical grade and only water complying with 5.1.

5.1 Water for dilutions and the reagent blank.

The VOC's content of the water shall be as low as possible. In case of contamination, the water may be treated.

5.2 Operating gases for the gas chromatographic system (nitrogen, helium) according to the manufacturer's instruction.

5.3 Calibration Standard Substances, each of highest purity

Benzene	C6H6
Methylbenzene (toluene}	C7H8
1,2-Dimethylbenzene (o-xylene}	C8H10
1,3-Dimethylbenzene (m-xylene)	C8H10
1,4-Dimethylbenzene (p-xylene)	C8H10
Methylene chloride	CH2Cl2
Acetone	C3H6O

5.4 Dimethyl sulfoxide, (DMSO) ,(CH3)2SO, as solution aid.

5.5 Sodium Chloride NaCl, anhydrous, ACS- grade

5.6 Preparation of matrix- modifying solution- Add 180 g of ACS- grade sodium chloride (NaCl) (5.5) to 500 ml of reagent water (5.1). Mix well until all components are dissolved. Other water-soluble salts may be appropriate.
Store the prepare matrix- modifying solution in a sealed bottle in an area free of organic chemicals at ≤ 6° C.
5.7 Mixture of matrix modifier (5.6) & DMSO (5.4) in 1:1 ratio (freshly prepared before use). Analyze a 5 ml portion from each batch to verify that the solution is free of contaminants.

6 Sampling and sample preparation

1. Head-space analysis vials (4.7) may directly be used as sampling containers.
2. Weigh approximate 1 gm homogenized sample in head space vial add 5 ml of mixer of matrix modifier and DMSO sample (5.7) seal the vial.
3. Agitate above seal vial (on rotor or shaker) at least 5 mins. Place the vial in the autosampler carrousel at room temperature. The individual vials are heated to 80 °C and allowed to equilibrate for 50 mins. Each sample mixed by mechanical vibration during this equilibrium period. Each vial is pressurized with helium carrier gas to a minimum pressure of 10 psi. To obtain constant conditions for head-space analysis, the quantities of salt added and the weight of samples and blanks must be identical.

Parallel to taking the sample, take an air blank consisting of a head-space vial filled with the air present at the sampling site, and a reagent blank using water.

7 Procedure

7.1 General

A temperature of at least 60 °C for at least 1 h has been found sufficient. The minimum time and the temperature shall be the same for samples and blank. If the procedure is changed, repeat the check on the establishment of the equilibrium.

After static equilibrium has been reached, inject an aliquot of the head space into the gas chromatograph, with calibration, handling blank and air blank samples arranged at the beginning and at the end of a sampling series.

7.2 Gas chromatography

Adjust the gas chromatograph according to the manufacturer's instructions.

7.3 Blank measurement

Benzene is present ubiquitously in trace levels. For this reason, perform blank measurements using Reagent Blank prior to and during a series of analyses. Blank measurements should include all steps of the analytical procedure from sampling to the evaluation of the gas chromatogram. If blank values are unusually high (more than 10 % of the lowest measured values), of the target molecules every step in the procedure shall be checked in order to find the reason for these highblank values. Blank values should be reduced as much as possible by various procedures such as elimination of contamination by ambient air and checking of the gas chromatographic or integration parameters.

If sample concentrations are close to the limit of detection, however, blank values higher than 10 % of the lowest measured value shall be tolerated.

7.4 Identification of individual compounds

Identify an individual compound by comparing its retention time in the sample with that corresponding in the calibration solutions.

In order to ensure correct identification, the retention times should not differ from one another in a series of analyses by more than ± 0,02 min, given comparable concentrations, or ± 1 % of relative retention times under 2 min.

If there is no peak at the characteristic retention time using one column only, and the chromatogram is normal in all other respects, the substance is deemed not to be present.

If there is a peak at the characteristic retention time, the presence of the substance is possible, and the identity of the substance shall be confirmed by further analysis.

8.0 Prepare Stock Solution and Calibration using matrix modifier DMSO (1:1)

For calibration of the total method, use aqueous solutions of the compounds to be determined. Use dimethyl- sulfoxide, (D M S O) (5.7) as solution aid, to ensure rapid and even distribution of the compounds in water.

8.1 Preparation of the stock solution

Place into 10 ml crimp-top vials {4.9) 5 ml of dimethylsulfoxide and matrix modifier (1:1) and 100 µI each of benzene and the other compounds needed. Close with the septum and shake vigorously. Prior to use, leave the solution at room temperature for 15 min.

Store the stock solutions preferably at – 20 °C in the dark; they are stable for at least a week.

8.2 Preparation of the calibration solution

Fill a graduated 1 000-ml-flask with DMSO & water (1:1) and place it on a magnetic stirring apparatus. O p e n the crimp-top vial and take an appropriate amount of stock solution (usually 2.5 ml). Stir the solution in the flask so that there is a vortex, and dose the stock solution into the DMSO & water, dipping the tip of the syringe needle into the DMSO & water.

Immediately after dosing the stock solution, reduce the rotational speed of the magnetic stirrer, close the flask and stir for another hour.

If 2.5 ml of stock solution are used, the concentration of benzene in this calibration solution is 50 mg/ kg.
Prepare Calibration Solution with higher and lower concentrations in a similar way, reducing or increasing the amount of the stock solution Table 1 show the series of calibration solution.

Table 1 – Examples of calibration solutions

Measuring Range mg/ kg	Amount of VOC's in 5 ml from stock solution in ml	Amount of stock solution, mg/ kg
5	0.5	50
2	0.2	50
1	0.1	50
0.5	0.05	50
0.2	0.02	50
0.1	0.01	50

Prepare the calibration solution immediately before use.

If several compounds are added to the solution aid, take into account the increase in volume: with six compounds added, for instance, the volume of the stock solution is increased from 5 ml to 5,6 ml. Calculate the mass concentration using the densities of the compounds given in Table 2.

Table 2 - Densities of benzene and its derivatives

Compound	Density
Benzene	0,878
Acetone	0.788
Methanol	0.79
Methylene Chloride	1.326
Toluene	0.87
Xylenes (O, P, M)	0.87

Prepare calibration solutions of concentrations not given in the table in a similar way, using 5 ml or 10 ml solution aid and appropriate amounts of stock solution.

Table 3 -Correlation coefficients

Compound	Correlation coefficient
Benzene	0,998
Acetone	0,998
Methanol	0,998
Methylene Chloride	0,998
Toluene	0,999
Xylenes (O, P, M)	0,999
Xylenes (O)	0,999

All solutions shall be at room temperature before the standard solutions are prepared.

8.3 Preparation of the calibration curve

Analyze, beginning with the lowest concentration, each calibration solution once using the gas chromatograph according to the manufacturer's instructions·.

Check the quality of the linear adjustment of the calibration curve.

8.4 CALCULATIONS & EXPRESSION OF RESULTS:

The detection and quantification of defined volatile organic compounds. The content of voc's are calculated in milligram per kilogram of the sample

W (mg/kg)= C x D/m

Where;

W = content in mg/kg of voc's in sample
C = Concentration from Graph in mg/ kg.
m = Weight of sample in gm.

D = 5 ml of matrix modifier solution.

9 Summary and expression of results

A quantitative result may be obtained only after the substance has been identified.

The mass concentration of benzene and derivatives shall be reported to the nearest microgram per liter, giving two significant digits.

EXAMPLES:

benzene	**8.0 µg/ l**
Methylbenzene (toluene)	**11.0 µg/ l**

10 Test report

The test report shall include the following information:

a) a reference to this part of method and to the head-space method;

b) expression of results according to clause 9.

11 References:

1) ISO 11423-1: Determination of benzene and other derivatives- Head-space gas chromatographic method

2) EPA Method 5021-A: Volatile Organic Compounds in Soils and other Solid matrices using equilibrium headspace analysis

Annex A
(informative)
Typical gas chromatographic conditions

Table B.1-Typical gas chromatographic conditions of separation with high resolution capillary

Column Temperature	Temperature Program	Retention time						
		Methanol	Acetone	Methylene Chloride	benzene	Toluene	Xylene (M,P)	Xylene (o)
DB-624 (30 m x0.32mm x 1.8 µm)	40 °C during 3 min; raise temperature at 5 °C/min to 180 °C; 15 min at	2.48	3.88	4.52	8.19	12.22	16.21	17.21

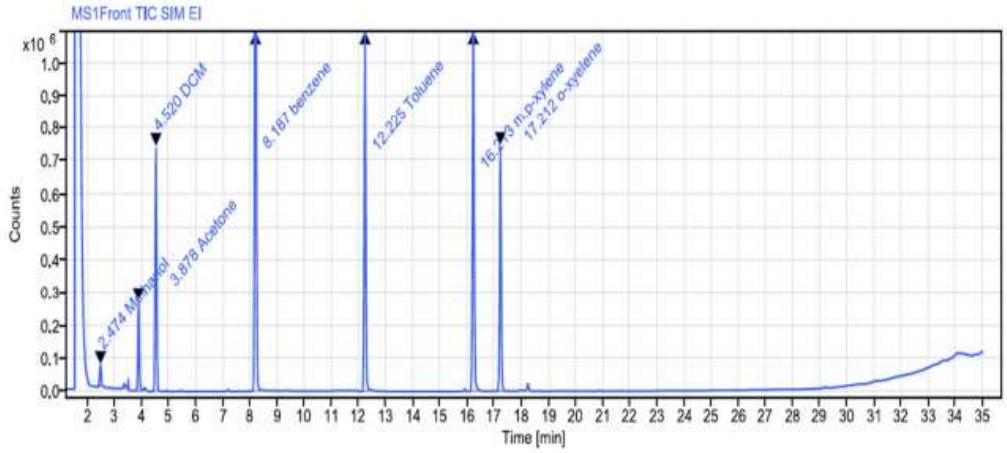
Annex B
(informative)
Example of chromatograms

Conditions of the gas chromatograph to obtain Figure C

Injection Volume	1000 ill
Injection Temperature	180 °C
Detector Temperature	250 °C

Columns	0,32 mm; length 30m

Figure C



Signal: MS1Front TIC SIM EI

Name	RT [min]	Area	Concentration [ppm]
Methanol	2.47	243505.556	1.053
Acetone	3.88	1023910.712	1.018
DCM	4.52	2716838.727	1.035
benzene	8.19	7504290.843	1.023
Toluene	12.22	4287073.371	1.038
m,p-xylene	16.21	4884365.226	1.030
o-xyelene	17.21	2882802.366	1.033

ANNEX 11

(Item 8.1)

COMMENTS ON PUBLISHED STANDARDS - IS 5405 : 2019, SANITARY NAPKINS — SPECIFICATION (SECOND REVISION) AND IS 17514 : 2021, REUSABLE SANITARY PAD / SANITARY NAPKIN / PERIOD PANTIES — SPECIFICATION

COMMENTS ON TEST METHOD OF VOLATILE ORGANIC COMPOUNDS FROM SHRI PADMANABAN KS - SGS, CHENNAI

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)
8.2 Preparation of calibration solutions	Amount of stock solution unit is mg/kg	Suggest considering stock and calibration solutions unit as mg/L instead of mg/kg		
9 Summary and expression of results	Unit for results expression	Suggest changing it to mg/kg		

ANNEX 12

(Item 8.2)

COMMENTS ON PUBLISHED STANDARDS

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

AGENDA AND MINUTES OF PANEL MEETING FOR REVISION OF IS 17334

For BIS Use Only

BUREAU OF INDIAN STANDARDS

AGENDA

Panel meeting for revision of IS 17334 Surgical Gowns and Surgical Drapes under TXD 36

Date	Time	Venue
18 May 2023 (Thursday)	1100 h	Video Conference through CISCO Webex

CONVENOR: Dr. E Santhini, Convenor, SITRA, Coimbatore

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

Item 0 WELCOME & INTRODUCTORY REMARKS

Item 1 COMMENTS ON PUBLISHED STANDARDS

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

In the last meeting of TXD 36, the committee decided to constituted a panel with the following experts/members for preparation of revised draft of IS 17334: -

i) **Dr. E. Santhini, Senior Scientific Officer, SITRA (Convenor)**
ii) Dr. Ravikant Sharma/Representative, CDSCO, New Delhi
iii) Dr. Sanjiiv, FICCI/PWMAI, New Delhi
iv) Dr. Prabha Hegde, 3 M Bangalore
v) Shri Sumit Marwah, Dispoline India Pvt. Ltd., Bangalore
vi) Shri R. Krishnakumar , Cologenesis Healthcare Private Limited, Salem
vii) Dr. J. Jayalakshmi, KMCH Hospital, Coimbatore
viii) Dr. Vijaydeep Sidharth, AIIMS, New Delhi
ix) Shri Apoorva Ranka, Alpha Foam Private Limited, Pune

x) Shri Khalil Khan, Surya Textech, Chandigarh
xi) The convenor/panel may co-opt the users/stakeholders as required
xii) Member Secretary, TXD 36, BIS New Delhi

The committee further decided that the panel shall discuss the following aspects/comments and provide their recommendation to BIS: -

a) The requirement of Isolation Gown, Professional Gown and Patient Gown to include during revision of IS 17334.
b) Table 3 General guidelines/recommendations for use of different levels of surgical gowns/surgical drapes with users/doctors/surgeon
c) The test parameter for fabric stage and final product may be defined separately.
d) The testing frequency and sampling plan.
e) Moisture vapour transmission rate /breathability requirement.
f) Any other aspects.

The comments received on IS 17334 were also discussed in earlier meeting of panel held on 24 November 2022 through video conferencing to prepare the revised draft. The agenda and minutes of this panel meetings are given in **Annex 1 (Pages 3-31).**

The comments received from SITRA on IS 17334 has been given in Annex 2 (Pages 32-37) of the agenda**.**

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

ANNEX 1
(Item *1.1*)
AGENDA AND MINUTES OF EARLIER MEETING OF PANEL FOR REVISION OF IS 17334 : 2019 HELD ON 24 NOVEMBER 2022

For BIS Use Only

BUREAU OF INDIAN STANDARDS

AGENDA
Panel meeting for revision of IS 17334 Surgical Gowns and Surgical Drapes under TXD 36

Date	Time	Venue
24 November 2022 (Thursday)	1100 h	Video Conference through CISCO Webex

CONVENOR: Dr. E Santhini, Convenor, SITRA, Coimbatore

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

Item 0 WELCOME & INTRODUCTORY REMARKS

Item 1 COMMENTS ON PUBLISHED STANDARDS

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

In the last meeting of TXD 36, the committee decided to constituted the following panel for preparation of revised draft of IS 17334: -

i) **Dr. E. Santhini, Senior Scientific Officer, SITRA (Convenor)**
ii) Dr. Sanjiiv, PWMAI, New Delhi
iii) Dr. Prabha Hegde, 3 M Bangalore
iv) Shri Sumit Marwah, Dispoline India Pvt. Ltd., Bangalore
v) Dr. Vijaydeep Sidharth, AIIMS, New Delhi
vi) 2-3 Fabric manufacturers of surgical drape and gown
vii) The convenor/panel may co-opt the users/experts as required
viii) Shri Dharmbeer, Member Secretary, TXD 36, BIS New Delhi

The comments received on IS 17334 has been given in Annex 1 (Pages 2-6) of the agenda**.**
The copy of standard IS 17334 : 2019 along with amendment has been given in in **Annex 2 (Pages 7-21)** of the agenda.

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

ANNEX 1
(Item *1.1*)
COMMENTS ON PUBLISHED STANDARDS

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

a) Shri Sumit Marwah, Dispoline India Private Limited, Bangalore

Levels
We should change the levels to 1, 2, 3 & 4 instead of the present 0, 1, 2, & 3
This would harmonize the levels used in other standards like AAMI PB 70 and also remove the confusion behind level “Zero”.
(Level 4 has become synonymous with the highest protection)
Even would be in sync with the levels in the PPE Standard .
Introduction of Isolation Gowns in the standard
It is imperative to add isolation gowns to this standard.

The performance requirements and levels would remain the same as for Surgeon Gowns, would only require inclusion of a diagram for definition of critical area. In Isolation gowns the critical area is the entire gown including the back and the joints

Microbial Penetration-Wet & Microbial Penetration-Dry

Further Discussion on Microbial Penetration- Wet and Microbial Penetration- Dry is warranted.

The Microbial penetration test – Wet has had issues with standardization, and also is also not available widely in India.

(The standard already has 2 liquid penetration tests for the first 3 levels and also has Synthetic blood/ Viral test method for the highest level.)

In my opinion The Dry Microbial test does not mimic / reproduce conditions in the Operating theatre.

Sampling and Criteria for Conformity

The sampling plan needs to be discussed and clarified, especially with respect to Validation and Parametric Release

Isolation gown: Item of protective apparel used to protect health care personnel and patients from the transfer of microorganisms and body fluids in patient isolation situations.

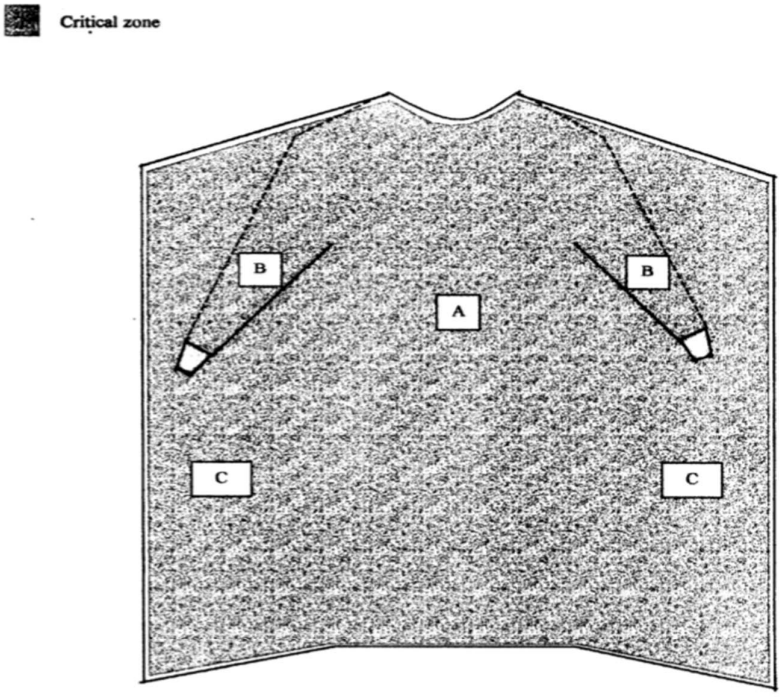


Figure B.2—Example of a gown intended for isolation applications

NOTE 1—The entire isolation gown (areas A, B, and C), including seams but excluding cuffs, hems, and bindings, is required to have a barrier performance of at least Level 1 (as per 4.2.3.1).

NOTE 2—Table B.2 illustrates the requirements of 4.2.1.1 and 4.2.3.1 and shows how the barrier performance classification of the isolation gown would be determined.

Table B.2—Barrier performance classification of isolation gowns

Area A (Front)	Area B (Sleeve)	Area C (Back)		Final barrier performance classification
Level 1, 2, 3, or 4	Level 1, 2, 3, or 4	Level 1		Level 1
Level 1, 2, 3, or 4	Level 1	Level 1, 2, 3, or 4		Level 1
Level 1	Level 1, 2, 3, or 4	Level 1, 2, 3, or 4		Level 1
Level 2, 3, or 4	Level 2, 3, or 4	Level 2		Level 2
Level 2, 3, or 4	Level 2	Level 2, 3, or 4		Level 2
Level 2	Level 2, 3, or 4	Level 2, 3, or 4		Level 2
Level 3 or 4	Level 3 or 4	Level 3		Level 3
Level 3 or 4	Level 3	Level 3 or 4		Level 3
Level 3	Level 3 or 4	Level 3 or 4		Level 3
Level 4	Level 4	Level 4		Level 4

b) Dr. Sanjiiv, FICCI, New Delhi

i) The size (small, medium, large, extra-large etc..) of surgical gown and drape should be included in the standard.
ii) For products made through sewing/stitching, the requirement of stich density should be specified.
iii) Clause 8, Sampling plan referred in the standard should be simplified.
iv) Guidelines for reusability of surgical gown and drape should be specified in the standard.

c) Dr. Prabha Hegde, 3 M India, Bengaluru

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Specific Proposal (Draft clause to be add/amended)	Remarks	Technical References and justification on which (2), (3), (4) are based
(1)	(2)	(3)	(4)	(5)
clause 4.3	The requirements given in 4.1 to 4.3 are for guidance of the manufacturer. Reference may also be made to the Medical Devices Rules 2017.'	The statements in the standard need to be continued	There is no need for the changes to the standards	As the gowns and drapes are used in the critical applications like surgery the manufacturing environment need to be maintained to make sure that the product meets all the BIS specified guidelines
clause 5.2	The requirements given are for guidance of the manufacturer. Reference may also be made to the Medical Devices Rules 2017.	The statements in the standard need to be continued	There is no need for the changes to the standards	As the gowns and drapes are used in the critical applications like surgery the manufacturing environment need to be maintained to make sure that the product meets all the BIS specified guidelines
Clause 10	'NOTE — The requirements given are for guidance of the manufacturer and user.	The statements in the standard need to be continued	There is no need for the changes to the standards	As the gowns and drapes are used in the critical applications like surgery the manufacturing environment need to be maintained to make sure that the product meets all the BIS specified guidelines

d) Shri Rajiv Ranka, Alpha Foam ltd., Pune

1. We can see that AAMI level uses impact penetration as a important parameter for surgical drapes and gowns. We have missed this parameter in the Level 1 and level 2 gowns. It is included in the Level 0 products. Impact penetration measure the leakage of a fabric when the fluid is sprayed. It is the level 1 and level 2 where doctors and patients are at the most risk of being sprayed as the utilisation is for simple and complicated surgeries respectively. Thus impact penetration (test ISO 18695) of >1 gram should be included.

2. The level 2 gowns and drapes are used for surgical procedures where blood is present. In level 2 gown blood resistance is not required. Internationally the level 3 gown is equivalent to the Level 2 gown in the Indian standards. Thus alcohol repellant and blood resistance needs to be included in the Level 2 gown. The blood and alcohol surface tension is significantly lower than water that is used to check the hydrostatic pressure head. (ISO 811) Thus Alcohol resistance and antistatic specs should be included in the Level 2 gown and drapes. The standards used for alcohol repellency are WSP 80.8. This standard can be used as a basis for incorporating it in the Indian standards. The antistatic or Surface resistivity standard of WSP 40.1 should also be included.

e) <u>Dr. E. Santhini, SITRA Coimbatore</u>

As CDSCO regulated Isolation gown, patient gown and professional examination gown and we are getting enquiries on the details of testing to be conducted for obtaining manufacturing license for these products, we request BIS to look for the possibilities to include these gowns during the panel meeting

ANNEX 2
(Item *1.1*)
IS 17334 : 2019 MEDICAL TEXTILES — SURGICAL GOWNS AND SURGICAL DRAPES — SPECIFICATION

AMENDMENT NO. 1 JANUARY 2021 TO
IS 17334 : 2019 MEDICAL TEXTILES — SURGICAL GOWNS AND SURGICAL DRAPES — SPECIFICATION

(Page 2, clause 4.3) — Insert the following note at the end:

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

(Page 2, clause 5.2) — Insert the following note at the end:

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

(Page 6, clause 10) — Insert the following note at the end:

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

Indian Standard
MEDICAL TEXTILES — SURGICAL GOWNS AND SURGICAL DRAPES — SPECIFICATION

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textile Division Council.

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

This standard addresses the performance of surgical gowns and surgical drapes designed to protect against exposure of healthcare workers to blood, body fluids, and other potentially infectious materials during surgery and other healthcare procedures. This standard defines testing and reporting performance requirements levels for surgical gowns and surgical drapes manufacturers in order to provide information to end users that can be used in making informed decisions in the selection and purchase of surgical gowns and surgical drapes according to the anticipated exposures.

The composition of the Committee responsible for the formulation of this standard is given in Annex C.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 ‘Rules for rounding off numerical values (revised)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1 SCOPE

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

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

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

2 REFERENCES

The standards listed in Annex A contain provisions which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated are valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards.

3 TERMS AND DEFINITIONS

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

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

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

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

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

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

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

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

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

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

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

3.11 Invasive Surgical Procedure — Surgical procedure penetrating skin or mucosa

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

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

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

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

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

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

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

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

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

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

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

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

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

4 WORKMANSHIP AND FINISH

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

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

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

5 GENERAL REQUIREMENTS

5.1 Product (s) shall meet all the requirements specified in this standard throughout their useful life. If the manufacturer does not specify critical and/or noncritical area of a product, the product shall meet at least level "0" performance requirements as given in Table 1 and Table 2.

5.2 Manufacturing and Processing Requirements and Documentation

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

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

Microbiological monitoring (as per ISO 14698-1), air monitoring of clean room (as per ISO 14644-1), sterilization (as per IS/ISO 11135), packaging [as per IS/ISO 11607 (Part 1 and Part 2)], validation [as per IS/ISO 11137 (Part 1 and 2), ISO 11138-t 7] and residual sterility (IS/ISO 10993-7) shall be maintained by the manufacture.

5.3 Barrier Properties

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

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

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

6 PERFORMANCE REQUIREMENTS

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

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

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

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

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

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

7 MARKING

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

a) Name of the product ;

b) Dimension /size of the product;

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

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

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

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

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

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

j) Performance level; and

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

Table 1 Performance Requirements for Surgical Gowns

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

Sl No.	**Characteristics**	**Requirement**				**Method of Test,**
		Level 0	Level 1	Level 2	Level 3	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
i)	Impact penetration (g)	≤ 4.5	NA	NA	NA	ISO 18695
ii)	Hydrostatic resistance (cmwc)	NA	≥ 20	≥ 50	NA	ISO 811
iii)	Blood resistance	NA	NA	NA	Pass	IS 16546
iv)	Viral resistance	—	—	—	Pass	IS 16545
v)	Particle release [log10 (lint count)]	≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0	IS 15891 (Part 10)
vi)	Tensile strength (dry and wet) (N)	≥ 20	≥ 20	≥ 20	≥ 20	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)
vii)	Bursting strength (dry and wet) (kPa)	≥ 40	≥ 40	≥ 40	≥ 40	IS 1966 (Part 1)

viii)	Cleanliness– microbial (CFU/100 cm^2)		≤ 300	≤ 300	≤ 300	≤ 300	ISO 11737-1
ix)	Resistance to microbial penetration — Dry (CFU)		NA	≤ 300	≤ 300 (for less critical zones)	NA	IS 16548
x)	Resistance to microbial penetration — Wet (I_B)		NA	NA	6.0 (for critical zones)	—	IS 16549
xi)	*Biocompatibility Evaluation	Cytotoxicity	None	None	None	None	IS/ISO 10993-5
		Irritation and skin sensitization	Non-irritant and nonsensitizer	Non-irritant and nonsensitizer	Non-irritant and nonsensitizer	Non-irritant and nonsensitizer	IS/ISO 10993-10
xii)	Moisture vapour transmission rate (*Max*.) (optional)		NA	NA	NA	40 m^2 Pa/W	ISO 11092
*Remarks: Confirm the biocompatibility of raw material at designed stage for all levels. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product.							

Table 2 Performance Requirements for Surgical Drapes

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

Sl No.	Characteristics	Requirement				Method of Test,
		Level 0	Level 1	Level 2	Level 3	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
i)	Impact penetration (g)	≤ 4.5	NA	NA	NA	ISO 18695
ii)	Hydrostatic resistance (cmwc)	NA	≥ 20	≥ 50	≥ 100	ISO 811
iii)	Blood resistance	NA	NA	NA	Pass	IS 16546
iv)	Particle release [log10 (lint count)]	≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0	IS 15891 (Part 10)
v)	Tensile strength (dry and wet) (N)	≥ 20	≥ 20	≥ 20	≥ 20	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)

vi)	Bursting strength (dry and wet) (kPa)		≥ 40	≥ 40	≥ 40	≥ 40	IS 1966 (Part 1)
vii)	Cleanliness– microbial (CFU/100 cm^2)		≤ 300	≤ 300	≤ 300	≤ 300	ISO 11737-1
viii)	Resistance to microbial penetration — Dry (CFU)		NA	≤ 300	≤ 300 (for less critical zones)	NA	IS 16548
ix)	Resistance to microbial penetration — Wet (I_B)		NA	NA	6.0 (for critical zones)	—	IS 16549
x)	*Biocompatibility Evaluation	Cytotoxicity	None	None	None	None	IS/ISO 10993-5
		Irritation and skin sensitization	Non-irritant and nonsensitizer	Non-irritant and nonsensitizer	Non-irritant and nonsensitizer	Non-irritant and nonsensitizer	IS/ISO 10993-10
* Remarks: Confirm the biocompatibility of raw material at designed stage for all levels. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product.							

Table 3 General Guidelines/Recommendations for Use of Different Levels of Surgical Gowns/Surgical Drapes
(Clause 6.3)

Performance Level	Examples of Procedures with Anticipated Exposure Risks
Level 0	Simple excisional biopsies Excision of "lumps and bumps" Ophthalmological procedures Simple ear, nose and throat (ENT) procedures
Level 1	Tonsillectomies adenoidectomies Endoscopic gastrointestinal procedures Simple orthopedic procedures with tourniquets Open hernia repair Minimally invasive surgery Interventional radiology or catheter lab procedures
Level 2	Mastectomies Arthroscopic orthopedic procedures

	Endoscopic urological procedures (for example, transurethral prostate resections) Open gastrointestinal and genito-urinary procedures
Level 3	Any procedure in which the surgeon's hands and arms are in a body cavity Orthopedic procedures without a tourniquet Open cardiovascular or thoracic procedures Trauma procedures Caesarean sections

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

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

7.2 BIS Certification Marking

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

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 Lot

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

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

NOTES:

1 For level 0, 1, 2 and 3 surgical gowns, the conformance of the performance requirements as given in Table 1 may be accepted at fabric stage (except cleanliness microbial, resistance to blood and resistance to viral) for a product if desired by buyer/ user. In such cases, the traceability certificate for conformance of the performance requirement of fabric shall be maintained by the product manufacturer for each lot.

2 Similarly, for level 0, 1, 2 and 3 surgical drapes, the conformance of the performance requirements as given in Table 2 may be accepted at fabric stage (except cleanliness microbial and resistance to blood) for a product if desired by buyer/user. In such cases, the traceability certificate for conformance of the performance requirement of fabric shall be maintained by the product manufacturer for each lot.

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

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

8.2 Number of Tests and Criteria for Conformity

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

8.2.1.1 Any surgical gowns/ surgical drapes failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 3 of Table 4. Otherwise, the lot shall be rejected.

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

Lot Size	Non-destructive Testing		Destructive Testing	
	No. of Gown/Drape to be Selected	Acceptance Number	No. of Gown/Drape to be Selected	Acceptance Number
N	N	a	n_1	a_1
(1)	(2)	(3)	(4)	(5)
Up to 50	5	0	2	0
51 to 150	8	0	3	0
151 to 280	13	1	3	0
281 to 500	20	2	3	0
501 to 1 200	32	3	5	0
1 201 to 3 200	50	5	5	0
3 201 and above	80	7	5	0

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

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

9 MOISTURE VAPOUR TRANSMISSION RATE (OPTIONAL TEST FOR SURGICAL GOWN)

Moisture vapour transmission is the ability of water vapour to pass through a material. This attribute has a significant effect on comfort, because materials without the ability to allow moisture transmission are generally uncomfortable. This test is recommended to be performed for level 3 surgical gowns as given in Table 1, as level 3 gowns are being used in high risk surgeries with prolonged duration where the doctors/ healthcare personnel are subjected to heat stress due to which they may feel uncomfortable.

10 EDUCATION

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

a) the performance level of the product, and

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

10.1 Information on Critical and Less Critical Areas

The manufacturer shall differentiate between the critical and less critical areas of the product, if applicable, and identify the different areas.

11 PACKAGING AND STERILIZATION

For packaging of the products, requirements as per IS/ ISO 11607-1 and 2 shall be followed.

For packaging and sterilization, the Medical Device Rule, 2017 shall be followed.

Validation of sterilization process shall be done as per IS/ISO 11135, IS/ISO 11137 -1 and 2, ISO 11138-7 and, IS/ISO 10993-7 standards.

ANNEX A
(*Clause* 2)

LIST OF REFERRED INDIAN STANDARDS

IS/Other Publication	*Title*
1966 (Part 1): 2009	Textiles — Bursting properties of fabrics determination of bursting strength and bursting distension: Part 1 Hydraulic method (*second revision*)
1969 (Part 1): 2018	Textiles — Tensile properties of fabrics: Part 1 Determination of maximum force and elongation at maximum force using the strip method (*fourth revision*)
4905: 2015	Random sampling and randomization procedures (*first revision*)
15891 (Part 3): 2011	Textiles — Test methods for nonwovens: Part 3 Determination of tensile strength and elongation
15891 (Part 10): 2017	Textiles — Test methods for nonwovens: Part 10 Lint and other particles generation in dry state
16545: 2016	Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X174 bacteriophage

16546: 2016	Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood
16548: 2016	Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration
16549: 2019	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
IS/ISO 10993-5: 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 10993-7: 2008	Biological evaluation of medical devices: Part 7 Ethylene oxide sterilization residuals
IS/ISO 10993-10: 2010	Biological evaluation of medical devices: Part 10 Tests for irritation and skin sensitization
IS/ISO 11137-1: 2006	Sterilization of health care products — Radiation: Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices
IS/ISO 11137-2: 2013	Sterilization of health care products — Radiation: Part 2 Establishing the sterilization dose
IS/ISO 11135: 2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
IS/ISO 11607-1: 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 811: 2018	Textile fabrics — Determination of resistance to water penetration — Hydrostatic pressure test
ISO 11092: 2014	Textiles — Determination of physiological effects — Measurement of thermal and water-vapour resistance under steady-state conditions (sweating guarded-hot plate test)
ISO 11138-7: 2019	Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results

ISO 14698-1: 2003 Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and Methods

ISO 14644-1: 2015 Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration

ISO 18695: 2007 Textiles — Determination of resistance to water penetration — Impact penetration test

ANNEX B
(*Clause* 5.3)
B-1 PRINCIPLES OF THE CRITICAL ZONE

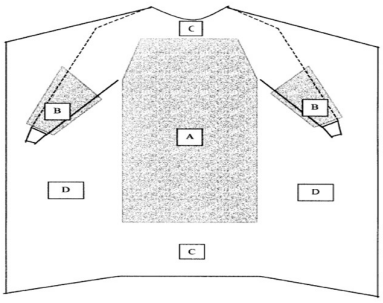
The critical zone can be described as an area approximately 12 inches around the fenestration of a drape where it is thought that reinforcement is needed to resist the penetration and strike through of fluids. Additionally, the critical zone (see Fig. 1) on surgical gown encompasses the front area from mid-chest to waist and the sleeves to 2 inches above the elbows.

However, there are two important factors as related to the critical zone. Fluid is often not always contained in the proximity of the critical zone. For example, during an arthroscopic procedure a large amount of fluid can be used during the procedure and is not contained within the critical zone of the arthroscopic drape.

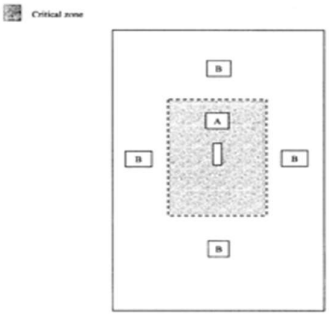
Specialty drapes, such as extremity drapes, may have a reinforced critical zone (*see* Fig. 2). However, due to the amount of fluids that may be encountered and/or manipulation of the body parts the surgical team should consider draping reinforcement of the areas outside of the critical zone. For example, during a hip arthroplasty, the leg is placed through several maneuvers to initially dislocate the joint, facilitate bone excision and placement of the prostheses, put the joint back into place, and further maneuvers to test the prostheses prior to closing the surgical wound. This calls for draping reinforcement of the entire leg and foot in order to prevent an SSI.

In this situation, it may be considered that the critical zone should be further expanded outside of the manufacturers region of reinforcement around the fenestration, thus further suggesting that the critical zone is a fluctuating zone that dependent on the procedure to be performed.

The final performance requirement level of the product shall be based on the performance of the critical zone component.



A and B - Critical zone
C and D - Less critical zone



A - Critical zone
B - Less critical zone

FIG. 1 SURGICAL GOWN FIG. 2 SURGICAL DRAPE

For BIS Use Only

BUREAU OF INDIAN STANDARDS

MINUTES

Panel meeting for revision of IS 17334 Surgical Gowns and Surgical Drapes under TXD 36

Date	Time	Venue
24 November 2022 (Thursday)	1100 h	Video Conference through CISCO Webex

Convenor: Dr. E. Santhini, Head - In-charge, Medical Textiles, SITRA, Coimbatore

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

ATTENDEES:

i)	**Dr. E. Santhini (Convenor)**	SITRA Coimbatore
ii)	Shri Rajiv Ranka	Alpha Foam Private Limited, Pune
iii)	Shri Apurva Ranka	-do-
iv)	Shri Sandeep	-do-
v)	Shri Suraj	CDSCO, New Delhi
vi)	Shri Sumit Marwah	Dispoline India Private Limited, Bengaluru
vii)	Dr. Sanjiiv Rehlan	FICCI/PWMAI (Shalex Overseas), New Delhi
viii)	Ms. Tulsi	-do-
ix)	Dr. J. Jayalakshmi	KMCH Hospital, Coimbatore
x)	Dr. Anju Bhalotra	Maulana Azad Medical College, New Delhi
xi)	Shri Khalil Khan	Surya Textech, Chandigarh
xii)	Shri Veerasubramanian	SITRA, Coimbatore
xiii)	Dr. Prabha Hegde	3 M Bangalore
xiv)	Shri Dharmbeer (Member Secretary, TXD 36)	BIS New Delhi

Item 0 WELCOME & INTRODUCTORY REMARKS

Dr. E. Santhini (Convenor) extended a hearty welcome to the members of panel. She emphasized for active participation from the members and requested for the precise inputs so as to arrive at consensus.

Member secretary also welcomed the Convenor and all other members.

Item 1 COMMENTS ON PUBLISHED STANDARDS

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

1.1 The panel considered the comments received from M/s Dispoline India Pvt. Ltd., M/s Shalex overseas (FICCI), M/s 3 M India, M/s Alpha Foam ltd. and SITRA as given in **Annex 1** of the agenda. A brief presentation was made by Dr. E. Santhini (Convenor), SITRA Coimbatore on **'Suggestions for the revision of IS 17334: 2019 Surgical gowns and drapes specification standard'.**

After deliberations, the panel recommended the following: -

iii) The title of the standard is to be updated as 'Medical and Surgical Gowns and Surgical Drapes — Specification'.

iv) The levels given in the standard are to be updated as 1, 2, 3 and 4 (instead of the present 0, 1, 2, and 3) for both gowns and drape.

v) The Isolation gown, professional gown and patient gown are to be included in the existing standard. The panel requested **Dr. E. Santhini** to review IS 17334 : 2019, Table 3 General guidelines/recommendations for use of different levels of surgical gowns/surgical drapes with users/doctors/surgeon and provide the information/technical input to update the same for guidance.

vi) The panel requested **Dr. Sanjiiv** and **Shri Sumit Marwah** to share the technical information if the requirement of patient gown is different from the requirement as mentioned in level 1 for gown. BIS may also request users/hospital for clarification for performance parameter for patient gown.

vii) It was suggested that the dry and wet microbial tests for gown are not required for level 4.

viii) It was suggested that cleanliness–microbial (CFU/100 cm^2) test is required in case of unsterile gown and drapes.

ix) A clarification note to be put up under performance table in case of gown for level 4 when a sample fails in blood resistance test, viral tests shall not be carried out and the sample shall be reported as non-compliance/failure to the standard.

x) The blood resistance and viral resistance test for gown (level 4) shall be performed for pressure cycle upto 14 kPa, procedure D as per IS 16546 and IS 16545 respectively.

xi) Impact penetration test for level 2 and level 3 (≤ 1.0) gown and drapes shall be included as IS 17375: 2020/ISO 18695 : 2007.

xii) Reference to Indian standard shall be updated.

xiii) The panel requested **Shri Kalil Khan** to review the Moisture vapour transmission rate /breathability requirement and provide his comments for any change in requirement and method of test along with technical evidence and justification.

xiv) Based on above inputs, panel requested that BIS shall prepare the revised draft standard within 07 days. BIS may carry out the necessary editorial changes if the draft.

xv) It was decided that BIS will circulate the revised draft with panel members for 07 days for their comments. If required, another panel meeting may be planned in consultation with Convenor in 15 days.

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

ANNEX 2
(Item *1.1*)
COMMENTS ON PUBLISHED STANDARDS

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

SITRA Comments/Technical Inputs on the Indian Standards – TXD 36

S.No.	IS Standard	Item, Clause Sub-Clause No. Commented Upon (Use Separate Box Afresh)	Comments	Specific Proposal (Draft Clause to be Added / Amended)	Remarks
	(1)	(2)	(3)	(4)	(5)
1.	IS 17334	Table No. 1 – Sl. No. ii) **Hydrostatic resistance (cmwc)**	For Hydrostatic resistance, the requirements are Level 2 >/= 20 cmWc, Level 3 >/= 50 cmWc with ref. test standard as ISO 811 where there are two rate of rising conditions (10 cmWc/min or 60 cmWc/min). To be in line to match the requirments derived based on AAMI standard (where rate of rising is mbar as per AATCC 127), the rate of rising is performed at **60 cmWc/min**.	Note on rising to be mentioned as 60 Cmwc/min	
2.	IS 17334	Table 1 – Sl. No. v) **Particle release [log10 (lint count)]**	The method of test referred to is IS 15891 (Part 10), where the particle size range provided as 0.3 micrometer or 0.5 micrometer to 25 micrometer. But, as per practical conditions suitable	The particle size range may be mentioned as **3 micrometer to 25 micrometer** while testing as per IS 15891.	This is in line with EN 13795 requirement, where the method of test is done as per EN ISO 9073-10 and the requirement is to sum the count of particle size range

			for medical gown wearers' environment exposure, the particulate size range of 3 micrometer to 25 micrometer is appropriate to be considered.		between 3 micrometer to 25 micrometer. This is based on the rationale, that the particles smaller than 3 micrometer are too small to carry microorganisms and particles larger than 25 micrometer are too large to remain airborne because of gravity.
3.	IS 17334	Table 1 – Sl. No. xii) **Moisture vapour transmission rate**	The method of test referred to is ISO 11092, where the test parameter measured using is water-vapour resistance (which unit of measurement is m^2.Pa/W). The nomenclature provided in standard is different than the test method parameter.	1. If method of test is ISO 11092, then test performance requirement to be named as Water vapour resistance (Water vapour transmission rate is an inverse function of Water vapour resistance). Moreover, when tested against ISO 11092, test report cannot be mentioned the result as Moisture vapour transmission rate. **(or)** 2. ASTM E96 is the test method standard which measures Water vapour Transmission of materials	

				(measured in $g/m^2/day$)	

SITRA'S Recommendations on Revision of IS 17334 – Surgical Gowns & Drapes following to the first panel meeting held on 24.11.2022

1. **Title**: Medical Protective Gowns and Drapes

2. **Scope**: Any protective apparels used at healthcare setting which are intended to have barrier performance to liquid/microorganisms. This includes:

1. Surgical Gown
2. Isolation Gown
3. Patient Gown
4. Professional Examination Gown
5. Surgical Drapes and Drape accessories
   (This is in line to include all the PPE apparels classified by CDSCO)

Different type of protective apparels used in healthcare setting:

Nature of Gown	Gown type	Protection Level	Definition by CDSCO	Usage
Non-Surgical	**Patient Gown**	Level 1 Level 2 Level 3 Level 4	A garment made of natural and/or synthetic materials (e.g., paper, cloth, plastic) **intended to be worn by patients in a clinical setting (e.g., during hospitalization, during examination in a doctor's office).** A patient gown is usually short-sleeved and may be closed by ties at the back/side of the garment.	Can be used for Standard Precautions and Contact Precautions. • Basic Care • Standard Hospital Medical Unit
	Professional Examination Gown		A garment made of natural and/or synthetic materials **intended to be worn by healthcare providers, sometimes over scrub suits, while examining patients. It can be fluid resistant or impervious to fluid**. An examination gown is used during patient examination procedures to protect both the patient and staff from the transfer of contaminants such as microorganisms or body fluids.	Can be used by Nurses, Standard Precautions, Contact Precautions. • Blood draw from a vein • Suturing • ICU • Pathology lab
Surgical	**Surgical Gown**		A sterile or non-sterile garment made of natural	Used in the Emergency Room, the

			and/or synthetic materials **intended for surgical procedures to help protect both the patient and operating room personnel from the transfer of microorganisms, body fluids, and particulate material**.	ICU, by Nurses, for Standard Precautions, Contact Precautions. • Arterial blood draw • IV insertion • Emergency room • Trauma • Typically pathogen resistant
	Isolation Gown		A sterile or non-sterile garment made of natural and/or synthetic materials **intended to be worn by healthcare providers or visitors to isolate themselves from patients to protect themselves** from a contagious agent which has infected the patient.	Used in the Emergency Room, the ICU, by Nurses, for Standard Precautions, Contact Precautions. • Pathogen resistance • Infectious diseases (non-airborne) • Large amounts of fluid exposure over long periods
	Surgical Drapes & Drape accessories			

3. **General Guidelines / recommendations for use of different levels of Medical protective Gowns & Drapes**:

Performance Level	**Examples of Procedures with Anticipated Exposure Risks (IS 17334 existing)**	**Proposal (Ref. Source: FDA site & L.R. Pasternak: Screening Patients – Strategies and Studies. In ambulatory Anesthesiology)**
Level 1	• Simple excisional biopsies • Excision of "lumps and bumps" • Ophthalmological procedures • Simple ear, nose and throat (ENT) procedures	• Minimal risk to the patient independent of anesthesia • Minimally invasive procedures with little or no blood loss • Often done in an office setting with the operating room principally for anesthesia and monitoring **Eg:** During basic care, standard isolation, cover gown for visitors, or in a standard medical unit **Includes:** Breast biopsy, removal of minor skin or subcutaneous lesions, myringotomy tubes, hysteroscopy, cystoscopy, fiber optic bronchoscopy

Level 2	• Tonsillectomies adenoidectomies • Endoscopic gastrointestinal procedures • Simple orthopaedic procedures with tourniquets • Open hernia repair • Minimally invasive surgery • Interventional radiology or catheter lab procedures	• Minimal to moderately invasive procedure • Blood loss less than 500 cc • Mild risk to patient independent of anesthesia **Eg:** During blood draw, suturing, in the Intensive Care Unit (ICU), or a pathology lab **Includes:** Diagnostic laparoscopy, dilatation, and curettage, fallopian tubal ligation, arthroscopy, inguinal hernia repair, laparoscopic lysis of adhesions, tonsillectomy/adenoidectomy, umbilical hernia repair, septoplasty/rhinoplasty, percutaneous lung biopsy, expensive superficial procedures
Level 3	• Mastectomies • Arthroscopic orthopaedic procedures • Endoscopic urological procedures (for example, transurethral prostate resections) • Open gastrointestinal and genito-urinary procedures	• Moderate to significantly invasive procedure • Blood loss potential 500-1,500 cc • Moderate risk to patient independent of anesthesia **Eg:** During arterial blood draw, inserting an Intravenous (IV) line, in the Emergency Room, or for trauma cases **Includes:** hysterectomy, myomectomy, cholecystectomy, laminectomy, hip/knee replacement, major laparoscopic procedures, resection/reconstructive surgery of the digestive tract **Excludes:** Open thoracic or intracranial procedure
Level 4	• Any procedure in which the surgeon's hands and arms are in a body cavity • Orthopaedic procedures without a tourniquet • Open cardiovascular or thoracic procedures • Trauma procedures • Caesarean sections	• Highly invasive procedure • Blood loss greater than 1,500 cc • Major/critical risk to patient independent of anesthesia • Usual post-operative ICU stay with invasive monitoring **Eg:** During long, fluid intense procedures, surgery, when pathogen resistance is needed or infectious diseases are suspected (non-airborne) **Includes:** • Major orthopedic-spinal reconstruction, major reconstruction of the gastrointestinal tract, major vascular repair without postoperative ICU stay, Cardiothoracic procedure, intracranial procedure, major procedure on the oropharynx, major vascular skeletal, neurologic repair

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BUREAU OF INDIAN STANDARDS

MINUTES

Panel meeting for revision of IS 17334 Surgical Gowns and Surgical Drapes under TXD 36

Date	Time	Venue
18 May 2023 (Thursday)	1100 h	Video Conference through CISCO Webex

Convenor: Dr. E. Santhini, Head - In-charge, Medical Textiles, SITRA, Coimbatore

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

ATTENDEES

xv)	**Dr. E. Santhini (Convenor)**	SITRA Coimbatore
xvi)	Ms. Rama Venugopal	AIMED, New Delhi
xvii)	Shri Apurva Ranka	Alpha Foam Private Limited, Pune
xviii)	Shri Arvind Hiwale	CDSCO, New Delhi
xix)	Shri Sumit Marwah	Dispoline India Private Limited, Bengaluru
xx)	Dr. Sanjiiv Rehlan	FICCI/PWMAI (Shalex Overseas), New Delhi
xxi)	Dr. J. Jayalakshmi	KMCH Hospital, Coimbatore
xxii)	Dr. Pawanindra Lal	Maulana Azad Medical College, New Delhi
xxiii)	Dr. Vijay Tadia	PGIMER, Chandigarh
xxiv)	Shri Khalil Khan	Surya Textech, Chandigarh
xxv)	Shri S. Sivakumar	SITRA, Coimbatore
xxvi)	Shri Dharmbeer (Member Secretary, TXD 36)	BIS New Delhi

Item 0 WELCOME & INTRODUCTORY REMARKS

Dr. E. Santhini (Convenor) extended a hearty welcome to the members of panel. She emphasized for active participation from the members and requested for the precise inputs so as to arrive at consensus.

Member secretary also welcomed the Convenor and all other members.

Item 1 COMMENTS ON PUBLISHED STANDARDS

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

1.2 The panel considered the minutes of panel meeting held on 24 November, 2022 as given in **Annex 1** along with comments received from SITRA as given in **Annex 2** of the agenda. After deliberations, the panel recommended the following: -

xvi) It was informed that patient gown is used for the convenience of the patient care/treatment, comfort and dignity of patient. The material and performance parameter for patient gown are different from level 1 of IS 17334 medical/surgical gown so the panel suggested that the patient gown should not be included in the existing standard.

xvii) The panel requested the following stakeholders to share the working draft of patient gown within 30 days :

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

It was decided that Dr. Sanjiiv Rehlan will co-ordinate with the stakeholders for the preparation of working draft on patient gown.

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

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

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

Performance Level	**Examples of Procedures with Anticipated Exposure Risks (IS 17334 existing)**	**Anticipated risk of exposure**
Level 1	• Simple excisional biopsies • Excision of "lumps and bumps" • Ophthalmological procedures • Simple ear, nose and throat (ENT) procedures	• Minimal risk to the patient independent of anesthesia • Minimally invasive procedures with little or no body fluid loss • Often done in an office setting with the operating room principally for anesthesia and monitoring
Level 2	• Tonsillectomies adenoidectomies • Endoscopic gastrointestinal procedures • Simple orthopaedic procedures with tourniquets • Open hernia repair • Minimally invasive surgery • Interventional radiology or catheter lab procedures	• Minimal to moderately invasive procedure • Mild body fluid loss • Mild risk to patient independent of anesthesia

Level 3	• Mastectomies • Arthroscopic orthopaedic procedures • Endoscopic urological procedures (for example, transurethral prostate resections) • Open gastrointestinal and genito-urinary procedures	• Moderate to significantly invasive procedure • Moderate body fluid loss • Moderate risk to patient independent of anesthesia
Level 4	• Any procedure in which the surgeon's hands and arms are in a body cavity • Orthopaedic procedures without a tourniquet • Open cardiovascular or thoracic procedures • Trauma procedures • Caesarean sections	• Highly invasive procedure • High body fluid loss • Major/critical risk to patient independent of anesthesia • Usual post-operative ICU stay with invasive monitoring

xx) It was suggested to add the requirement and test method of **seam strength (dry and wet)** for all levels as per the International Practice. The panel requested **SITRA** to suggest the requirement and test method for seam strength as per International Practices.

xxi) It was suggested that performance requirements as given in Table 1 of IS 17334 may be accepted at fabric stage (except cleanliness microbial, resistance to blood and resistance to viral, seam strength test).

xxii) The panel requested **Shri Sumit Marwah** and **Dr. Sanjiiv** to provide their proposal for **testing frequency and sampling plan** for the final product.

xxiii) Dr. Pawanindra Lal informed that as a user, some parameters like size of gown, elastic at cuff, sterilization and packaging standard are very important. It was clarified that sterilization and packaging requirement have been already included in the standard. It was decided that the size of gown and drape shall be as per agreement between the buyer and the seller. The size of gown shall be designated based on the measurement of height and chest. In case of elastic cuff/waist, it should have proper fit and should be adhered with glue to minimize risk of exposure.

xxiv) The remaining comments of SITRA on test procedure and reporting (Hydrostatic resistance, Particle release test and Biocompatibility test), requirement of dry and wet microbial penetration will be discussed in next panel/technical committee meeting.

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

ANNEX 13

(Item 9.1)

INTERNATIONAL ACTIVITIES

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

ISO/TC 338 **N 41**

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

Agenda_rev_2nd plenary meeting ISO TC 338 Menstrual Products

Document type	**Related content**	**Document date Expected action**
Meeting /Agenda	Meeting: Normalm (Sweden) 20 April 2023	2023-04-04

NOTICE OF MEETING / DRAFT AGENDA

Date 2023-04-04	**Reference** ISO/TC 338 N 41
Number and title of TC/Numéro et titre du TC **ISO/ TC 338 Menstrual Products**	
Secretariat/*Secretariat* SIS, Swedish Institute for Standards Jenny Acaralp +46 70 7162057 jenny.acaralp@sis.**s**	**Meeting/*Réunion*** Meeting dates / Dates de la réunion: Thursday 20 April, at 10.00-16.00 (CET) Friday 21 April, at 09.00-12.00 (CET**)**
Host/Invitant SIS, Swedish Institute for Standard	**Place/*Lieu*** Address/*Adresse*: Solnavagen 1 E/Torsplan, 113 65 Stockholm + Virtual by Zoom **Tel:** +46 8 - 555 520 00

To support developing country participation in TC 338 at an early stage, ISO's Capacity Building Unit and SIS organizes a training session on April 19th in conjunction with the TC meeting.

Registration for the meeting is open in the ISO Meeting tool: https://sd.iso.org/meetings/all

P-and O-members are invited to inform the secretariat of the committee concerned, within one month of the receipt of this notice of meeting, of their intention to be represented at the meeting, the approximate number of their delegates and their need for interpretation.

Whenever possible, the names of delegates (or observers) and the name of the head of the delegation should also be sent to the secretariat of the committee concerned at least one month before the opening of the meeting.

For more information about meetings, see the brochure 'My ISO Job', available at: http://www.iso.org/iso/my_iso_job.pdf

Agenda item
1.Opening of the meeting (April 20, at 10.00)
2. Roll call of delegates
3.Work environment: Presentation on the Code of Conduct **Direct link to Code of Conduct**
4. Adoption of the agenda Doc. ISO/TC 338 **N 41**
5. Appointment of the drafting committee
6. Report of the ISO/TC 338 Secretariat Doc. **N 39** Secretariat report to ISO TC 338 plenary
7. Information from ISO/CS, ISO Central Secretariat
8. Progress reports
8.1 WG 1 General Requirements Doc. ISO/TC 338 **N 40**
8.2 Ad hoc group Terminology Doc. **N 38** AHG 1 Terminology Doc. **N 35** AHG 1 Terminology report
8.3 Task group Strategic Business plan Doc. **N 36** TG 1 Strategic Business Plan report

9.Conclusions of these reports and actions to be taken
10. Liaison reports
10.1 EDANA Doc. **N 34** EDANA Liaison 2nd TC 338 meeting
10.2 UNFPA Doc. **N 33** Liaison report UNFPA
10.3 ISO/TC 6 Paper board and pulps / SC 2 Test methods and quality specifications for paper and board
11. Overview of potential liaisons
12. Requirements concerning a subsequent meeting, offers to host
13. Any other business **13.1 ISO/TC 338 dedicated committee website** **13.2 Presentation** Menstrual products in Japan, Mr. Shinya Takahashi (day 1) **13.3 Presentation** Brazilian scenario regarding menstrual products, Kamilla Carmona Albertini Duarte (day 2) **13.4 Meeting feedback survey**
14. Approval of resolutions Closure of the meeting (April 21, at 12.00)

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BUREAU OF INDIAN STANDARDS

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

Date	Time	Venue
13 April 2023 (Thursday)	1100 h	Video Conference through CISCO Webex

ATTENDEES:

1) Shri S. Sivakumar, SITRA, Coimbatore
2) Dr. E. Santhini, SITRA, Coimbatore
3) Shri Nirav Mehta, M/s Dima Products (ITTA), Mumbai
4) Ms. Roocha Khedkar, Johnson and Johnson, Mumbai
5) Shri Prashant Jadhav, P & G, Mumbai
6) Ms. Shivani Swamy, Livinguard Technology Pvt. Ltd., Mumbai
7) Smt. Tanya Mahajan, The Pad Project (NGO), India
8) Shri Jitender Gupta, Head, Textiles
9) Shri Dharmbeer, Scientist D and Member Secretary, TXD 36

Item 0 WELCOME AND INTRODUCTORY REMARKS

Shri Jitender Gupta, Head Textiles extended a hearty welcome to the experts and members nominated in ISO/TC 338. He emphasized for active participation from the members and requested for the precise inputs so as to decide the India's point of view during the plenary meeting.

Member secretary also welcomed the expert and member.

Item 1 SALIENT OUTCOMES OF THE BRIEFING MEETING

1.1 After discussion, the following was decided: -

i) It was decided that the scope of ISO/TC 338 tentatively finalized during adhoc group meeting should be proposed for change during plenary meeting on 20-21 April 2023.
ii) It was also discussed that change of scope of ISO/TC 338 is difficult to change (as informed by Jenny) and Indian delegation should be flexible and the scope proposed by adhoc group may be used as a guidance for working group for general requirement.
iii) The terminology which has been yet to be finalized/discussed should come under working group for general requirement.
iv) The terminology tentatively finalized by adhoc group/ working group for general requirement may be proposed as new item proposal.
v) The progress report of Adhoc group will be reported by Shri Dharmbeer, Scientist D/Dr. E. Santhini, SITRA.
vi) The revised working document prepared by sub-group (Dr. Santhani, Ms. Tanya Mahanan, Ms. Louise, Klinter, Ms. Sharadha Dongre, Ms. Jenny, Shri Dharmbeer) should be uploaded on the ISO portal by Dr. Santhini for review and comments of experts of task group.
vii) The next meeting of task group for strategic business plan should be fixed by Dr. Santhani after the plenary meeting giving at least 2 weeks' time.
viii) The progress report of strategic business group should be reported by Shri Jitender Gupta, Head, Textiles/ Dr. E. Santhini, SITRA.
ix) The progress report working group of general requirements should be reported by Shri S. Sivakumar and other experts will support him.
x) The next meeting of working group for general requirement should be fixed by Shri S. Sivakumar after the plenary meeting giving at least 4 weeks' time.
xi) The title of WG1 is to be modified and the scope is to be defined as follows

Title WG 1- General, performance and safety requirement of menstrual product.

Scope – The scope of WG 1 should include the standardization of menstrual products on Classification and terminology, Method of Test, Product specification and performance requirement, Safety requirement (material, microbiological, physical, toxicological), Environmental safety of products (compostable, organic, environmentally friendly), Packaging and labelling

xii) The following option for the strategic road map of WG 1 should be reported during the plenary meeting:-

Option 1

a) Part 1- Safety Requirement of externally used menstrual products
b) Part 2- Safety Requirement of internally used menstrual products
c) Part 3 – General and Performance requirement of externally used menstrual products
d) Part 4 – General and Performance requirement of internally used menstrual products

Option 2

a) Part 1- General, Performance and Safety Requirement (Disposable menstrual pad)
b) Part 2 – General, Performance and Safety Requirement (Reusable menstrual pad)
c) Part 3- General, performance and Safety Requirement (Other menstrual products e.g menstrual cups, tampons….)

xiii) It was decided that Indian delegation should be flexible for discussion during plenary meeting but it should be in favour of Indian Interest.

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

ISO/TC 338 **N 42**

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

N 42 Resolutions ISO TC 338 2nd Plenary meeting 2023_04_20__21

Document type	Related content	Document date	Expected action
Meeting / Other	Meeting: Norrmalm (Sweden) 20 Apr 2023	2023-04-21	

Resolutions taken at the 2nd plenary meeting of ISO/TC 338, 20-21 April 2023

Resolution 1 -2023

ISO/TC 338 agrees that the draft agenda (N 41) to be accepted with minor modifications.

Resolution 2 -2023

ISO/TC 338 agrees that the secretariat of ISO/TC 338 together with Veronica Viscovich (Argentina), Laurent Houillon (France), Florence Uwatwembi (Rwanda) with the help of Maho Takahashi (ISO/CS) to be appointed to the resolutions drafting committee.

Resolution 3 -2023

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

Resolution 4 - 2023

ISO/TC 338 thanks the presentations provided by Veronica Viscovich (Argentina), Yuyama Aki/Shinya Takahashi (Japan), Kamilla Duarte (Brazil), Jorge Garcia (Australia) and Elisabeth Mertl (Austria).

Resolution 5 – 2023

ISO/TC 338 requests the committee manager to launch a Committee Internal Ballot (CIB) for 4 months to call for comments on document ISO TC 338 N 38 Menstrual Products — Terminology prepared by AHG1 Terminology.

Resolution 6 – 2023

ISO/TC 338 agrees to establish a liaison to ISO/TC 38 Textiles and to appoint Laurent Houillon (France) as liaison officer.

Resolution 7 – 2023

ISO/TC 338 agrees to establish a liaison to ISO/TC 133 Clothing sizing systems - size designation, size measurement methods and digital fittings and to appoint Laurent Houillon (France) as liaison officer.

Resolution 8 – 2023

ISO/TC 338 agrees to establish a liaison to ISO/TC 194 Biological and clinical evaluation of medical devices and to appoint Elisabeth Mertl (Austria) as liaison officer.

Resolution 9 – 2023

ISO/TC 338 agrees to establish a liaison to ISO/TC 173/SC 3 Aids for ostomy and incontinence and to appoint Jenny Acaralp (Committee manager) as liaison officer.

Resolution 10 – 2023

ISO/TC 338 agrees to establish a liaison to ISO/TC 210 Quality management and corresponding general aspects for products with a health purpose including medical device and to appoint Veronica Viscovich (Argentina) as liaison officer.

Resolution 11 – 2023

ISO/TC 338 agrees to establish a liaison to ISO/TC 157 Non-systemic contraceptives and STI barrier prophylactics and to appoint Veronica Viscovich (Argentina) as liaison officer.

Resolution 12- 2023

ISO/TC 338 approves to create a dedicated committee TC website. Presentation and maintenance will be handled by the secretariat together with the chair.

Resolution 13- 2023

ISO/TC 338 agrees on meeting twice a year, a virtual meeting in Q3 and a hybrid meeting in Q2 2024.

Resolution 14- 2023

ISO/TC 338 thanks the host SIS for hosting the meeting.

ISO/TC 338 **N 56**

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

N 56 Report of the 2nd plenary meeting ISO TC 338

Document type	Related content	Document date	Expected action
Meeting / Minutes	Meeting: Norrmalm (Sweden) 20 Apr 2023	2023 2023-05-31	

Report of the 2nd ISO/TC 338 Menstrual products plenary meeting, 20-21 April 2023 (hybrid meeting)

1. Opening of the meeting

The Chair opened the meeting and welcomed all attendees to the 2nd plenary meeting with ISO/TC 338. Gerda Mazi Larsson (Chair), Jenny Acaralp and Ulla Hihldor (secretariat) and Maho Takahashi(ISO/CS) presented themselves.

2. Roll call of delegates

The attendees introduced themselves.

Attendance list, N 43.

3.Work environment

The committee manager presented the ISO Code of Ethics and Conduct.

Presentation ISO Code of Ethics and Conduct.

ISO - ISO Code of Ethics and Conduct

4. Adoption of the agenda

The revised agenda N 41 was accepted with minor modifications, presentations from Austria and Australia was included to the agenda.

5. Appointment of the drafting committee

Verónica Viviana Viscovich (Argentina), Maho Takahashi (ISO/CS), Florence Uwatwembi (Rwanda)and Laurent Houillon (France) kindly volunteered to assist the committee manager in the preparation of the draft resolutions.

6. Report of the ISO/TC 338 Secretariat and presentation from ISO Central Secretariat

The committee manager presented the secretariat's report, the TC currently has 23 participating (P-members) and 19 observing members (O-members).

At the first meeting the TC scope was discussed, present members approved the title Menstrual products and scope as follows:

Standardization in the field of menstrual products, covering all products intended for both single and multiple use, regardless of material.

At the first plenary meeting it was decided to establish:

- an ad hoc group to work on related terminology and to define terms related to menstrual products.
- a working group, WG 1 General requirements, with the task to start to work on a PWI (Preliminary Work Item) based on the proposal included in the ISO voting.

- a task group to draft the ISO/TC 338 Strategic Business plan. The TC has a new TC organization in liaison, ISO/TC 173/SC 3 Aids for ostomy and incontinence.

7. Presenations

7.1 Japan, Mr. Shinya Takahashi/ Yuyama Aki (day 1)

Presentation - overview of Japanese Regulations on Menstrual Products and Related Laws, N 44.

7.2 Austria Elisabeth Mertl (day 1)

Dr. Elisabeth Mertl made a presentation about a research project currently carried out at the OFI (Austrian Research Institute for Chemistry and Technology). The Project "LEIFS" (let it flow safely) focusses on methods for safety assessment of different kinds of menstrual products. During the initial phase, the team collaborated with industry stakeholders and consumer agencies to pinpoint various safety-related concerns. These topics of concern shall be addressed within the project. Consequently, methods for their evaluation shall be developed. The methods can be divided into three main categories: chemical analysis, biological/in-vitro testing, tests addressing reusability. Chemical analysis focusses on non-targeted screenings of organic and non-organic substances. Biological testing shall address cytotoxicity, mucosal skin irritation and sensitization with in-vitro methods. Reusability testing focusses on the change of the products through their lifetime and the impact of different cleaning scenarios

7.3 Argentina, Verónica Viviana Viscovich (day 1)

In Argentina they are working on several standards on products for menstruation and they have also initiated a study of a standards on menstrual cups. Several regulations have recently been approved but there is no regulation or standard for menstrual cups. The meeting discussed if a New Work Item Proposal on menstrual cups could be proposed, one comment was that the idea is good but that it´s too premature and that the work withing WG 1 need to be further developed. It was concluded that NWIP can be discussed again in the future when the work with the general requirement standard has properly started.

Maho informed us about new ISO rules that will apply from 1st of May, Preliminary Work Items (PWI)can only be developed in ad hoc groups, a working group can't be established for developing a PWI. PWIs can be assigned to an existing WG or another group, for example an ad hoc group.

7.4 Brazil, Kamilla Carmona Albrtini Duarte (day 2)

Kamilla presented the Brazilian scenario regarding menstrual products, regulation for menstrual products and the Brazilian specifications that they have, N 50.

7.5 Australia, Jorge Garcia (day 2)

The regulation and standardization of menstrual products in Australia, N 51.

Australia has had a Tampon Standard for several decades, compliance with that standard is made mandatory by Therapeutic Goods Regulations.

8. Progress reports

8.1 WG 1 General requirements
S. Sivakumar WG 1 convenor reported, N 45.

The meeting discussed the options included in the presentation on how the work could be organized:

Option I
Part 1- Safety Requirement of externally used menstrual products
Part 2- Safety Requirement of internally used menstrual products
Part 3 – General and Performance requirement of externally used menstrual products
Part 4 – General and Performance requirement of internally used menstrual products

Option II
Part 1- General, Performance and Safety Requirement (Disposable menstrual pad)
Part 2 – General, Performance and Safety Requirement (Multiuse menstrual pad)
Part 3- General, performance and Safety Requirement (Other menstrual products e.g menstrual cups, tampons....)

The general requirements standard should be kept product neutral and with a consumer/end user perspective in focus. The first part could be a general requirement standard, the other parts could be divided into products and material, since there are different requirements for different products.

One part could handle classification, work/manufacturing, environment, labelling and marking. Another part is to dela with safety and materials, toxics etc. user/care instructions, warning statements, disposal of products and performance.

Another comment was that you can point to other existing ISO standards, e.g., environmental standards.

At the first WG 1 meeting the outline of the document was discussed, it was suggested to include a separate section on Classification of Menstrual products to cover the various menstrual products, with focus on the general view of the products and not to limit it to products already on the market. The standard should be kept open to include innovative products. WG 1 members have been requested to share their national standards, documents and regulations on Menstrual products in their respective countries.

The scope states: internally and externally, single use and multiple products. This has also been covered in AHG 1 Single use and multiple use menstrual pads, pantyliners, menstrual underwear, tampons, maternity pads, and sponges.

Externally used products; menstrual products used to collect or absorb menstrual fluid after leaving the body. Include single use and multiple use menstrual pads, pantyliners, maternity pads and menstrual underwear.
Internally used menstrual products: menstrual products used to collect or absorb menstrual fluid before leaving the body. Include single use tampons, reusable tampons and sponges, menstrual cups, and menstrual discs.

8.2 Ad hoc group Terminology
Mr Dharmbeer reported, N 46

The scope of ISO/TC 338 Menstrual product has also been discussed within the ad hoc group.

This specific task was included in the resolution from the first meeting.

Tentative TC scope: Standardization in the field of menstrual products (absorbing and collecting), covering all products intended for both single and multiple use, regardless of material. This includes menstrual products like single use/disposable menstrual pads, panty-liners, tampons, menstrual underwear, reusable menstrual pads, reusable tampons and sponges, menstrual cups, reusable menstrual underwear, maternity product and menstrual discs etc.

It was concluded that the TC scope as per today includes all mentioned.

There was a discussion about if the terminology document, N 38, could be proposed as NWIP?

The conclusion was to either:

1. keep it as a working document, updated on a regular basis.
2. propose to develop it as a vocabulary standard in a new ISO TC 338 working group.

It was further clarified that if such a document were to be developed the name of the document would be "vocabulary". Vocabulary documents can be published as IS (International Standards), TS (Technical Specifications) and PAS (Publicly available specifications) not as TR (Technical Reports).

To be able to finalize the work and to collect comments from a wider perspective, it was decided to launch a CIB, Committee Internal ballot and submit N 38 for comments. The CIB will be open for 4 months. (See Resolution 5 – 2023) and the comments will be handled in AHG 1.

The decision about disbanding ad hoc group 1 will be postponed to the next plenary meeting.

8.3 Task group Strategic Business plan
Jitender Gupta reported from Task group 1, N 47

All ISO technical committees need to prepare a strategic business plan for their field of activity within 18 months of their creation, for this task a task group has been created. The strategic business plan describes the main aspects and dynamics of the economic, social, regulatory, or other environment in which the committee operates, as well as its main objectives and current strategies, its internal structure and cooperation with other organizations. It includes the areas of activities of all the subcommittees operating under a technical committee.

A draft document has been submitted for task group 1 members for comments until April 29, after the commenting period TG 1 will schedule a meeting to handle the comments.

9. Conclusions of these reports and actions to be taken
- the terminology document, N 38, to be submitted for a 4-month commenting period. Comments to be handled by AHG 1.

- decision on the disbandment of ad hoc group 1 was postponed to the next plenary meeting

10. Liaison reports

10.1 Report EDANA

Marta Roche gave a presentation about EDANA as an organization in liaison to ISO/TC 338, N 34.

Marta also mentioned related European activities:

CEN Workshop Agreement on a test method to assess the potential presence of trace chemicals in absorbent hygiene products, kick-off meeting in Berlin at DIN on April 26.

CEN Workshop agreement:

https://www.cencenelec.eu/news-and-events/news/2023/workshop/2023-02-02-ahps/

The aim is to publish a test method suitable for assessing the potential presence of trace chemicals in AHPs. This is required as methods that weren't specifically devised for this purpose, may lead to unreliable results that cause further confusion and negatively impact the wider discussion.

The EU Ecolabel for Absorbent Hygiene Products and Reusable Menstrual Cups has been reviewed and will be officially published in July.

For the list of possible trace chemicals:

https://www.edana.org/docs/default-source/product-stewardship/230313_codex_v1 4.pdf?sfvrsn=ae1efcf3_2

10.2. Report UNFPA

Linda Serwaa gave a presentation and introduced UNFPA, N 48.

https://www.unfpa.org/updates/unfpa-raises-bar-quality-menstrual-product

Linda also submitted information/documents to WG 1 regarding Material use in menstrual cups, a desk review of liquid silicone rubber (LSR) and Thermoplastic Elastomer (TPE) and review document on the comparative review performed for LSR and TPE.

10.3 Report ISO/TC 6 Paper board and pulps / SC 2 Test methods and quality specifications for paper and board

Sylvie Moreau-Tabiche gave a presentation including an overview of the ISO TC 6 work programme and ongoing activities, N 49.

11. Overview of potential liaisons

Liaisons between ISO committees ensure that common interests are being addressed by the correct committee and that the right experts are involved in standards development. TC liaisons help to prevent scope overlaps.

The meeting approved on establishing the following TC liaisons:

-liaison to ISO/TC 38 Textiles and to appoint Laurent Houillon (France) as liaison officer.

-liaison to ISO/TC 133 Clothing sizing systems - size designation, size measurement methods and digital fittings and to appoint Laurent Houillon (France) as liaison officer.

- liaison to ISO/TC 194 Biological and clinical evaluation of medical devices and to appoint Elisabeth Mertl (Austria) as liaison officer.

- liaison to ISO/TC 173/SC 3 Aids for ostomy and incontinence and to appoint Jenny Acaralp (Committee manager) as liaison officer.

- liaison to ISO/TC 210 Quality management and corresponding general aspects for products with a health purpose including medical device and to appoint Veronica Viscovich (Argentina) as liaison officer.

- liaison to ISO/TC 157 Non-systemic contraceptives and STI barrier prophylactics and to appoint Veronica Viscovich (Argentina) as liaison officer.

(See resolutions, N 42).

It was further decided that Gerda and Louise Klintner should reach out to SWANA, Solid waste association of north America, Global Menstrual Collective and EU ECO label.

12. Requirements concerning a subsequent meeting, offers to host

The frequency of plenary meetings was discussed, the next meeting will be a shorter virtual meeting in the autumn and the next face-to -face meeting will take place in the spring of 2024.

The secretariat invited all TC members to consider if there is interest in hosting future meetings.

Linda Serwaa, UNFPA offered to investigate, if possible, for UNFPA to host a future meeting in Copenhagen.

13. Any other business

13.1 ISO/TC 338 dedicated committee website

The secretariat proposed to set up a dedicated website for TC 338. The website will include for example, information about meetings, what's going on in WGs/other groups, FAQs, activities, news, relevant articles, interviews with the Chair/convenors, members. The target audience is the TC members and interaction with organizations/persons interested in the area. Presentation and maintenance will be handled by the secretariat together with Gerda, input regarding content will be gathered from members.

13.1 Meeting feedback survey

A meeting feedback survey will be sent to all attendees automatically after the meeting. Please answer the survey and provide your feedback since this is a way for us to improve our work, it is anonymous.

14.Approval of resolutions

The meeting reviewed the resolutions, all resolutions were approved unanimously.

Meeting resolutions, N 42

15. Closure of the meeting

The Chair thanked all delegates for their commitment and for discussions held with a positive and enthusiastic approach.

ANNEX 14

INTERNATIONAL ACTIVITIES

(ITEM 9.1)

REPORT OF THE INDIAN DELEGATION ON OUTCOMES OF PLENARY MEETING

REPORT OF PLENARY MEETING OF ISO/TC 338 HELD ON 20-21 APRIL 2023

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

Hygiene-related practices of women during menstruation are of considerable importance, as it has a health impact in terms of increased vulnerability to reproductive tract infections (RTI). Menstrual Hygiene is vital for the empowerment and well-being of women and girls worldwide and gender equality.

ISO TC 338 on Menstrual product is newly established committee. There are 3 working groups (adhoc, working group, task group) in ISO TC/338 and in all the groups **BIS (India) has leadership role and nominated experts from India.**

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

The second plenary meeting of ISO/TC 338 'Menstrual Product' was held on 20-21 April 2023 in Stockholm, Sweden 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 plenary meeting to represent India's point of view-

1) **Shri J.K. Gupta, Sc-E & Head, Textiles (Head of Delegation) (Physical mode)**
2) Shri S. Sivakumar, (Head, Medical Textiles), SITRA, Coimbatore (Physical mode)
3) Shri Dharmbeer, Sc-D, Textiles, Member Secretary TXD 36 (Physical mode)
4) Dr. E. Santhini, SITRA, Coimbatore (Virtual Mode)
5) Ms. Shivani Swamy, Livinguard Technology Pvt. Ltd., Mumbai (Virtual Mode)
6) Smt. Tanya Mahajan, The Pad Project (NGO), India (Virtual Mode)

Presentations on the progress report of the task group for Strategic Business Plan, working group for general requirements and adhoc group for terminology were made by Shri Jitender Gupta, Head (Textiles), Shri S. Sivakumar, SITRA and Shri Dharmbeer, Sc- D, Textiles respectively.

Shri Jitender Gupta, Head Textiles during his presentation informed that ISO/TC 338/TG 1 was entrusted with the task of preparing the Strategic Business Plan for ISO/TC 338. This task group deals with the preparation of the strategic document covering the following major points:

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

The first meeting of task group was convened on 15 March, 2023.The task group discussed on the economic, technical, regulatory, legal, sustainability, and social aspects related to menstrual product along with market dynamics, benefits from the work of ISO/TC 338 and challenges etc. Based on the discussions, a working document was prepared incorporating the suggestions of the participants and the same was uploaded on ISO portal. The task group members were requested to scrutinize the working document on strategic business plan and provide their comments by 29 April, 2023.

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

The first meeting of WG 1 was convened on 16 March 2023 through virtual mode during which the members / experts got introduced to each other and started the deliberations on the scope of WG 1 and outline of the draft standard on menstrual products. It was further proposed to modify the title, scope of the working group and decide the way forward for standardization of menstrual products.

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

This includes menstrual products like single use/disposable menstrual pads, panty-liners, tampons, menstrual underwear, reusable menstrual pads, reusable tampons and sponges, menstrual cups, reusable menstrual underwear, maternity product and menstrual discs etc.

5 meetings of adhoc group were convened and the working draft on terminology on menstrual products was prepared.

1st Nov, 2022 (Virtual)
13th Dec, 2022 (Virtual)
14th Feb, 2022 (Virtual)
6th Mar, 2023 (Virtual)
10th Mar, 2023 (Virtual)

It was proposed that the working document on terminology prepared by adhoc group may be circulated to the member countries for comments. The comments on draft terminology shall be discussed in next meeting of Adhoc group meeting and the preliminary work item on terminology shall be proposed as new work item proposal.

BENEFITS ACCRUED TO BIS

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

a) The progress reports presented by India on the above 3 groups were accepted by the committee and leadership roles (Convenorship) of India have been continued in all the 3 WG1/TG1/AHG1.
b) The committee agreed for issuing committee internal balloting for preliminary work item on terminology prepared by adhoc group under the Convenorship of India.
c) The committee agreed to discuss and define the Scope and Title of Working Group 1 as proposed by India in the next meeting of WG 1.
d) The proposal of Argentina for the constitution of a new working group for 'Tampons' was not agreed upon due to objection by India.
e) The liaisoning with the following committee were agreed by the ISO/TC 338 Committee: -

i) ISO/TC 38 'Textiles'
ii) ISO/TC 133 'Clothing sizing system – size designation, size measurement methods and digital fittings'
iii) ISO/TC 194 'Biological and clinical evaluation of medical devices',
iv) ISO/TC 173/SC 3 'Aids for ostomy and incontinence',
v) ISO/TC 210 'Quality management and corresponding general aspects for products with a health purpose including medical devices
vi) ISO/TC 157 'Non-systemic contraceptives and STI barrier prophylactics'.

• Conclusion and recommendations

1) ISO/TC 338 agreed to launch a Committee Internal Ballot (CIB) for 4 months to call for comments on working document on terminology of menstrual product prepared by adhoc group.
2) The meeting of adhoc group (AHG1) shall be planned to resolve the comments received from member countries on Committee Internal Ballot (CIB) on terminology.
3) The terminology once finalized by adhoc group shall be proposed as new work item proposal.
4) The meeting of task group on strategic business plan shall be planned after 29th April, 2023 and the comments of member countries shall be discussed and resolved for preparation of revised working document on strategic business plan.
5) The meeting of working group on general requirement shall be planned during 4th week of May 2023 to discuss and modify the scope and Title of Working Group 1; and to decide the way forward.
6) India has published the following standards covering the general, performance and safety requirement which may be used as base/guidance document for WG 1 to start for preparation of working document on standardization of menstrual products: -

a) IS 5405 : 2019, Sanitary Napkins — Specification (Second Revision)
b) IS 17514 : 2021, Reusable Sanitary Pad / Sanitary Napkin / Period Panties — Specification

A BRIEF SUMMARY OF THE REPORT

Sl. No.	Purpose of foreign visit	Officer(s) deputed from the department along with	Countries visited with duration	Specific deliverables from the proposed visit	Expected outcome (as envisaged before the visit)	Final outcome (to be submitted after the visit)

		justification (for visit and nomination of deputed officer), PAN and Aadhar No.				
1	To participate in the plenary meeting of ISO/TC 338 held on 20-21 April 2023	Shri Jitender Gupta, Scientist E and Head, Textiles Shri Dharmbeer, Scientist D, Textiles Shri S. Sivakumar	Sweden, 20-21 April, 2023	To continue the leadership roles (Convenorship) of India in in all the 3 groups-WG1/TG1/AHG1. To propose preliminary work item on terminology as Committee Internal Ballot (CIB) The proposal to modify the title and scope of WG 1	To continue the leadership roles (Convenorship) of India in in all the 3 groups-WG1/TG1/AHG1. To propose preliminary work item on terminology as Committee Internal Ballot (CIB) To seek comments on working document on strategic business plan To discuss and define the Scope and Title of Working Group 1 Opportunity to interact with like-minded countries/International Experts and soliciting their support on important items of Indian interest.	The progress reports presented by India on the above 3 groups were accepted by the committee and leadership roles (Convenorship) of India have been continued in all the 3 WG1/TG1/AHG1. The committee agreed for issuing committee internal balloting for preliminary work item on terminology prepared by adhoc group under the Convenorship of India. The committee agreed to discuss and define the Scope and Title of Working Group 1 as proposed by India in the next meeting of WG 1. The proposal of Argentina for the constitution of a new working group for

						‘Tampons’ was not agreed upon due to objection by India. The liaisoning with ISO/TC 38, ISO/TC 133, ISO/TC 194, ISO/TC 173/SC 3, ISO/TC 210, and ISO/TC 157 were agreed by the ISO/TC 338 Committee.

ANNEX 15

INTERNATIONAL ACTIVITIES

(ITEM 9.1)

AGENDA OF THE PANEL MEETING FOR WORKING GROUP WG 1 'GENERAL REQUIREMENT' HELD ON 29-30 MAY 2023

ISO/TC 338/WG 1 **N 8**

ISO/TC 338/WG 1 "General requirements"
Convenorship: **BIS**
Convenor: **Sivakumar S Mr**

N007 - Agenda of the meeting

Document type	Related content	Document date	Expected action
Meeting / Agenda	Meeting: VIRTUAL 29 May 2023	2023-04-29	INFO by 2023-05-29

Description

Dear Expert / Member,

Please find attached herewith the agenda for the 2nd meeting of WG1. For your kind perusal.

Thanks & regards,

S. Sivakumar

2ND MEETING OF ISO/TC 338/ WG1 – GENERAL REQUIREMENTS

Dates: 29th and 30th May 2023
Time: 10.00- 12.30 CET/ 13.30- 16.00 IST on each day
Mode: Virtual meeting (Zoom meeting link shared)

Agenda of the meeting

1) Opening of the meeting (29th May 2023 10.00 CET)
2) Roll call of delegates
3) Code of conduct
4) Adoption of the agenda
5) Review of discussions held during ISO/TC 338 plenary meeting held on 20th and 21st April 2023
6) Discussion on scope of ISO/TC338/ WG1
7) Roadmap for WG1 – Options for categorising the standards
8) Review of working document / existing resources
9) Any other business
10) Summing up / resolutions for further progress
11) Closure of the meeting

*****

ISO/TC 338/WG 1 **N 10**

ISO/TC 338/WG 1 "General requirements"
Convenorship: **BIS**
Convenor: **Sivakumar S Mr**

Points to be discussed during the meeting

Document type	Related content	Document date	Expected action

Meeting / Working documents for discussion	Meeting: VIRTUAL 29 May 2023	2023-05-27	INFO by 2023-05-29

2nd MEETING OF ISO/TC 338 WORKING GROUP 1 – GENERAL REQUIREMENTS

Dates: 29th and 30th May 2023
Time: 10.00 - 12.30 CET/ 13.30 - 16.00 IST on each day
Mode: Virtual meeting (Zoom meeting link - https://sis.zoom.us/j/87095537797?pwd=a2oxcnE4ekxpK1R3TGd6VWhUZ01iUT09)

WORKING DRAFT

Agenda Point No. 6:

The title of WG1 is to be modified to make it relevant and inclusive. The proposed title is provided as follows:

Title WG 1- General, Performance and Safety requirements of menstrual product.

Scope of ISO/TC338/ WG1

Proposed scope of WG1 as presented during the plenary meeting is given below:

The standardization of internally and externally used menstrual products (single use and multiple use) for terminology, general, performance and safety requirements.

Agenda Point No. 7: Options for categorizing the standards for preliminary work items

Option I
Part 1- Safety Requirement of externally used menstrual products
Part 2- Safety Requirement of internally used menstrual products
Part 3 – General and Performance requirement of externally used menstrual products
Part 4 – General and Performance requirement of internally used menstrual products

Option II
Part 1- General, Performance and Safety Requirement (Disposable menstrual pad)
Part 2 – General, Performance and Safety Requirement (Multiuse menstrual pad)
Part 3- General, performance and Safety Requirement (Other menstrual products e.g menstrual cups, tampons....)

From the discussions of plenary meeting, the following points were noted:

1) There are products which are used both internally and externally
2) It will be better to have product-wise standards formulated.

- Working group has to decide whether to elect project leaders to work parallelly in all 4 subjects or not

- Title of the proposed preliminary work item is to be decided

- The working document on Disposable and Multiuse Menstrual Products are – IS 5405: 2019, IS 17514: 2021 which may be further discussed and modified keeping International Aspects/Scenario for preparation of preliminary work item.
- Proposed project leader for Disposable Menstrual Products – Dr. E. Santhini, SITRA – India.

- Project Leaders are to be decided - Project leader will prepare the preliminary work item on the subject

- Time line for preliminary work item is to be decided.

- The recommendations of the WG1 are to be approved by ISO/TC 338 either in plenary meeting or by way of Committee Internal Balloting (CIB).

Agenda Point No. 9 **Any other business**

*****

ISO/TC 338/WG 1 **N 9**

ISO/TC 338/WG 1 "General requirements"
Convenorship: **BIS**
Convenor: **Sivakumar S Mr**

Presentation made at the plenary meeting of TC 338

Document type	Related content	Document date	Expected action
Meeting / Practical information	Meeting: VIRTUAL 29 May 2023	2023-05-27	INFO by 2023-05-29

ISO/ TC 338 WORKING GROUP 1
General Requirements

Presented by,

S. SIVAKUMAR
Convenor of ISO/TC 338 WG1
Principal Scientific Officer Gr. 'A'
Head – CoE Medical Textiles & Textile Chemistry
SITRA, Coimbatore, India
e-mail: ssk@sitra.org.in Phone: +91 9842307924

WORKING GROUP 1

- Formation of the committee

- Ballot voting for appointment of convenor

- Purpose of this working group – drafting of standards on Menstrual products

- Title of the WG1 : General requirements

- 25 members attended

1st meeting of WG 1

- Introduction and roll call
- Started deliberations on the outline of the draft standard for Menstrual Products

- A few of the suggestions during the meeting are:

  - a separate section on Classification of Menstrual products
  - to keep the standard open to include innovative products in near future
  - Section 5 to cover General and safety requirements including material and product safety
  - Sterilization and cleanliness to be included in section 7

- to include Risk assessment based approach

- Members suggested to decide the scope of WG1

- Further, it was decided to deliberate on the scope and outline of the working document in subsequent meetings.

- Members were requested to share the information / standards available with them

- Next meeting of WG1 – last week of May 2023 (29th and 30th)

ROAD MAP – THE WAY FORWARD

- **Define the scope of WG 1**

Proposed scope:

The standardization of internally and externally used menstrual products (single use and multiple use) for terminology, general, performance and safety requirements.

- Products intended to covered

    - Externally used products

    - Internally used products

WG 1 may start working on the following:

Option I

Part 1 — Safety Requirement of externally used menstrual products

Part 2 — Safety Requirement of internally used menstrual products

Part 3 — General and Performance requirement of externally used menstrual products

Part 4 — General and Performance requirement of internally used menstrual products

Option II

Part 1 — General, Performance and Safety Requirement (Disposable menstrual pad)

Part 2 — General, Performance and Safety Requirement (Multiuse menstrual pad)

Part 3 — General, performance and Safety Requirement (Other menstrual products e.g menstrual cups, tampons….)

Terminology by AHG 1

- Need to be finalized
- To bring under WG 1
- New Work Item Proposal

Collection of Details on available standards

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

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

Existing Standards

Country	Standard	Authority
Ethiopia	ES: 6345- Sanitary Pads — Specification-Disposable (2018)	Ethiopian Standards Agency
	ES: 6346- Sanitary Pads — Specification-Reusable (2018)	
Kenya	DKS: 2881- Disposable Maternity Pads — Specification (2018)	Kenya Bureau of Standards
	KS 2925:2020- Kenya Standard-Textiles-Reusable Sanitary Towels —Specification First Edition (2020)	
Malawi	MS 890:2013 SANITARY TOWELS — SPECIFICATION (2013)	Malawi Bureau of Standards
	MS 1445:2018- Reusable sanitary towels —Specification (2018)	

Tanzania	TZS: 1659- Disposable Sanitary Towels — Specifications (2014)	Tanzania Bureau of Standards
	TBS: 6136- Reusable Sanitary Towels — Specifications (2nd Edition - 2019)	
Uganda	UBS: 1782- Disposable Sanitary Towels — Specifications (2017)	Uganda National Bureau of Standards
	US: 1782- Reusable sanitary towels — Specification (2017)	
South Africa	SANS: 1043 for disposable sanitary napkins (2010)	South Africa Bureau of Standards (SABS)
	SANS: 1812 for reusable sanitary napkins (2019)	
Zambia	HS Code: 4818.40 (import guidelines 2011) for sanitary napkins	Zambia Bureau of Standards
Zimbabwe	ZWS 1023: Reusable sanitary pads (2019)	Standards Association of Zimbabwe
	ZWS: 730- Manufacture of Sanitary Pads (2015)	
East African Community*	EAS 96-1: Sanitary towels Specification- Disposable (2008)	East African Standards Committee
	FDEAS:96- Sanitary towels- Specification- Reusable (2019)	
ARSO**	DARS 653:2017 for disposable sanitary napkins	African Organization for Standardization
	DARS 1575:2017 for reusable sanitary napkins	
Bangladesh	BDS 1261:2016 Sanitary Towels Mandatory	Bangladesh Standards and Testing Institute
Pakistan	PS: 1449-1979 for disposable sanitary napkins	Pakistan Standards and Quality Control Authority
China	GB/T 8939—2018, Sanitary absorbent pads (panty liner) GB/T 39391—2020, Sanitary absorbent pants GB/T XXXX—20XX , Disposable tampons （ in DIS stage, will be published）	Bureau of Standards, Metrology and Inspection
Japan	PFSB No. 0325-17: Standards for Approval of Sanitary Napkins (2015)	Japanese Industrial Standards
South Korea	MFDS Quasi-drugs Group 1 (A) (2009)	Korean Ministry of Food and Drug Safety

Vietnam	TCVN 10585:2014 Sanitary Pads for Women	Directorate for Standards, Metrology and Quality (TCVN)
Indonesia	SNI 16-6363-2000: Sanitary Pads (2000, was taken under revision in 2015)	National Standardization Agency of Indonesia (Badan Nasional Standardisasi - BSN)
UNGM	Technical Specifications for Disposable Sanitary pads, Reusable Menstrual Pads and Menstrual cups (2021)	UNICEF, UNFPA, UNHCR
European Union	C(2014) 7735: EU Ecolabel for disposable Sanitary Napkins (2014)	EU Ecolable
United States of America	Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) (2005)	US FDA
Australia	AS 2869:2008 Tampons - Menstrual	Standards Australia
	Therapeutic Goods (Standard for Menstrual Cups) Order 2018 (Therapeutic Goods Order 99)	

ANNEX 16

INTERNATIONAL ACTIVITIES

(ITEM 9.1)

AGENDA OF THE PANEL MEETING FOR STRATEGIC BUSINESS PLAN (TG 1) HEDL ON 01 JUNE 2023

N X

Agenda: ISO/TC 338 AHG 1 Terminology

1. Opening of the meeting
2. Roll call of delegates
3. Adoption of the agenda
4. Revise the working document/resolve remaining issues, questions
5. Any other business
6. Future meetings
7. Closure of the meeting

STRATEGIC BUSINESS PLAN 20XX – 20XX OF ISO/TC 338 MENSTRUAL PRODUCT '

EXECUTIVE SUMMARY

(To be made at the end of completion of document)

1.0 INTRODUCTION

1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritise among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 167 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the International Standard.

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its Technical Committees are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

2.0 BUSINESS ENVIRONMENT OF THE ISO/TC 338

2.1 Description of the Business Environment:

Qualitative factors

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of ISO/TC 338, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

Menstrual health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity, in relation to the menstrual cycle. As per a globally accepted definition of menstrual health, achieving menstrual health implies that women, girls, and all other people who experience a menstrual cycle, throughout their life-course, are able to, among other critical aspects, care for their bodies during menstruation such that their preferences, hygiene, comfort, privacy, and safety are supported. They should also be able to experience a positive and respectful environment in relation to the menstrual cycle, free from stigma and psychological distress and decide whether and how to participate in all spheres of life, including civil, cultural, economic, social, and political, during all phases of the menstrual cycle[1]. Standards for menstrual products can contribute to these by

- determining a globally relevant and acceptable definition of quality of menstrual products in terms of effectiveness (fitness for purpose) and safety
- reducing cost of manufacturing and distributing quality menstrual products, thus contributing to affordability
- contributing to a positive and constructive global narrative around menstruation and making it easier for consumers to access information about menstruation and menstrual products

[1] Hennegan J, Winkler IT, Bobel C, Keiser D, Hampton J, Larsson G, Chandra-Mouli V, Plesons M, Mahon T. Menstrual health: a definition for policy, practice, and research. Sex Reprod Health Matters. 2021 Dec;29(1):1911618. doi: 10.1080/26410397.2021.1911618. PMID: 33910492; PMCID: PMC8098749.

Menstrual products are used by half of the world's population and thus, access to safe products is a prerequisite to being able to participate in and contribute to society fully, which benefits the individual and society at large. Menstrual products exist to enable people who menstruate to carry on with their normal lives, as much as possible. Menstrual products are used on or inside the body by those who have access to and can afford them. The scope of ISO/TC 338 includes all manufactured menstrual products intended for collecting or absorbing menstrual blood or discharge during the menstrual cycle. This includes products for internal and external use as well as single- and multiple-use products. Examples of products include single and multiple use menstrual pads, tampons, panty liners, menstrual underwear, menstrual cups, menstrual discs, sponges etc.

Other products used on or inside the body like condoms, plasters and wound dressings, are highly regulated, tested and monitored[2]. However, there is a lack of global, harmonized standards that ensure the safety of the contents and physical properties of menstrual products for both people and the planet. This international standard is a step in the direction of broadening access to safe and effective menstrual products for all people who menstruate when and where they need them.

Diversity in markets for menstrual products

Mature markets in high-income countries (HICs) in regions like North America, Europe and Australia pose very different challenges than those of growth markets in low- and middle-income countries (LMICs) in regions like South Asia, Sub-Saharan Africa and Latin America.

Mature markets have reached saturation in terms of market penetration but offer growth opportunities on account of product innovation – both in existing product categories like disposable products (pads, tampons etc.) and new categories like reusable products (menstrual cups, reusable pads and menstrual underwear etc.). Growth markets offer an opportunity for increasing market penetration due to urbanization, reducing gender disparities and increasing awareness of menstrual health. This has, in turn, spurred 1) industry investment in product innovations to reach the wide spectrum of low-, medium- and high-income consumers, 2) promotional strategies for driving aspirational demand for products, and 3) distribution strategies for reaching remote territories. However, margin pressures in growth markets, which are detailed below, also pose challenges for industry stakeholders trying to enhance product access in these markets. Standards should ensure that while people who menstruate have improved access, the performance and safety of products is not compromised on account of increasing costs of materials, distribution, innovations etc., and reducing prices to reach lower wealth quintiles.

Historically, disposable products have formed a majority share of the menstrual product market. However, new innovations are slowly catching the attention of consumers. The market share of reusable products is still fairly small across both growth and mature markets[3] but preliminary evidence indicates that both external and internal reusable products have good acceptability amongst consumers in growth[4,5,6,7] and mature markets. As innovations in existing product categories and the advent of new

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[2] Klintner, L. (2021). Normalizing the Natural: A study of menstrual product destigmatization. [Doctoral Thesis (monograph), Lund University School of Economics and Management, LUSEM]. MediaTryck Lund.

[3] https://leap.rhsupplies.org/#/menstrual-hygiene

[4] Shah, Shobha & Nair, Rajesh & Shah, Pankaj & Modi, Dhiren & Desai, Shrey & Desai, Lata. (2013). Improving quality of life with new menstrual hygiene practices among adolescent tribal girls in rural Gujarat, India. Reproductive health matters. 21. 205-213. 10.1016/S0968-8080(13)41691-9.

[5] Garikipati, S., and Boudot, C. (2017) To Pad or Not to Pad: Towards Better Sanitary Care for Women in Indian Slums. J. Int. Dev., 29: 32– 51. doi: 10.1002/jid.3266.

[6] Hennegan, J., Dolan, C., Wu, M. et al. Schoolgirls' experience and appraisal of menstrual absorbents in rural Uganda: a cross-sectional evaluation of reusable sanitary pads. Reprod Health 13, 143 (2016). https://doi.org/10.1186/s12978-016-0260-7

[7] Wilson, E. & Reeve, J. & Pitt, A. & Sully, B. & Julious, S. (2012). INSPIRES: Investigating a reusable sanitary pad intervention in a rural educational setting - evaluating the acceptability and short-term effect of teaching Kenyan school girls to make reusable sanitary towels on absenteeism and other daily activities: a partial preference parallel group, cluster randomised control trial.

categories continue to grow and expand the choice available to consumers, standards should ensure that products are safe and meet common benchmarks for performance.

With growing awareness of the environmental impact of our everyday behavior, consumers continuously search for more sustainable alternatives including in the area of menstrual products. There are a large number of environmental concerns regarding especially disposable menstrual products, which hold around 97 % of the world market. To name a few, these include the chemicals used in the development process, in plastic applicators and polyester linings, including pesticides in cotton plantations (25 % of all pesticides in the USA are used on cotton), which have harmful long-term effects on the ecosystem.[8] For LMICs, the lack of appropriate waste management infrastructure combined with the increasing waste load due to disposable products poses additional challenges. For developed country settings also, the impact of disposable products on wastewater infrastructure is also starting to be noted.[9] Standards for menstrual products can provide clear pathways of incorporating environmental safety guidelines for various contexts to address these emerging issues. They can also ensure that sustainability parameters are defined so that innovation of more sustainable menstrual products – both disposable and reusable, can be encouraged. Additionally, recent research shows that menstrual product standards can enable innovation by providing entrepreneurs and product developers with a platform of safety requirements. This saves them time, effort and other resources in figuring out the safety measures needed to place a healthy product on the market.

Increasing consumer demand for environmentally products has also led to the emergence of products that claim to be environmentally friendly. Many oxo-degradable products have been noted to be promoted as biodegradable where clean definitions and standards for the same do not exist. Standards can also safeguard consumers against such products by defining terms and specifications related to environmental safety.

Standards for menstrual products can also help Governments achieve Sustainable Development Goals (SDGs). Unfortunately, menstruation is not mentioned, specifically, under any of the SDGs, nonetheless, the matter can be connected to several of them and standards on menstrual products can drive the sustainable development in these areas. The most significant SDGs include SDGs 1 (no poverty), 3 (health and well-being), 4 (quality education), 5 (gender equality), 6 (clean water and sanitation), 10 (reduced inequalities) and 12 (responsible consumption and production)[10]. Increasing all consumers' access to safe menstrual products and helps to improve menstrual health.

Quantitative factors

Some of the quantitative indicators that highlight the need to establish international standards for menstrual products are given below:

1. **Demographic considerations (consumer)**

Menstrual products are used by half of the world's population. Everyday 300 million people menstruate. Most people who menstruate do so between three to seven days each month for about 40 years, which amounts to around 2400 days in a lifetime, meaning a person is expected to use up to 12-15,000 single-use products in a lifetime. Aside from ensuring access to safe products and creating market

[8] Klintner, L. (2021). Normalizing the Natural: A study of menstrual product destigmatization. [Doctoral Thesis (monograph), Lund University School of Economics and Management, LUSEM]. MediaTryck Lund.

[9] https://www.rhsupplies.org/activities-resources/webinars/menstrual-waste-management-series-role-of-systemic-stakeholders-209/

[10] ISO. 2020. How ISO Standards Help Meet the SDGs. ISO: Standards. Available online: https://www.iso.org/sdgs.html.

pathways for different product categories, standards can enhance consumers' ability to make an informed choice, with the fundamental principle that all consumers should have this right. Additionally, standardizing menstrual products can have a destigmatizing effect, which increases gender equality[11].

2. Market size and distribution

The menstrual product market size was valued at USD 21.2 Billion in 2022 and is projected to reach USD 33.1 Billion by 2030, growing at a CAGR of 4.9 percent from 2023 to 2030[12].

The continuing importance of mature markets in this is demonstrated by the projected market growth. According to the Annual & Sustainability Report published by Essity AB, a leading hygiene products manufacturer, in 2020, the highest usage of menstrual products was witnessed in Western Europe, followed by North America and Eastern Europe 2020[13]. As per the same source, women in Western Europe aged 10 to 54 use more than 380 units of menstrual products per year. Europe is projected to account for 34 percent of market growth by 2023. The United States market for menstrual products reached a size of USD 26.5 Billion in 2022 with a projected 5 year CAGR of 4.93 percent.

The increasing importance of growth markets is also reflected in the market size and growth rates. In low-and-middle-income countries (LMICs), the largest manufacturers are experiencing double-digit growth annually, led by India and China.

Currently, there are an estimated 1.67 billion menstruators across low- and middle-income countries. 90 percent of people who menstruate in upper-middle-income countries use consumer menstrual products, compared to 62 percent in lower-middle-income countries and 39 percent in low-income countries. India and China are the two countries driving market growth in these regions overall due to the population size, manufacturing intensity and relative trade openness. Amongst lower-middle-income and upper-middle-income countries, India and China respectively account for 45-46 percent of the use of consumer menstrual products.[14] Among low-income countries, Ethiopia, the Democratic Republic of the Congo, Uganda, Sudan, and the Democratic People's Republic of Korea make for more than half the use.

The total Asia Pacific market stood at USD 11.96 billion in 2020[15]. In 2023 by comparison, the market size of menstrual products in China alone was approximately USD 11.37 billion with a 5-year projected CAGR of 6.16 percent[16] and in India, it was estimated at USD 6.2 billion with a 5-year projected CAGR of 4.76 percent[17].

3. Pressures on margins

With changing dynamics of the menstrual product market globally and efforts to increase access and affordability, there are increasing pressures on margins. Many of these pressures were exacerbated

[11] Klintner, L. (2021). Normalizing the Natural: A study of menstrual product destigmatization. [Doctoral Thesis (monograph), Lund University School of Economics and Management, LUSEM]. MediaTryck Lund.

[12] https://www.verifiedmarketresearch.com/product/feminine-hygiene-products-market/

[13] https://www.essity.com/sustainability/sustainability-reporting-governance-and-data/annual-and-sustainability-report/

[14] https://leap.rhsupplies.org/#/menstrual-hygiene

[15] https://www.fortunebusinessinsights.com/feminine-hygiene-products-market-103530

[16] https://www.statista.com/outlook/cmo/tissue-hygiene-paper/feminine-hygiene/china

[17] https://www.statista.com/outlook/cmo/tissue-hygiene-paper/feminine-hygiene/india

during the COVID19 crisis that impacted supply chains globally[18]. Standards are needed to ensure these pressures do not result in lower quality products.

Pricing pressures

A study conducted by Mann Global Health stated that in Kenya, disposable pads are available in the range of $0.32-0.76 per pack and in India, $0.38-$3.56 per pack, indicating the efforts on the part of manufacturers to reach across wealth quintiles[19]. Another study states that the annualized cost per menstruator on sanitary pads is $19.69 in lower-middle income countries compared to $27.19 in upper-middle income countries. 46 percent of all consumers are from lower-middle income countries while they contribute only 32 percent of overall global spend on menstrual products[20]. This data reflects manufacturer's efforts in the last two decades to increase market penetration in lower-middle income countries. Increasing competition and the high price sensitivity of the market puts pressure on margins for menstrual products.

Distribution costs

In many lower-middle income countries, distribution and logistics infrastructure for the last mile is highly fragmented. Many manufacturers in LMICs are using highly competitive distribution strategies to reach areas where menstrual products were not commercially available till now. For example, Visionaari, a manufacturer of tampons in India, reports that almost 50 percent of its purchases come from smaller cities via internet channels, indicating the role of innovative distribution strategies in reaching new markets[21]. Other distribution strategies include leveraging traditional FMCG and medical product supply chains, which also require marketers to take into account increasing distribution margins in a highly competitive category. These efforts also put additional cost pressures on manufacturers as they try to ensure that products are available at the last mile.

Import dependence

Most of the growth markets are either dependent on imports of final products or of raw materials. India, which is the largest growth market amongst LMICs, is the top importer of sanitary napkin raw materials in terms of number of import shipments, followed by Bangladesh and Vietnam[22]. China, the United States of America and Japan are the key exporters of materials. Many LMICs, including those that have manufacturing capacity like India and Vietnam, are also dependent on import of the finished products. Uganda, Sri Lanka, India, Namibia, Pakistan, Bangladesh, Kenya are some of the largest importers of sanitary napkins globally (in terms of number of shipments) and India, China and South Africa are the largest exporters[23]. This means that in many of these countries, higher export and import taxes put additional pressures on margins, especially in LMICs where consumers are more price sensitive. After COVID, global supply chains have also been challenged and the cost of logistics has exacerbated these pressures.

High degree of competition

In addition to the cost and pricing constraints that influence individual market players, the sheer number of players that have entered the market across different product types has increased the competition in the industry manifold. For example, India has at least 20 disposable sanitary napkin brands, 16 reusable sanitary napkin brands, 5 tampon brands and 24 menstrual cup brands. Similarly, Kenya, Nigeria and Tanzania have 25, 19 and 13 disposable sanitary napkin brands respectively also. In most LMICs, the majority market share belongs to the large multinational corporations. However, slowly there are a number of local brands - either locally manufactured or imported that have grown and captured some market share. In India and a few other countries, there has also been an impetus for small scale cottage industries to manufacture and distribute disposable and reusable sanitary pads. The increasing number

[18] https://medium.com/its-about-supplies/access-to-menstrual-health-supplies-during-covid-19-what-have-we-learnt-%C2%B9-ec8b55e5f390

[19] https://www.rhsupplies.org/uploads/tx_rhscpublications/Landscaping_Supply_Side_Factors_to_Menstrual_Health_Access.pdf

[20] https://leap.rhsupplies.org/#/menstrual-hygiene

[21] https://qz.com/india/1655862/flipkart-visionaari-fuel-indian-tampon-menstrual-cup-sales-boom

[22] https://www.volza.com/p/sanitary-napkin-raw-material/import/

[23] https://www.volza.com/p/sanitary-pads/buyers/

of small and medium sized players have led to increased access to affordable products. However, without lack of clarity on the regulatory requirements for menstrual products, it has also led to unregulated products with unsubstantiated claims coming into the market, especially in the case of LMICs. Standardardization can help ensure that while access is being increased, quality is also assured simultaneously.

4. Existing regulations[24],[25]

Many countries have standards for disposable sanitary pads but only a few countries in Africa and India have developed standards for reusable sanitary pads. Limited regulation is available on insertion products from the US FDA and Standards Australia - namely tampons and menstrual cups respectively. The United Nations General Marketplace now offers technical specifications for disposable and reusable sanitary pads, tampons and menstrual cups. Within the EU there is a voluntary label manufacturers can apply for, called the ECOlable. In Europe there is also an association of the nonwovens and related industries (EDANA) who has developed a code of practice for tampon manufacturers and a guide for supply chain information for absorbent hygiene care products. However, across the board, there is a high degree of variability in the specifications covered in standards in different countries and there is need for harmonization. The classification of products also varies widely. Menstrual products are mostly categorized as medical devices, therapeutic goods or consumer products in different countries and regions. For example, in most European countries they fall under the General Product Safety Directive which means there is no obligation for manufacturers to list the composition of the product or perform biocompatibility testing. Whereas in the USA menstrual products are considered a medical device, with additional testing requirements. There are also countries that classify menstrual products in other categories, for example the legislation in Thailand covering this area is the Ministry of Public Health's Cosmetic Act. In Australia there is specific legislation for tampons, where all tampons on the internal market need to comply with Therapeutic Goods (Standards for Tampons) (TGO 103). In Japan menstrual products are included in the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. A list of known standards (not comprehensive) is given below:

Country	Standard	Authority
Ethiopia	ES: 6345- Sanitary Pads- Specification- Disposable (2018)	Ethiopian Standards Agency
	ES: 6346- Sanitary Pads- Specification- Reusable (2018)	
Kenya	DKS: 2881- Disposable Maternity Pads- Specification (2018)	Kenya Bureau of Standards
	KS 2925:2020- Kenya Standard-Textiles-Reusable Sanitary Towels-Specification First Edition (2020)	
Malawi	MS 890:2013 SANITARY TOWELS – SPECIFICATION (2013)	Malawi Bureau of Standards
	MS 1445:2018- Reusable sanitary towels-Specification (2018)	
Tanzania	TZS: 1659- Disposable Sanitary Towels - Specifications (2014)	Tanzania Bureau of Standards

[24] Mahajan T, Joshi S. 2021. Development and compliance of standards for menstrual products in South Asia and Africa. Development Solutions Inc. and Reproductive Health Supplies Coalition

[25] Original proposal for TC 338

	TBS: 6136- Reusable Sanitary Towels – Specifications (2nd Edition - 2019)	
Uganda	UBS: 1782- Disposable Sanitary Towels - Specifications (2017)	Uganda National Bureau of Standards
	US: 1782- Reusable sanitary towels — Specification (2017)	
South Africa	SANS: 1043 for disposable sanitary napkins (2010)	South Africa Bureau of Standards (SABS)
	SANS: 1812 for reusable sanitary napkins (2019)	
Zambia	*HS Code: 4818.40 (import guidelines 2011)* for sanitary napkins	Zambia Bureau of Standards
Zimbabwe	ZWS: 730- Manufacture of Sanitary Pads (2015)	Standards Association of Zimbabwe
	ZWS 1023: Reusable sanitary pads (2019)	
Ghana	GS 1248:2019: Specification for single-use disposable sanitary towels (pads) for external use	
Nigeria	NIS 291 (2018) Disposable Sanitary Pads	
East African Community*	EAS 96-1: Sanitary towels Specification- Disposable (2008)	East African Standards Committee
	FDEAS:96- Sanitary towels- Specification- Reusable (2019)	
ARSO**	DARS 653:2017 for disposable sanitary napkins	African Organization for Standardization
	DARS 1575:2017 for reusable sanitary napkins	
Bangladesh	BDS 1261:2016 Sanitary Towels Mandatory	Bangladesh Standards and Testing Institute
India	IS 5405:2019 for disposable sanitary napkins (1980, revised in 2019)	Bureau of Indian Standards
	IS 17514:2021 for reusable sanitary napkins	
Pakistan	PS: 1449-1979 for disposable sanitary napkins	Pakistan Standards and Quality Control Authority
China	CNS 9324:2004 Feminine sanitary napkins	Bureau of Standards, Metrology and Inspection

Japan	PFSB No. 0325-17: Standards for Approval of Sanitary Napkins (2015)	Japanese Industrial Standards
South Korea	MFDS Quasi-drugs Group 1 (A) (2009)	Korean Ministry of Food and Drug Safety
Vietnam	TCVN 10585:2014 Sanitary Pads for Women	Directorate for Standards, Metrology and Quality (TCVN)
Indonesia	SNI 16-6363-2000: Sanitary Pads (2000, was taken under revision in 2015)	National Standardization Agency of Indonesia (Badan Nasional Standardisasi - BSN)
UNGM	Technical Specifications for Disposable Sanitary pads, Reusable Menstrual Pads and Menstrual cups (2021)	UNICEF, UNFPA, UNHCR
European Union	C(2014) 7735: EU Ecolabel for disposable Sanitary Napkins (2014)	EU Ecolable
United States of America	Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) (2005)	US FDA
Australia	AS 2869:2008 Tampons - Menstrual	Standards Australia
	Therapeutic Goods (Standard for Menstrual Cups) Order 2018 (Therapeutic Goods Order 99)	

*Burundi, Kenya, Rwanda, South Sudan, Tanzania, Uganda
**36 member countries of United Nations Economic Commission for Africa and the African Union

Given the complexity and variability in classification and specifications around the world, and in many instances lack of clear requirements, international standards can help bridge the gap where regulations are not clear or strong enough.

An international standard would be useful in addressing the issues identified above, as requirements of testing and transparency can reduce the information asymmetry between producers and consumers regarding product safety (pertaining to health as well as environmental safety), performance and fitness to purpose. These matters should be addressed on an international level, since, as previously mentioned, they apply to all consumers of these products, globally.

3.0 Benefits expected from the work of the ISO/TC 338

The principal benefit expected from the work of ISO/TC 338 is the standardization in the field of menstrual products and the future deliverables produced by the committee contribute to the improvement

of safety and performance of the menstrual product. The standard is expected to benefit all stakeholder categories including consumers, manufacturers, other supply chain stakeholders and Governments and the environment.

Anticipated benefits of the work of ISO/TC 338 committee include but are not limited to:

- Addressing the widespread gap in standardization of menstrual products for safety, fitness for purpose and quality control globally, which will drive demand.
- Creation of a common definition of fitness of purpose and safety of menstrual products for use by the consumer
- Increasing consumers' ability to make informed choices, with the fundamental principle that all consumers should have this right, and the associated consumer protections
- Destigmatizing menstruation and menstrual products, contributing to greater gender equality
- Harmonization of national and regional standards, reducing the duplication of standards work at national level and gaining learning opportunities across borders
- Facilitate trade and increase market access by reducing regulatory barriers and cost involved in conducting business across geographies
- Standardization of menstrual products will ensure that the minimum requirements are the same all over the world and facilitate fair practices in international trade of commodities.
- Stimulating innovation by providing market newcomers with a platform of safety requirements, cutting back on their time to market
- Diversifying the product offering on a historically homogeneous market as a result of increased innovation
- Support Governments in reaching Sustainable Development Goals including but not limited to those related to Gender, WASH, Health and Education

4.0 REPRESENTATIONS AND PARTICIPATION IN THE ISO/TC 338

4.1 Membership

ISO/TC 338 committee at present has 22 Participating members and 19 Observing members. The list of current members of the TC and their corresponding national standards bodies may be accessed at: https://www.iso.org/committee/8933440.html?view=participation

4.2 Analysis of the participation

The TC committee works towards increasing stakeholder engagement to reflect the complexity, size, requirements, needs and diversity.

ISO/TC 338 identifies, recognizes and appreciates the importance of broad representation of members from different regions of the world. The current composition of the committee contains representation from North America, South America, the Middle East, Australia, Africa, Europe and Asia. The

committee continuously works towards a well-balanced geographical spread by seeking participation from LMICs, small- and medium-sized enterprises (SMEs), stakeholders including manufacturers of different types of menstrual products, technical experts for different aspects of performance, safety (materials, bio-burden, environmental etc) and health, consumers and government to a greater degree.

4.3. Liaison relationship

- UNFPA - United Nations Population Fund
- EDANA 'European Disposables and Nonwovens Association – EDANA'

These ISO committees have been identified as possible collaboration partners, however not overlapping in scope: -

ISO/TC 6 Paper, board and pulps

ISO/TC 6/SC 2 Test methods and quality specifications for paper and board

The committee would continue liaising with other external organizations and ISO/TC committees in the future to come up with quality standards for menstrual products.

5 OBJECTIVES OF THE ISO/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1 Defined objectives of the ISO/TC 338

1. To create standards for menstrual products that meet the requirements of the industry, as well as consumers and other concerned stakeholders throughout the world.
2. To identify terminology and prepare definitions for standardization in the field of menstrual products.
3. To provide clear guidance to menstrual product manufacturers on the safety, performance of menstrual products and requirements on key manufacturing processes and facilities.
4. To provide clear guidance to the testing laboratories on the methods of evaluation of performance of different menstrual products and consumers on the safety requirement of menstrual products.
5. To continue working closely with other ISO/TCs to avoid repetition and conflict.

5.2 Identified strategies to achieve ISO/TC338's defined objectives

ISO/TC 338 intends to use a variety of strategies to achieve its objectives and create overall priorities for the TC. The strategies will include but will not be limited to the following:

a. Prioritizing the project by forming different groups such as task group, working group etc to discuss and deliberate various sections of the standards such as scope, terms and definition and technical details.
b. Wherever possible, parallel meetings would be planned with the task group and working group with the experts from different fraternities. This would assist ISO to come up with the standard within scheduled time.

c. Working groups with a small group of experts would also be planned to draft the working document which would be further discussed in the main meeting. This would ease the process of discussion and finalization in the main meeting.
d. Wherever required and available, data published in reputed research journals, magazines and output of in-house R&D from members and external experts etc. will be considered while drafting technical specifications.
e. Regulatory requirements of different countries would also be taken into account while drafting the working document of the standard.
f. Develop consensus on terminologies used among different stakeholders engaged in the standardization to ensure equitable representation of consumer interests.
g. Arrangement for physical plenary meetings would be planned at least once in an year with the option to attend virtually to allow for maximum participation
h. For work-items and projects, virtual meetings or hybrid meetings will be encouraged and the frequency of the meeting for task groups and work groups would be increased to ensure development of outputs in a timely manner.
i. Project teams will be developed for each work-item with a designated project leader for efficient and timely completion of outputs
j. Attempting to liaise with as many other appropriate TCs as is practical and necessary to carry out the work of the technical committee and liaising with other global organizations outside of TCs as is appropriate and practical.
k. Increasing LMIC participation by:
   - ✓ Exploring the possibility to co-locate plenary meetings whenever possible with other ISO TCs and members and the meeting would also be arranged in a LMICs
   - ✓ Capacity building initiatives from ISO and SIS as well as advocacy in the menstrual health community to encourage LMICs to participate in ISO/TC 338

6.0 Factors Affecting Completion and Implementation of the ISO/TCC Work Programme

The following factors have been identified which may affect, to a lesser or greater degree, the development of standards in accordance with the objectives and strategies of this business plan:

a. Many types of products are covered in the scope of ISO/TC 338. This implies challenges of applicability of test methods, raw materials, relevant expertise, etc. to the various product categories. Additionally, scientific data is not publicly available equally for all product categories. Specifications within product categories will also vary.

b. Variance in legal classification and related regulatory frameworks of menstrual products from consumer products to medical devices across countries can affect the approach towards creation and final implementation of the standard

c. Variation in legislation and infrastructure relating to disposal and waste management of menstrual products across country and regional contexts may affect the implementation of the standard

d. Increased cost of testing to comply with the standard may limit adoption among SMEs.

e. Stigmatization of menstruation affects the standardization, adoption and implementation at every level

f. Technical specifications established in different countries and regions can reflect social and cultural norms and pose barriers for harmonization under one unifying standard.

7.0 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC

7.1 Overall Structure of the TC

The current structure of ISO/TC 338 has adhoc group, task groups and working groups. The ISO Central secretariat oversees global standards development. The Technical Management Board (TMB) reports to the Central Secretariat and oversees TC operations. ISO/TC 338 develops ISO standards and is administered by Swedish Institute for Standards (SIS). The ISO/TC 338 oversees work groups that develop menstrual product standards. The working groups and task groups take on topics that are discussed and voted on by participating countries and national standard boards and mirror committees.

7.2 Current projects and publications

Ad Hoc, Task- and working groups of ISO/TC 338

Adhoc group 1: terminology

an ad hoc group works on the related terminologies and defining terms related to menstrual products

Task group 1: Strategic Business Plan

- a task group to draft the ISO/TC 338 Strategic business plan

Working Group 1: General requirements

- A working group developing standard for general safety, performance and health requirements of menstrual products.

7.3 Stakeholders

Priority stakeholders for the current work programme are identified as:

- National, regional and international consumer representation bodies
- Academic and Research bodies
- Representations from industry and commerce

Information on ISO online

The link below is to the TC's page on ISO's website:

https://www.iso.org/committee/8933440.html

Click on the tabs and links on this page to find the following information:

- About (Secretariat, Secretary, Chair, Date of creation, Scope, etc.)
- Contact details
- Structure (Subcommittees and working groups)
- Liaisons
- Meetings
- Tools

ANNEX 17

INTERNATIONAL ACTIVITIES

(ITEM 9.2)

COMMITTEE INTERNAL BALLOT (CIB) - ISO TC 338 N 38 MENSTRUAL PRODUCTS — TERMINOLOGY

Preliminary Work Item (PWI), Menstrual Products — Terminology

1 Scope

This document provides terms and definitions related to menstrual products.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp
— IEC Electropedia: available at https://www.electropedia.org/

3.1
absorption capacity
total amount of menstrual fluid absorbed without leakage or spot without application of pressure

3.2
absorption
process of a fluid being taken in from the surface or space around

3.3
absorbency rate
rate at which the menstrual fluid is absorbed by the menstrual product

3.4
absorbent core
absorbent material of menstrual product internal layer (s)

3.5
absorbent products

menstrual products that use absorption as the mechanism of management of menstrual fluid

Note 1 to entry: Absorbent products include single use and multiple use menstrual pads, pantyliners, menstrual underwear, tampons, maternity pads, and sponges.

3.6
antibacterial finish
treatment designed to prevent or mitigate the growth of bacteria, to reduce the number of bacteria or to kill bacteria

[SOURCE: ISO 20743: 2021,3.3]

3.7
antibacterial activity
activity of an antibacterial finish used to prevent or mitigate the growth of bacteria, to reduce the number of bacteria or to kill bacteria

[SOURCE: ISO 20743: 2021,3.4]

3.8
antifungal treatment
treatment to prevent or mitigate the growth of fungi or to reduce the number of fungi

3.9
back sheet
barrier layer
bottom layer
outer most layer of a menstrual product that prevents surrounding areas from being stained or wetted by fluids retained

Note 1 to entry: Bottom layers are applicable to any multiple layer product including pads or panty liners, maternity pads.

3.10
bioburden
population of viable microorganisms on or in a product and/or sterile barrier system

Note 1 to entry: Bioburden is the presence of microorganisms on a surface (or complete item), inside a device, or from a portion of liquid, prior to sterilization.

[SOURCE: ISO 11139:2018, 3.23]

3.11
biocompatibility
ability of a material to be in contact with a living system without producing an adverse effect

3.12
biodegradable material
material capable of undergoing biological aerobic or anaerobic degradation during a fixed period leading to a release of carbon dioxide and/or biogas and biomass depending on the environmental conditions of the process

[SOURCE: ISO/DIS 5157:2022, 3.1.1

3.13

biodegradation
degradation caused by biological activity especially by enzymatic action leading to a significant change in the chemical structure of a material

[SOURCE: ISO 16929: 2021, 3.2]

3.14
biological risk
combination of the probability of harm to health occurring as a result of adverse reactions associated with medical device or material interactions, and the severity of that harm

3.15
biological safety
freedom from unacceptable biological risk in the context of the intended use

3.16
collecting product
menstrual products that use collection as the mechanism of management of menstrual fluid

Note 1 to entry: Collecting products include menstrual cups and discs.

3.17
compost
soil conditioner obtained by biodegradation of a mixture consisting principally of vegetable residues, occasionally with other organic material and having a limited mineral content

[SOURCE: ISO 18606: 2013,3.1]

3.18
composting
aerobic process designed to produce compost

3.19
cover/top sheet
the cover/top sheet is the material which comes in contact with skin during use

3.20
cytotoxicity
the degree to which a test item causes damage (toxicity) to cells.

[SOURCE: ISO 10993-5: 2009]

3.21
externally used product
menstrual product used to collect or absorb menstrual fluid after leaving the body

Note 1 entry: Externally used products include but are not limited to single use and multiple use menstrual pads, pantyliners, maternity pads and menstrual underwear.

3.22
Good Hygiene Practices

GHPs
fundamental measures and conditions applied at any step within the manufacturing process of menstrual product to provide safe and suitable product

3.23
internally used product
menstrual product used to collect or absorb menstrual fluid before leaving the body
Note 1 to entry: Internally used products include but are not limited to single use tampons, reusable tampons and sponges, menstrual cups, and menstrual discs.

3.24
irritation
localized non-specific inflammatory response to single, repeated, or continuous application of a substance/material

Note 1 to entry: Skin irritation is a reversible reaction and is mainly characterized by symptoms like local erythema (3.6) (redness), swelling, itching, peeling, cracking and scaling of the skin.

[SOURCE: ISO 10993-23:2021, 3.7]

3.25
menstrual cycle
natural cycle controlled by female hormones that cause regular menstruation

Note 1 to entry: The menstrual cycle has four phases: menstruation, the follicular phase, ovulation, and the luteal phase.

3.26
menstruation
period
regular discharge of blood and mucosal tissue from the inner lining of the uterus through the vagina

Note 1 to entry: menstruation signals the beginning of a person's menstrual cycle. Normal menstruation lasts from two to seven days per menstrual cycle. Menstruation stops during pregnancy, early breastfeeding, and other times due to hormonal changes, extreme stress, or underlying medical issues.

3.26.1 light menstruation
Add text
3.26.2 medium menstruation
Add text
3.26.3 heavy menstruation
Add text

Members are requested to provide their comments on the terms 3.26.1, 3.26.2 and 3.26.3 and Note 1 to entry.

Note 1 to entry: menstruation signals the beginning of a person's menstrual cycle. Normal menstruation lasts from two to seven days per menstrual cycle. During menstruation, person who menstruates generally experiences light, medium and heavy menstruation. Menstruation stops during pregnancy, early breastfeeding, and other times due to hormonal changes, extreme stress, or underlying medical issues.

During defining heavy menstruation, care must be taken to distinguish between heavy menstruation and mennorrhagia, which can be a sign of a disorder or health issue.

3.27
menstruator
people who menstruate
people who experience menstruation

Note 1 to entry: This is an inclusive and gender-neutral term to refer to all people who can experience menstruation as a biological function. This inclusive term is used to denote that not all people who experience menstruation identify as women or girls (i.e., trans men, nonbinary or intersex individuals), and that not all women menstruate (i.e., post-menopausal women, or women who have undergone hysterectomy)

3.28
menstrual fluid
bodily fluid that is made up of blood, vaginal secretions, and cells of the endometrium which are released from the uterus to the vagina during menstruation

3.29
menstrual health
state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity, in relation to the menstrual cycle

3.30
menstrual product
manufactured product intended for collecting or absorbing menstrual fluid during the menstrual cycle

Note 1 to entry: Also known as sanitary or feminine hygiene products

3.31
microorganism
entity of microscopic size, encompassing bacteria, fungi, protozoa and viruses

[SOURCE: ISO 4833-1:2013]

3.32
multiple use product
reusable product
menstrual product intended to be used more than once

3.33
natural material
any product or physical matter that comes from plants, animals, or the ground

3.34
pH
co-logarithm of the hydrogen ion concentration in an aqueous extract

[SOURCE: ISO 3071:2020, 3.1]

3.35
retention
the action of keeping liquid inside rather than letting it escape

3.36
single use product
disposable product
menstrual product intended to be used once and then disposed of
Note 1 to entry: Single use products include but are not limited to menstrual pads, panty-liners, tampons, and menstrual underwear.

3.37
skin sensitisation
immunological response of the skin to a repeated exposure to a sensitising agent

Note 1 to entry: Following repeated exposure to the sensitising agent, the adverse health effect of allergic contact dermatitis (ACD) can be provoked due to immunologically mediated cutaneaous reaction to the sensitising agent.

3.38
sterilization
process that destroys or eliminates all forms of microbial life by physical or chemical methods

3.39
synthetic material
material made by any chemical modification and/or synthesis (option 1)

material made from polymers which has been chemically synthesised (option 2)

material that does not occur naturally (option 3)

(To be further discussed which option to include)

3.40
toxic
capable of causing an adverse biological response

[SOURCE: ISO 10993-1:2018, 3.22]

3.41
toxicological risk
probability of a specified degree of an adverse reaction occurring in response to a specified level of exposure

[SOURCE: ISO 10993-1:2018, 3.24]

3.42
toxicological risk assessment
act of determining the potential of a chemical to elicit an adverse effect based on a specified level of exposure

[SOURCE: ISO 10993-18:2020, 3.40]

3.43
Toxic Shock Syndrome (TSS)
rare, life-threatening complication of bacterial infections

Note 1 to entry: Known to be caused by Staphylococcus aureus or Streptococcus pyogenes. Risk factors include skin wounds, surgery, the use of tampons and other devices, such as contraceptive
sponges or diaphragms, left inside the body for an extended period of time. Symptoms include a sudden high fever, low blood pressure, vomiting or diarrhoea, a rash resembling a sunburn, particularly on palms or soles, confusion, muscle aches, redness of one's eyes, mouth, and throat, seizures, and headaches. TSS can affect all genders across varying stages of their lives.

3.44
vaginal flora
vaginal microbiota
VMB
community of commensal, symbiotic and pathogenic microorganisms that colonize the vagina.

(To be further discussed. Include Vulva microbiota? Vaginal microbiome should also be added as a synonym to microbiota and flora)

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ANNEX 18

(Item 10.1)

REVIEW OF PUBLISHED STANDARDS

IS 16111 : 2013, Elastic bandage

FORMAT FOR SENDING COMMENTS ON BIS DOCUMENTS

NAME OF THE COMMENTATOR/ORGANIZATION: **KOB Medical Textiles Pvt .Ltd. Coimbatore.**

Standard : IS 16111 : 2013

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Specific Proposal (Draft clause to be add/amended)	Remarks	Technical References on which (2), (3), (4) are based
(1)	(2)	(3)	(4)	(5)
Foreword	Foreword in existing version of standard	Foreword modified as per mentioned in draft standard	Forword in align with changes made in the proposed revision and in align with Indian MDR 2017	Amendments of IS 16111 standard and Indian MDR 2017.
1 : Scope	This standard covers the dimension and other requirement for Elastic bandages	Scope shall be as "Elastic bandages are Medical Devices categorized as Class A. This standard covers the dimensions and other requirement for elastic bandages"	Updation in align with CDSCO' medical device classification guideline.	MDR 2017 – medical device classification guideline
3.1 Elastic bandages	An elastic bandage is intended to provide support and immobilize dressings covering the wounds besides the function	Additionally the text "To be used in intact skin only" shall be added.	Updation in align with CDSCO' medical device	MDR 2017 – medical device classification guideline

	of compression and support for orthopedic purposes.		classification guideline.	
5 Dimensions and Tolerances	Amendment No. 3	Amendment No. 3 shall be incorporated	Incorporation of amendment No.3	As per amendment
6 Material	6.1 Elastic bandages shall be cellulosic / non -cellulosic yarn or combination of both yarn with following composition 6.1.1 hydrophilic / cellulosic fibre content, minimum 35 percent [See IS 189 (part 1)]. 6.2 Filament yarns made from partially oriented yarn (POY) of polyester, polyamide, polypropylene or equivalent material. 6.3 It consist of a core made of height stretch spandex, lycra, polyurethane ,rubber or similar material and covered/wrapped with synthetic filament yarn or grey/bleached/dyed cotton and /or viscose/rayon.	**Clause title shall be modified as 6 MATERIAL COMPOSITION :** **6.1 Elastic bandages** Shall be with cellulosic/non cellulosic yarn or combination of both yarn with following composition 6.1.1 Elastic bandages shall have minimum 35 % of hydrophilic / Cellulosic fiber content. [See IS 1889 (part 1)] **6.2 Raw material :** Cellulosic yarns; Non Cellulosic Filament yarn made from polyamide, polyester, polypropylene or equivalent materials; Core made of high stretch polyurethane or rubber or other similar material and covered/wrapped with synthetic filament yarn or grey/bleached/dyed cotton and/or viscose/rayon.	**a)** Elastic bandages shall have minimum 35 % hydrophilic content. Existing version of standard narrates the above requirement with ambiguity and misinterpreted as every yarn shall have minimum 35 % of hydrophilic content. b) for better clarity, bandage and raw material requirement shall be classified separately	Modification shall be done to avoid any potential ambiguity.

7.1 Weight	7.1.1 The weight of elastic bandage determined by weighing the whole bandage divided by the stretched surface area per width gives the weight per unit area.	7.1.1 The weight of elastic bandage determined by weighing the whole bandage divided by the stretched surface area per width gives the weight per unit area. **(text 'per width' shall be removed)**	Correct 'definition for measuring the weight per meter' is mentioned.	As per actual definition.
7.2 Stretched length and extensibility	The extensibility of elastic bandage shall be 65 to 220 percent.	The extensibility upper limit of specification increased from 220 to 270 percent	To include the elastic bandages manufactured through knitting technology which usually having more extensibility	Have the scope to include more elastic bandages from knitting technology.
9 TESTS **9.1**	Testing of elastic bandage shall be carried out at 65 +/- 5 relative humidity and temperature 25 +/- 2 C.	Testing of elastic bandage shall be carried out at 65 +/- 5 relative humidity and temperature 27°c +/- 2.	Testing condition shall be revised as mentioned in IS 4605 standard – to make uniform requirement between different bandage standards.	IS 4605 : 1981 standard for Crepe Bandage
10.2 Marking	10.2 Packing The packing shall be marked with the following information a) Name and trade- mark of the manufacturer b) Colour if any c) Width and stretched length d) Batch number	10.2 shall be mentioned as below "The packaging shall be marked as per Medical Device Rule 2017 guidelines"	Updation in align with CDSCO' medical device classification guideline	MDR 2017 – medical device classification guideline

A – 3 PROCEDURE :	A- 3.1 Method for measuring of stretched length and extensibility of elastic bandage	Shall be updated as per Amendment No. 2	Incorporation of amendment No. 2	As per amendment
B-3 PROCEDURES	B- 3.1 Method for measuring regain	Shall be updated as per Amendment No 2	Incorporation of amendment No.2	As per amendment

Technical Textiles for Meditech Applications Sectional Committee, TXD 36 :

DRAFT

INDIAN STANDARD : 16111 : 2013

ELASTIC BANDAGE

Newly added point
Modified point
As per amendment

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Technical Textiles for Meditech Applications Sectional Committee, TXD 36 :

This standard was originally published in 2013 and subsequently revised in 2022. The present revision has been

made in the light of experience gained since its first adoption and to incorporate the following major changes:

a) Amendment 1 Requirement of material and involved processes have been modified.
b) Amendment 1 Bandage dimension have been added
c) Amendment 2 Stretched length and extensibility % checking method have been further elaborated
d) Amendment 2 Regain parameter checking terminology have been redefined
e) Amendment 3 Bandage dimension and its tolerances have been redefined
f) Bandages different types removed and generally all types are covered.
g) Raw material parts clearly redefined
h) The text 'to be used in intact skin only' have been added
i) Testing condition have been redefined
j) Marking as per Medical Device Rule 2017 have been included

An elastic bandage is one continuous strip without joints, of woven/knitted material stretches along its intended to provide support and immobilize dressings covering the wounds besides the function of compression and support for orthopedic purposes.

For the purpose of deciding whether a particular requirement of this standard is compiled with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value of this standard.

1 SCOPE

Elastic bandages are Medical Devices categorized as Class A. This standard covers the dimensions and other requirement for elastic bandages.

2 REFERENCE

The following standard contains provisions, which through reference in this text, constitute provision of this standard. At the time of publication, the edition indicated was valid. This standard is 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 standard indicated below :

IS No.	Title
1889 (part 1) : 1976	Method for quantitative chemical analysis of binary mixtures of regenerated cellulose fibers and cotton: Part 1 Sodium Zincate method (first revision)

3 DEFINITION

For the purpose of this standard, the following definition shall apply.

3.1 Elastic Bandages – An elastic bandage is intended to provide support and immobilize dressings covering the wounds besides the function of compression and support for orthopedic purposes. To be used in intact skin only.

4 TYPES

Elastic bandages can be classified as follows based on type of yarn with their method of manufacturer.

A – Woven cellulosic yarn bandage
B - Knitted cellulosic yarn bandage
C – Woven non-cellulosic yarn bandage
D – Knitted non-cellulosic yarn bandage
E – Combination of both cellulosic yarn / non cellulosic yarns woven
F – Combination of both cellulosic yarn / non cellulosic yarns knitted

5 DIMENSIONS AND TOLERANCES

Description	Width (cm)	Tolerance for width (cm)	Stretched Length (m)	Tolerance for Stretched Length (cm)
Elastic Bandages	2-4	± 0.2	2.0 - 4.0	± 20
			Above 4.0 - 10.0	± 40
			Above 10.0 - 20.0	± 60
	Above 4 - 12	± 0.5	2.0 - 4.0	± 20
			Above 4.0 - 10.0	± 40

			Above 10.0 - 20.0	± 60
	Above 12 - 20	± 0.7	2.0 - 4.0	± 20
			Above 4.0 - 10.0	± 40
			Above 10.0 - 20.0	± 60

6 MATERIAL COMPOSITION :

6.1 Elastic bandages

Shall be with cellulosic/non cellulosic yarn or combination of both yarn with following composition

6.1.1 Elastic bandages shall have minimum 35 % of hydrophilic / Cellulosic fiber content. [See IS 1889 (part 1)]

6.2 Raw material :

Cellulosic yarns;

Non Cellulosic Filament yarn made from polyamide, polyester, polypropylene or equivalent materials;

Core made of high stretch polyurethane or rubber or other similar material and covered/wrapped with synthetic filament yarn or grey/bleached/dyed cotton and/or viscose/rayon.

7 REQUIREMENTS

7.1 Weight

The weight of the elastic bandage shall be 25 to 170 g/m2.

7.1.1 The weight of elastic bandage determined by weighing the whole bandage divided by the stretched surface area gives the weight per unit area

7.2 Stretched Length and Extensibility

The extensibility of elastic bandage shall be 65 to 270 percent.

Stretched length and extensibility shall be tested as per Annex A.

7.3 Regain

The regain of the elastic bandage shall be not less than 70 percent.

Regain parameter shall be tested as per Annex B.

8 MANUFACTURE, WORKMANSHIP AND FINISH

8.1 Elastic bandages shall be in woven/knitted bandages containing cellulosic or non-cellulosic yarns or a combination of both, with non-fraying closed selvedges/edges and in natural/white/coloured shade.

8.2 Finish

The use of optical brightening agents is prohibited. Under UV lamp no fluorescence shall be observed except for a few brightly illuminated individual fibres.

9 TESTS

9.1 Testing of elastic bandage shall be carried out at 65 +/- 5 relative humidity and temperature 27°c +/- 2.

9.2 Test for Width

The portion between and including the fast edges of the un-stretched bandage.

9.3 Test for Diameter

The distance as measure at the outer circumference while holding the bandage but not pressing the bandage.

10 PACKING AND MARKING

10.1 Packing

The bandage shall be rolled and packed suitably to prevent contamination from dust.

10.2 Marking

The packaging shall be marked as per Medical Device Rule 2017 guidelines.

11 CERTIFICATION MARKING

The elastic bandage may also be marked with the Standard Mark.

11.1 The use of the Standard Mark is governed by the provisions of *Bureau of Indian Standards Act*, 1986 and the Rules and Regulations made thereunder. The details of conditions, under which the license for the use of Standard Mark may be granted to manufacturers of produces, may be obtained from the Bureau of Indian Standards.

ANNEX A

(Clause 7.2)

METHOD FOR MEASUREING OF STRETCHED LENGTH AND EXTENSIBILITY OF ELASTIC BANDAGE

A-1 TEST SPECIMEN

For the purpose of this test, all rolls in the test sample constitute the test specimen.

A-2 APPARATUS

A-2.1 Stretch testing table of marked length 6 m with fixed clamp A at left end and moving clamp B at right end. The table has mechanical and pneumatic arrangement for the loading and un-loading the weights (see Fig. 1). The table is attached with a fixed measuring tape arrangement.

A-2.2 Standard weight up to 25 kg is denominations of 1 kg, 2 kg and 5 kg, whichever applicable.

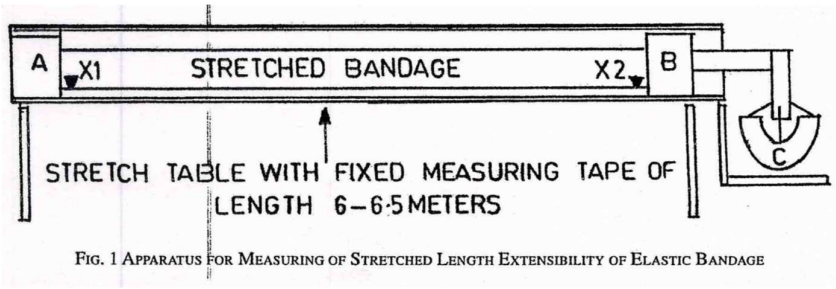

FIG. 1 APPARATUS FOR MEASURING OF STRETCHED LENGTH EXTENSIBILITY OF ELASTIC BANDAGE

A – 3 PROCEDURE :

A – 3.1 : Unwind the bandage on the stretch table and measure its unstretched length L 1 immediately.

Mark 5 cm on both ends and clamp A and clamp B on the bandage at both ends X 1 and X 2.

Connect the loading pan C weighing 1 Kg to the moving clamp B. (See Fig. 1)

Now apply load of 1 Kg for each cm of bandage width. Keep the load applied on the bandage kept in extended condition for 30 seconds. Measure the distance between two marks and record the stretched length L 2 in cm and release the load mechanically or by pneumatic arrangement.

To compensate the both ends clamped part (i.e 5 cm + 5 cm = 10 cm) we need to add correction factor (CF) to this stretched length L2 and derive the final stretched length L 3 = L2 + CF.

A – 3.1.1 : For bandage of stretched length above 5 m, measure the unstretched length L 1, mark the center point by dividing the unstretched length by two. Check the stretched length for the first part and second part separately by the same method.

A – 3.2 : Calculate the extensibility percent and correction factor (CF) as follows:

$$\text{Extensibility \%} = \frac{L3 - L1}{} \times 100$$

L 1

Notes :

1 : Correction factor in cm = 10 + (Standard extensibility % of particular product) / 10

Note 2 : Standard extensibility % of bandage (S) : This standard extensibility % is determined by measuring one time the stretched length for 100 cm unstretched length for 100 cm unstretched length. This is added for all subsequent tests for that product.

Find out extensibility % as follows

$$S = \frac{\text{Stretched length (for 100 cm unstretched length)} - \text{Unstretched length (100 cm)}}{\text{Unstretched length (100 cm)}} \times 100$$

ANNEX B

(Clause 7.3)

METHOD FOR MEASURING OF REGAIN

B-1 TEST SPECIMEN

For the purpose of this test all rolls in the test sample constitute the test specimen

B-2 APPARATUS

B-2.1 Stretch testing table of marked length of 6 m with fixed clamp A at left end and moving clamp B at right end. The table has mechanical and pneumatic arrangement for the loading and unloading the weights (*see* Figure 2). The table is attached with a fixed measuring tape arrangement.

B-2.1.1 Standard weight up to 25 kg in denominations of 1 kg, 2 kg and 5 kg, whichever applicable.

B-3 PROCEDURES

B-3.1 Measure the un-stretched length and mark 5 cm at the beginning and at the end of the bandage. In order to determine the regain, the **remaining** length must be determined. Make a second mark at the beginning of the bandage at a distance of 10 cm from the first mark. Measure the stretch length as per test procedure. Wait for 2 min and in this time the bandage must laying in zig-zag relaxed position (length of about 30 cm). To get the remaining length, measure the length of the marks at the beginning

and at the end of the bandage. Add the small part between the first and the second mark. This will give the remaining length.

B-3.2 Calculate the regain in percentage as :

$$\text{Extensibility regain, percent} = \frac{\text{Stretched length - remaining length}}{\text{Stretched length - un-stretched length}} \times 100$$

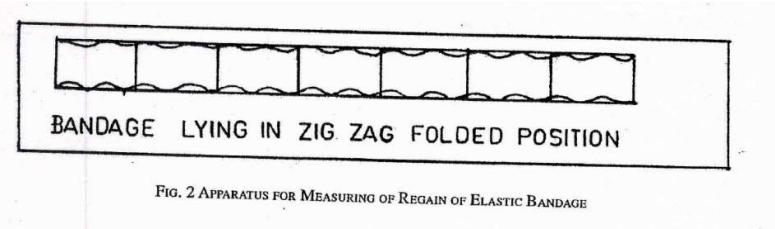

FIG. 2 APPARATUS FOR MEASURING OF REGAIN OF ELASTIC BANDAGE

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ANNEX 19

(Item 11.1)

NEW INITIATIVES IN STANDARDIZATION

DRAFT ROLLING ACTION PLAN 2023-24 FOR FORMULATION, REVISION AND REVIEW OF INDIAN STANDARDS FOR TXD 36

STANDARDS TO BE FORMULATED

Sl No.	Subject / IS	Total Timeline	Month and stage(s) to be completed during 2023-24			
			P-Draft	WC-Draft	F-Draft	Publication
New Standards						
1	Reprocessing of Multiple-use Healthcare Textiles/ Linen and Hospital Linen Products	07 Months	April 2023	May 2023	September 2023	October 2023
2	Non-woven gauze swab	07 Months	April 2023	May 2023	September 2023	October 2023
3	Sterilization wrap	9 Months	July 2023	Sept 2023	Jan 2024	March 2024
4	Dental floss	9 Months	July 2023	Sept 2023	Jan 2024	March 2024

TOTAL: 04

STANDARDS TO BE REVISED

Sl No.	Subject / IS	Total Timeline	Month and stage(s) to be completed during 2023-24			
			P-Draft	WC-Draft	F-Draft	Publication
Revisions						

1	IS 16111 : 2013 Elastic bandage	08 Months	July 2023	August 2023	January 2024	February 2024
2	IS 6237 : 1971 Specification for handloom cotton cloth for plaster of Paris bandages and cut bandages	08 Months	July 2023	August 2023	January 2024	February 2024
3	IS 757 : 1971, Specification for handloom cotton lint, absorbent, bleached, non-sterilized (first revision)	08 Months	July 2023	August 2023	January 2024	February 2024
4	IS/ISO 20743 : 2013, Textiles - Determination of antibacterial activity of textile products	04 Months	-	-	June 2023	July 2023
5	IS 10829 : 1993, X-Ray detectable gauze swabs and laparotomy sponges – Specification (first revision)	08 Months	July 2023	August 2023	January 2024	February 2024
6	IS 11046 : 1984, Specification for towel, operating	08 Months	July 2023	August 2023	January 2024	February 2024
7	IS 12839 : 1989, Wool/polyamide blended flannel, hospital, grey - Specification	08 Months	July 2023	August 2023	January 2024	February 2024
8	IS 14274 : 1995, Bandage, T - Shaped, calico - Specification	08 Months	July 2023	August 2023	January 2024	February 2024
9	IS 14306 : 1995, Bandage, triangular, calico – Specification	08 Months	July 2023	August 2023	January 2024	February 2024
10	IS 14316 : 1995, Swabs, small, in bag of 50 - Specification	08 Months	July 2023	August 2023	January 2024	February 2024
11	IS 1681 : 1998, Textiles – Hospital blankets, woollen, dyed – Specification (third revision)	08 Months	July 2023	August 2023	January 2024	February 2024

TOTAL: 11

2. and 3. IDENTIFICATION OF EMERGING AREAS FOR STANDARDS FORMULATION AND UPDATION AND IDENTIFICATION OF DOMAIN AREA EXPERTS

Following important events have been identified in the relevant fields:

Seminar/Webinar/Conference title	Date/month	Organizer/country	Area
International Conference on Medical Textiles for Healthcare	January 28-29, 2024	Bengaluru, India	Medical textiles and hygiene textiles
Non-Woven Tech Asia 2023	28-29-30 September, 2023	Pragati Maidan, Delhi,	Non-woven Medical textiles and hygiene textiles
Techtextil India 2023	12th Sep, 2023 to 14th Sep, 2023	Mumbai, India	Indutech, Medtech, Oekotech
Techtextil	23-26 April 2024	Frankfurt, Germaany	Indutech, Medtech, Oekotech

Startup ecosystem in the sectors

Startup Name	Area	Address
Fabiosys Innovations Pvt. Ltd	Medtech (Anti Viral/Anti bacterial Fabric)	contact@fabiosys.com New Delhi
Glora Sanitary Napkins	Medtech (Sanitary Pad)	Chelannur, kozhikode

IMPORTANT JOURNALS MAGAZINES AND RESEARCH PAPERS
Following journals, magazines etc. have been identified in relevant field for subscription:

Magazine/Books/ Other Documents	Field

Medical Textile by The Textiles Institute U.K	Medical Textiles
Nonwoven Report International (E. Copy) Global Nonwoven Markets Report 2020-2025	No woven Fabric and Product
Technical Textile international	Technical textiles
Asian Technical Textiles	Textile and Apparel, Technical Textiles
Indian Textile Research Journal	Fiber, yarn, fabric, technical textile
Indian Journal of Fibre & Textile Research (E-Copy)	Fiber, yarn, fabric, technical textile

Sr. No.	Sectional Committee No.	Sectional Committee Name	Name of Members & Organisation
1	TXD 36	Technical Textiles for Medtech Applications	Indian Technical Textiles Association, Mumbai Mr. Pankaj Kapoor(Team Leader), Park Nonwoven Pvt. Ltd.

Identification of eminent scientists/public figures

Sl no.	Scientist/Eminent personality	About /Field	Relevant committee
1	**Surg Vice Admiral Rajat Datta, AVSM, SM, VSM, PHS** Directorate General Armed Force Medical Services	Medical Textiles	TXD 36

4. EFFIECIENT WORKING OF TCs

Effective utilization of exchange forum for sharing technical information

- **Annual calendar based on the quarterly meeting of TC will be prepared in consultation with Chairpersons and members of TCs**
- **Training program shall be organized for Chairpersons and new committee members for their effective contribution in the work of committee.**
- **All the standards and amendment shall be made available in XML. All the old/superseded version of the standards along with their drawings shall also be made available in the portal.**
- **In the standardization module, provision shall be made for uploading ISO draft documents for circulation and comments by the National mirror committee members.**

Quarterly meeting

Technical Committee	**Q_1** (April - June)	**Q_2** (July - Sept)	**Q_3** (Oct - Dec)	**Q_4** (Jan - March)

TXD 36	09 June 23	Sept 23	Dec 23	March 24

Physical Meetings to be held other than Manak Bhawan

Technical Committee	**Q_1** (April - June)	**Q_2** (July - Sept)	**Q_3** (Oct - Dec)	**Q_4** (Jan - March)
TXD 36	—	—	—	SITRA, Coimbatore,

5. REVIEW OF STANDARDS

Due for 5 years:

Technical Committee	Due for 5 yearly Review (2023-24)	Overlapping with pre 2000 standards	Quaterly plan for review			
			Q_1	Q_2	Q_3	Q_4
TXD 36	7	2	2	2	2	1

Pre 2000 standards

Technical Committee	Status of Pre-2000 pending as on 1st April (2022-23)	Progress of work of pre 2000 (2022-23)			Work to be completed during 2023-24	Standards which are obsolete/ no need for revision/ merged	Quaterly plan for review			
		P-Draft	WC-Draft	Final/Print			Q_1	Q_2	Q_3	Q_4
TXD 36	14	8	1	5	8	0	2	2	2	2

due for review:

Export Promotion Councils identified for consultation: None

6. ALIGNING INDIAN STANDARDS TO INTERNATIONAL STANDARDS FOR BETTER INTEGRATION OF THE COUNTRY'S ECONOMY WITH THE GLOBAL SUPPLY CHAIN

1) Sterilization Wrap, BS EN 868-2:2017, Packaging For Terminally Sterilized Medical Devices. Sterilization Wrap. Requirements And Test Methods
2) ISO/CD 18184, Textiles — Determination of antiviral activity of textile products

7 Addressing the issue of sustainability

- Mapping of TXD 36 Standards with SDGs.
- Introduction of a compulsory address of applicable SDG has to be given in the foreword. This shall also include a list of other relevant Standards which will help in achieving that SDG in totality.
- Each Sectional Committee may have 2-3 members who have sound knowledge of sustainability and can completely focus on the sustainability of the Indian standards undertaken by the committee

List of companies to be approached for sharing their programme for Sustainability

a) Grasim Industries, Mumbai
b) Madura coats Private Ltd., Tamilnadu
c) Welspun India Pvt. Ltd., Mumbai
d) Reliance Industries, Mumbai
e) Any other organization working on sustainability

8 PROMOTING THE CULTURE OF RESEARCH

Project on revision of Indian Standards IS 5405 : 2019 Sanitary Napkin (Disposable) and IS 17514 : 2021 Reusable Cloth Pad

ANNEX 20

(Item 11.1)

BRIEF PRESENTATION ON THE PROCESS REFORMS PROPOSED FOR EFFECTIVE FUNCTIONING OF STANDARDIZATION ACTIVITY

PROCESS REFORMS IN STANDARDIZATION ACTIVITY OF BIS

WHY REFORM?

AREAS FOR IMPROVEMENT

- Identification of New Areas for Standardization
- Creating Support Structures
- Stakeholder Management
- Committee Management Strategy
- Enhancing International Footprint
- Digital Transformation
- Standards Promotion

IDENTIFICATION OF NEW AREAS FOR STANDARDIZATION

- Standards National Action Plan (SNAP) 2022-27
- Annual Programme for Standardization

For Central Ministries and Departments
State Governments
Industry Associations

- Creation of Standardization Cells

- Interaction with the Faculty of Prominent Technical Institutes

- Subscription of all important Scientific Journals and Magazines

CREATING SUPPORT STRUCTURES

STAKEHOLDER MANAGEMENT

- Annual Strategic Roadmap document, monitoring the progress and ensuring timely reviews.

- Identifying various stakeholder communities, sharing current and future strategic directions in standardization, encouraging participation, promoting synergy and harmonious development of standards between various bodies through interactions.

- Focused outreach activities with the leaderships of specific groups like industry, professional bodies, scientific and research groups, policy makers and regulators, innovators and startups, etc where relevant.

- Coordinating with Standardization Cells and their capacity building.

- Coordinating activities connected to collaboration with other national level SDOs under One nation One Standard Scheme.

COMMITTEE MANAGEMENT STRATEGY

- Standardization as a whole-organization activity, ending the compartmentalized approach.
- Focus on creation of a larger pool of experts.
- All Branch Offices to function as outposts of Standardization.
- Focus on Institutionalization of the participation of Civil Society Groups.
- Manak Manthan – a platform for the formal launch of new standards and deliberations on revisions, amendments and Wide Circulation Drafts.
- Half-Yearly Standards Conclaves by Branch Offices
- Ensuring adequate representation and expertise in Sectional Committees.
- Ensuring regular attendance in Sectional Committee meetings.

- Ensuring frequent meeting of Sectional Committees and timely communication with members through Standardization Portal.

- Keeping track of progress of the work of standards formulation through stage wise timelines and provision of monitoring progress through Standardisation Portal.

- Review of standards through Review Module in Standardization Portal following Action Research Based Approach.

- Mandatory submission of proposal for taking up formulation or revision of a standard through Standardization Portal with adequate justification

ENHANCING INTERNATIONAL FOOTPRINT

- Founder member of International Organization for Standardization (ISO).

- Member of Apex Governance Body i.e. ISO Council from 01 January 2022 to 31 December 2024 and ISO Council Standing Committee on Strategy & Policy.

- Member of Apex Governance Body for technical matters i.e. Technical Management Board of ISO from 01 January 2023 to 31 December 2025.

- Member of Standards Management Board of IEC since 2015, further elected from 01 January 2021 to 31 December 2023.

- . 32 MoUs and 09 BCAs

- Member of IEC Market Strategy Board from March 2022 to March 2024

- Secretariats for 03 Technical Committees and 08 Subcommittees of ISO.

- Leading SyC LVDC "Low Voltage Direct Current and Low Voltage Direct Current for Electricity Access" of IEC.

- Actively involved in standardization under regional and multilateral platforms such as South Asian Regional Standards Organization (SARSO), Pacific Area Standards Congress (PASC), BRICS, IBSA, etc.

- Chair of the Technical Management Board and of the Board for Conformity Assessment (BCA) of SARSO.

- Nominated convenors for 23 working groups of ISO and 12 working groups/system evaluation groups of IEC.

- Proposal sent for hosting ISO General Assembly meeting in 2025 and IEC General Assembly meeting in 2027.

- Next plenary of COPOLCO to be held at New Delhi in May 2023.

- Study tour of 19 BIS Scientific Officers to CEN-CENELEC, EFTA and AFNOR organized. Group of 4 Senior Officers also visited Standards Australia.

- Action plan for Indo-German working group finalized, and visit by German and Indian delegations to happen this year.

- Review of ISO/IEC Technical Committees for enhancing P Member status.

- Identification of indigenous standards to be proposed as new subjects at ISO/IEC level

DIGITAL TRANSFORMATION

- Structuring and framing the specifications of a revamped Standards Portal, future improvements in portal and in functioning of the portal on day to day basis.

- Generation of various reports for monitoring standards development activities.

- Review and undertake improvements in standardization processes including of project management and process KPIs.

- Restructuring of committees and review of committee compositions.

- Organize maintenance of all databases pertaining standardization.

- Monitor the standardization activities including that of publication of standards

STANDARDS PROMOTION

- 4200 new standards club formed since 1 April 2022.

- Residential training for mentors from each of these institutions.

- More than 1 lakh students enrolled.

- Student centric activities relating to standards and quality conducted with the help of mentors.
- Learning science via Standards taken up to popularize Indian Standards and improve the quality of science education
- 51 lesson plans under Learning science via Standards developed.
- A film on Orientation program for Standards Club
- Online Exchange Forum under development

- District Level Officers (DLO) sensitized on BIS activities and Indian Standards.

- Out of 766 districts , Sensitization programme in 491 districts organized.

- Focus on products under compulsory certification.

- To be followed up with Sensitization programmes for Sub-district level officials.

- Training programmes for State Government organizations and utilities.

- Webinar with State Consumer Affairs Secretaries and District Collectors.

- Quality Connect Programme organized on World Standards Day and BIS Foundation day involving 25,000 youth volunteers covering more than 5 lakh houses