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BUREAU OF INDIAN STANDARDS

AGENDA

Technical Textiles for Medtech Applications Sectional Committee, TXD 36 **23rd Meeting**

Date	Time	Venue
04 August 2023 (Friday)	1030 h	Video Conference through CISCO Webex

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

MEMBER SECRETARY: **Shri Dharmbeer, Scientist D, '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 22nd meeting of the TXD 36 committee held on 09 June 2023 through CISCO Webex Videoconferencing were circulated vide our reference TXD 36/A 2.22 email dated 21 June 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 9-12).**

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 22nd meeting is given in **Annex 2 (Pages 13-16).**

3.1.1 The Committee may **NOTE**.

Item 4 DRAFT AMENDMENTS FOR FINALIZATION

4.1 As decided by the committee in last meeting, the following draft amendments to Indian standards were issued in wide circulation for two months for eliciting comments from stake holders vide our letter reference no. TXD 36/22464 dated 15-05-2023: -

1) Amendment No. 3 to IS 5409 : 2019, Sanitary napkins — Specification (*second revision*) [Doc: TXD 36 (22464)]
2) Amendment No. 3 to IS 17514 : 2021, Reusable Sanitary Pad/Sanitary Napkin/ Period panties — Specification [Doc: TXD 36 (22465)]

The last date for comments was 15-07-2023.

The draft amendment as issued under wide circulation are given at **Annex 3 (Pages 17-18).**

The comments were received from Shri D. Veera Subramanium, SITRA and Shri Abhisek Saini, Lending Hand Foundation, New Delhi on IS 5405 and IS 17514 but the comments are not specific to draft amendment under finalization. The comments are given at **Annex 4 (Pages 19-23).**

4.1.1 The Committee may **DECIDE.**

Item 5 DRAFT AMENDMENT FOR WIDE CIRCULATION

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

In the last meeting, the committee decided that the informative annex on test liquid for dental bib is to be included and the inputs are to be suggested by SITRA.

The suggestion received from SITRA on suitable liquid for testing of dental bib is given at **Annex 5 (Page 24).**

5.1.1 The Committee may **DECIDE.**

Item 6 NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD

6.1 New Subject - IV Dressings (Film/Non-Woven), Synthetic Orthopaedic Cast Bandage, Synthetic Orthopaedic Cast Splint, Burn Sheet, Medical Wipes

In the last meeting of TXD 36, the committee requested the following member to share the additional inputs on scope, raw material/fabric, workmanship and finish, performance requirement, sampling, packing and marking on the above subjects :-

1) Dr. Manish Sabharwal, Dr. Sabharwal Wound Care, Baddi
2) Dr. Prabha Hegde, 3 M India, Bengaluru
3) Shri Khalil Khan, Surya Textech,
4) Shri T. Balaji, KOB Medical Textiles

However the information is yet to be received.

The technical inputs received during 22nd meeting of TXD 36 are given at **Annex 6 (Pages 25-27).**

6.1.1 The Committee may **DECIDE.**

6.2 In the last meeting of TXD 36, the committee further decided that the following committee members/stakeholders shall provide their technical inputs on the remaining subjects within 30 days :-

Sl No.	**Field**	**Subjects**	**Stakeholder Identified**
1	Medtech	Medical wipes	Dr. Manish Sabharwal, Dr. Sabharwal Wound Care Shri Prashant Jadhav, P & G
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
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. Sabharwal Wound Care 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 Aaditya Vats, Johnson and Johnson and Shri Mayank Rohtagi, Healthium Medtech Limited (on Surgical Sutures), Shri Dhaval Ghuge (on Sterilization Wrap), Ms. Shivani Swamy (on scrub suit) are given at **Annex 7 (Pages 28-55).**

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

6.2.1 The Committee may **DECIDE.**

Item 7 COMMENTS ON PUBLISHED STANDARDS

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

In, the last meeting of TXD 36, the committee decided that the recommendation of panel meetings dated 24 November 2022 and 18 May 2023 shall be incorporated in the revised draft of IS 17334. The minutes of panel meeting convened are given at **Annex 8 (Pages 56-63).**

The committee further decided that the following aspects/comments shall be discussed in next meeting of TXD 36 : -

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

7.1.1 The Committee may **DECIDE.**

7.2 IS 17351 : 2020, Medical textiles – Dressing, shell compressed – Specification

It is informed that Directorate of Standardization (DoS), Ministry of Defence has been recognized under the 'Scheme for Recognition of Standards Developing Organizations (SDOs)'. Under the scheme, the Bureau envisages the recognition of the other SDOs for attaining the vision of "One Nation One Standard. In this connection, DoS has submitted proposals (defence standards) on compressed dressing cell for considering as Indian Standards.

The defence standard on compressed dressing cell is given at **Annex 9 (Pages 64-72).**

7.2.1 The Committee may **DECIDE.**

Item 8 INTERNATIONAL ACTIVITIES

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

ISO/TC 338 secretariat issued a Committee Internal Ballot (CIB) for comments of member countries. The document was circulated to committee member/expert vide email dated 10 July

2023 for their comments and views. The last date of comments was 30 July 2023. The comments are yet to be received.

The document is given at **Annex 10 (Pages 73-86).**

8.1.1 The Committee may **DECIDE.**

8.2 ISO/NP 20384, Surgical clothing and drapes — Requirements and test methods

ISO/TC 94/SC 13, secretariat issued a new proposal for comments of member countries. The document is given at attached **Annex 11.**

The document was circulated to committee member/expert vide email dated 10 July 2023 for their comments and views. The last date of comments was 30 July 2023. The comments received from received Shri Harshal Patil, Venus Safety and Health Pvt Limited and Ms. Shivani Swamy, Livinguard are provided as follows :

Venus Safety and Health Pvt Limited

No.	Question	Possible options
1	Do you approve, disapprove or abstain on this NWIP?	Approve

Livinguard

Clause 3.1, addition, we should define the following terms - antibacterial, antibacterial finish, antibacterial activity, cross contamination, adsorption

Clause 5, addition, we should add an option for antibacterial activity as per IS 20743

8.2.1 The Committee may **DECIDE.**

8.3 The panel meeting of working group WG 1 'general requirement' and Strategic business plan (TG 1) under ISO/TC 338 were held on 29-30 May 2023 and 01 June 2023 through virtual mode.

The minutes of the panel meeting for Strategic business plan (TG 1) and the final documents of strategic business plan are given at **Annex 12 (Pages 87-103).**

The minutes of the panel meeting for working group WG 1 'general requirement' and the outline of the document are given at **Annex 13 (Pages 104-128).**

8.3.1 The Committee may **NOTE.**

Item 9 REVIEW OF PUBLISHED STANDARDS

9.1 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	Due Date
1	IS 5405 : 2019	Sanitary napkins – Specification (second revision)	March, 2024
2	IS 17243 : 2019	Medical textiles – Test methods for compresses for wound management and surgical procedures	March, 2024
3	IS 17334 : 2019	Medical textiles – Surgical gowns and surgical drapes – Specification	March, 2024

In the last meeting of TXD 36, 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 comments are yet to be received. Based on the information available, the review performas has been prepared which are given at **Annex 14 (Pages 129-168).**

9.1.1 The Committee may **DECIDE.**

Item 10 DATE AND PLACE OF NEXT MEETING

Item 11 ANY OTHER BUSINESS

ANNEX 1
(Item 2.1)

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

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

Meeting(s) held	**Date & Place**
20th Meeting	14 December 2022 (Through VC)
21st Meeting	27 March 2023 (Through VC)
22nd Meeting	09 June 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)	2/2
4.	Association of Indian Medical Device Industry (AiMeD), New Delhi	Dr. G.D. Agrawal (Shri Jitendra Sachchade)	1/3
5.	All Indian Institute of Medical Sciences New Delhi	Dr. Vijaydeep Siddharth (Dr. Anoop Daga)	1/3
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	2/3
8.	Defence Research & Development Establishment (DRDE), Gwalior	Dr. Vikas B. Thakre (Shri Suraj Bharati)	1/3
9.	DGAFMS, Ministry of Defence, New Delhi.	Surg Capt S.S. Dalawayi (Surg Lt Cdr Kotian V. Gopal)	2/3

SL NO.	ORGANIZATION REPRESENTED	NAME OF THE REPRESENTATIVE PRINCIPAL/(ALTERNATE)	ATTENDANCE
10.	DGQA (Ministry of Defence), New Delhi	Shri Senthil Kumar (Shri Arnab Das)	3/3
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	1/2
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)	0/3
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)	1/3
21.	Indian Technical Textile Association, Mumbai	Dr. Anup Rakshit (Shri Mahesh Kudav)	3/3
22.	Johnson & Johnson Ltd. Mumbai	Ms. Roocha Khedkar	2/3

SL NO.	ORGANIZATION REPRESENTED	NAME OF THE REPRESENTATIVE PRINCIPAL/(ALTERNATE)	ATTENDANCE
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	2/2
25.	Livinguard Technologies Pvt. Ltd. Mumbai	Ms. Shivani Swamy (Shri Virendra Madiyar)	3/3
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	1/3
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

SL NO.	ORGANIZATION REPRESENTED	NAME OF THE REPRESENTATIVE PRINCIPAL/(ALTERNATE)	ATTENDANCE
36.	Surya Textech, Chandigarh	Shri Khalil Khan (Shri Yogesh Yadav)	2/2
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	1/3
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 22nd 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** **Textiles — Determination of Antibacterial Activity of Textile Products [(First revision of IS/ISO 20743) (Doc : TXD 36 (22151)]** The committee decided that the above draft standard as given in agenda is FINALIZED for publication as Indian Standard.	Under Publication
5.1	**DRAFT STANDARD FOR FINALIZATION** Amendment 1 to IS 19022: 2023, Medical Textiles — Barrier Face Covering — Specification [Doc: TXD 36 (22649)] The committee decided that the matter is urgent and the wide circulation of the above amendment be waived off under Rule 22 (4) of BIS Rules 2018 notified vide GSR 584(E) dated 25 June 2018; and draft amendment 1 to IS 19022 : 2023 be held to have been FINALIZED for publication.	Amendment 1 to IS 19022: 2023 has been published.
5.2	**NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD** **IS 17354 : 2020, Medical Textiles — Dental Bib / Napkins — Specification** The committee decided that the informative annex on test liquid for dental bib is to be included and the inputs are to be suggested by SITRA.	Coming up for discussion under agenda **Item 5.1**

6.1	**PRELIMINARY DRAFT FOR APPROVAL FOR WIDE CIRCULATION** **Medical Textiles – Nonwoven Gauze (Sterile and Non-Sterile) - Specification** The committee decided that the preliminary draft shall be issued in wide circulation for 2 months for eliciting technical comments from stakeholders.	Wide circulation draft under preparation
7.1	**NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD** **New subject - IV Dressings (Film/Non-Woven), Synthetic Orthopaedic Cast Bandage, Synthetic Orthopaedic Cast Splint, Burn Sheet, Medical Wipes.** The committee requested the following member to share the additional inputs on scope, raw material/fabric, workmanship and finish, performance requirement, sampling, packing and marking on the above subjects: - 1) Dr. Manish Sabharwal, Dr. Sabharwal Wound Care, Baddi 2) Dr. Prabha Hegde, 3 M India, Bengaluru 3) Shri Khalil Khan, Surya Textech, 4) Shri T. Balaji, KOB Medical Textiles The committee also decided that the committee members/stakeholders shall provide their technical inputs on the remaining subjects within 30 days :	The technical inputs have been received on Sterilization wrap, scrub suits and sutures. Coming up for discussion under **agenda item 6.1 and 6.2.** The technical inputs on the other subjects are yet to be received.
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** The committee decided that the development of test method for determination of volatile organic compounds (VOCs) shall be taken up with Chemical	Coming up for discussion under agenda **item 4.1.**

	Methods of Test Sectional Committee, TXD 05 on top priority. Once the test method of VOCs is developed by TXD 05, then the chemical compound/substances, frequency and requirement of VOC test may be deliberated in TXD 36 for needful action in IS 5405 : 2019 and IS 17514 : 2021.	
8.2	**COMMENTS ON PUBLISHED STANDARDS** **IS 17334 : 2019, Medical Textiles — Surgical Gowns and Surgical Drapes — Specification** The committee decided that the following aspects/comments shall be discussed in next meeting of TXD 36 : - i) The remaining comments of SITRA on test procedure and reporting of (Hydrostatic resistance test, Particle release test and Biocompatibility test), requirement of dry and wet microbial penetration. **ii)** ii) Any other aspects.	Coming up for discussion under agenda **item 7.1.**
9.2	**INTERNATIONAL ACTIVITIES** Committee Internal Ballot (CIB) - ISO TC 338 N 38 Menstrual Products — Terminology The committee requested TXD 36 members/nominated experts to go through the document and share their suggestion/comments latest by 31 July 2023.	Coming up for discussion under agenda **item 8.1.**
10.1	**REVIEW OF PUBLISHED STANDARDS** The committee decided to reaffirm and revise the following Indian Standards: i) IS 16111 : 2013, Elastic bandage	Draft revision under preparation.

	ii) IS 6237 : 1971, Specification for handloom cotton cloth for plaster of Paris bandages and cut bandages iii) IS 757 : 1971, Specification for handloom cotton lint, absorbent, bleached, non - sterilized (first revision) The committee also decided that IS 5405 : 2019, IS 17243 : 2019 and IS 17334 : 2019 shall be reviewed by expert members for their comments and suggestion.	Coming up for discussion under agenda **item 9.1.**

ANNEX 3
(Item 4.*1*)

DRAFT AMENDMENTS FOR FINALIZATION

For Comments only **Doc: TXD 36 (22464)**

Draft **AMENDMENT NO. 3**

TO

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

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Last Date for Comments: 15 July 2023

(*Page* 3, *clause* **7.5**) **—** Insert the following new clause at the end:-

‘**7.6 Phthalate Test**

The amount of phthalate present in sanitary napkin shall be < 0.1 percent (individual or in combination) when tested as per the method given in IS 9873 (Part 6). The phthalate test shall be done at raw material stage once for existing raw material and whenever there is a change in the raw material for manufacturing the product. The manufacturer of final product shall also do the phthalate test once in a year.’

For Comments only **Doc: TXD 36 (22465)**

Draft **AMENDMENT NO. 3**

TO

IS 17514 : 2021 REUSABLE SANITARY PAD / SANITARY NAPKIN / PERIOD PANTIES — SPECIFICATION

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Last Date for Comments: 15 July 2023

(*Page* 3, *clause* **9.4**) **—** Insert the following new clause at the end: -

‘**9.5 Phthalate Test**

The amount of phthalate present in reusable sanitary pad/sanitary napkin/period panties shall be < 0.1 percent (individual or in combination) when tested as per the method given in IS 9873 (Part 6). The phthalate test shall be done at raw material stage once for existing raw material and whenever there is a change in the raw material for manufacturing the product. The manufacturer of final product shall also do the phthalate test once in a year.’

ANNEX 4
(Item 4.*1*)

DRAFT AMENDMENTS FOR FINALIZATION

COMMENTS RECEIVED ON IS 5405 :2019 AND IS 17514 : 2021

a) Shri Veera D Subramanian, SITRA, Coimbatore

NAME OF THE COMMENTATOR/ORGANIZATION:
The South India Textile Research Association, Coimbatore
DOCUMENT NO: TXD 36 (22464)

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)
IS 5405 Clause 7.1 pH Value	Testing portion taken for pH test	The existing statement "The pH of the absorbent material" needs to be amended as "The *p*H of the absorbent core material"	-	It helps to provide more clarity on the material taken for pH test from the product
IS 5405 Clause 7.1 pH value : Test method adopted to evaluate the pH test	Kindly remove the term "cold method"	IS 1390 may be given in the method.	Current version of the standard does not have different methods (cold and hot, as it was in earlier version) for testing pH.	IS 1390 standard
IS 5405 Clause 7.4 Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization	Cytotoxicity testing requirement Existing standard requirement for	It may be changed to non-cytotoxic.	Though the standard has got different methods for studying the cytotoxicity of a sample, the performance	IS/ISO 10993-5 Clause 8.5

	cytotoxicity is "None"		requirement as given in the standard is non-cytotoxic.	
IS 5405 Annex-B	Dimension of standard weight (1 Kg) may be given in the standard.	150 mm X 50 mm (Tolerance ± 0.1 mm)	Dimension of standard weight is required to obtain uniform test results	1) FDKS 2925:2021 Textiles – Reusable Sanitary Towels – Specification 2) US 1782:2017 Reusable sanitary towels - Specification

b) Shri Abhishek Saini, Lending Hands Foundation, New Delhi

Subject: Representation imploring implementation of guidelines, benchmarks or standards in regard to minimum incidence to toxic and harmful substances in female hygiene products, in public interest.

Respected Sir,

I, Abhishek Saini, am the authorized representative of Lending Hands Foundation, which its registered office at 3rd Floor 3391, Arya Pura, Subzi Mandi, Delhi-110007. Please find herein under our representation to your esteemed office:

1. Lending Hands Foundation is a not for profit organization. working towards various social causes plaguing our society, throughout the country.

2. Using a hygienic method of menstrual protection is important for women's health and personal hygiene. Recognizing the importance of menstrual products and menstrual hygiene, various schemes and programs have been initiated in our country to increase awareness and access of menstrual products.

3. Women using female hygiene products are extremely susceptible to toxic and harmful substances present in such products as the mucous membranes in the vagina and vulva absorb chemicals without metabolizing them.

4. However, there is an absence of mandatory guidelines, benchmarks or standards for

    (i.) Minimum incidence of toxic and harmful substances in female hygiene products;

    (ii.) Labeling requirements for manufacturers of female hygiene products to disclose ingredients used and substances present in the final product; and

    (iii.) Testing and certification of female hygiene products for safe-use.

5. In the absence of above-mentioned mandatory guidelines, benchmarks or standards, menstruaters in our country are unknowingly exposed to harmful substances, including plasticizers such as phthalates and Volatile Organic Compounds, such as Benzene. pesticides residue and dioxin. These substances are potential carcinogens, repro-toxic and mutagenic and cause harmful effects to human body.

6. Continued long-term exposure to such substances can have severe and disastrous health related consequences on an individual. This is also detrimental to the overall social and economic wellbeing of the country.

7. Due to known toxicity of the abovementioned chemicals and compounds, their presence is regulated by the government in many consumer products, children toys and teethers, and plastic packaging. Moreover, Draft Chemicals (Management & Safety) Rules, 20xx has also listed certain phthalates under Schedule —II list of priority substances.

8. This need for mandatory guidelines, benchmarks or standards for female hygiene products has been recognized internationally, including in many states in the USA, the European Union and Japan.

9. The Bureau of Indian Standards vide IS 5405:1980 laid down standards for Sanitary Napkins in 1969, which were subsequently revised in 1980, which however, were confined only to the physical attributes of the sanitary napkins, such as texture, without any

specifications regarding the toxicity of the ingredients. The 1980 standards failed to specify the permissible limits of chemicals used in the manufacturing process.

10. The BIS standard (IS 5405: 2019) was notified in 2019, which, apart from the requirements pertaining to physical attributes of the sanitary napkins, also added biocompatibility of the material, which is to be detected by evaluating the cytotoxicity, irritation and skin sensitization tests.

11. Furthermore, vide Amendment No. 1 dated January 2022 to IS 5405:2019 Sanitary Napkins-Specification (Second Revision), the requirement for Biocompatibility Evaluation- Cytotoxicity, Irritation and Skin sensitization was made optional.

12. The Amendment No. 2 dated October 2022 to IS 5405:2019 Sanitary Napkins-Specification (Second Revision) inserted the marking requirement on the consumer pack indicating information whether the material of the product is biocompatible, that is, whether it meets the requirement of the standard for biocompatibility evaluation-cytotoxicity, irritation and skin sensitization (if applicable).

13. However, meeting the said BIS standards and the use of the standard mark is voluntary for manufactures and has not been directed as mandatory for manufactures by the central government under section 16 of the Bureau of Indian Standards Act, 2016, As a result, none of the manufacturers of the most widely used Sanitary Pads are obligated to meet the said requirements.

14. Female Hygiene Products were also sought to be regulated as Medical Devices as per the Draft Medical Device Risk Classification released on 03.09.2020, however, the final list of the classification of the Medical Devices pertaining to Obstetrical and Gynecological, released on 03.06.2022 by CDSCO left out sanitary pads and tampons from the classification. Resultantly, the products are not regulated under the Medical Devices Rules, 2017. Pertinently, menstrual cups were retained and placed in Category-B, without specifying the parameters followed, for retaining menstrual cups, but omitting sanitary pads and tampons.

15. A recent study conducted by an NGO Taxies Link, which published its findings in a report titled "Wrapped in Secrecy- Toxic Chemicals in Menstrual Products" on 21.11.2022 demonstrated the presence of harmful substances in samples of the most popular and widely used Sanitary Napkins.

16. A Public Interest Litigation titled *Ayyaa Vs. Govt. of India & Ors. [WP (MD) No. 9162 of 2021]*- filed before the Madurai Bench of Madras High Court sought directions upon the

appropriate authorities, including Ministry Of Health & Family Welfare, to make BIS Certification mandatory for manufacturers of Female Hygiene Products as well as Baby diapers, and ensure mandatory disclosure all ingredients used for producing sanitary napkins on the packaging. On 01/06/2021, the Hon"ble High Court was pleased to issue notice to the respondents, and directed the authorities to submit Counter. However, as on date no steps have been taken by the respondents.

17. Given the widespread concerns regarding the possibility of emission of toxic chemicals from Female Hygiene Products, naturally certain queries have risen, regarding the existence of any benchmarks/ permissible limits to regulate the presence of toxic substances and chemicals in Female Hygiene Products. The concerns are particularly valid. in the face of the Amendment No. 1 dated January 2022 to IS 5405:2019, making the requirement for Biocompatibility Evaluation- Cytotoxicity, Irritation and Skin sensitization optional. It seems that the Government is lacking in addressing this issue with the importance that it deserves.

The issue at hand is grave, considering that vast proportion of the population is being exposed to life threatening toxins every month during the menstrual cycle. Also, in the absence of any statutory requirement to disclose ingredients, and clear standards applicable to such

products, the consumers are denied vital information necessary to make informed decisions about our health. In light of these grave concerns, it is pertinent that this important issue of Public Health is addressed timely.

I thank you for your time and assistance.

ANNEX 5
(Item 5.*1*)

DRAFT AMENDMENT FOR WIDE CIRCULATION

Comments from Shri S. Sivakumar, SITRA Coimbatore

COMMENTS 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 ISO 20701:2017.**

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.

[@] All reagents shall be of analytical grade
[#] Tolerances are ± 1% of the mass

Preparation of the artificial saliva

Dissolve the potassium and sodium salts in about 900 ml of demineralised water (atleast grade 3 in accordance with ISO 3696) in a 2 l beaker. 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 drop by drop 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 up to volume with demineralised water. Smaller volumes can be prepared as required. 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 is recommended to use water that has been heated to boiling for ten minutes. For each and every usage, check the pH of artificial saliva. Discard the solution if the pH is not within 6.8 ± 0.1.

** It may be deliberated during the meeting.

ANNEX 6
(Item 6.*1*)

NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD

New Subject - IV Dressings (Film/Non-Woven), Synthetic Orthopaedic Cast Bandage, 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 7
(Item 6.*2*)

NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD

Mayank Rohatgi, Healthium Medtech Limited Technical Inputs on Surgical Sutures

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	**Comments**	**Specific Proposal (Draft clause to be add/amended)**
(1)	**(2)**	**(3)**
ISO 13485	Quality management systems - Requirements for regulatory purposes	ISO 13485:2016 A11:2021 to be added. Per (EU requirement)
ISO 14971	Application of Risk Management	EN ISO 14971:2021: A11 To be added. Per (EU requirement)
EN 1041: 2008	*Information supplied by the manufacturer of medical devices*	ISO 15223-1 Following the above EU standard
ISO 16061	*Instrumentation for use in association with non-active surgical implants -- General requirements*	Not for suture as we don't sell instruments
ISO 14630	*Non-activesurgical implants--General requirements*	Not followed for suture as we need to follow ISO13485

ISO 10993-1. [Packaging-Materials	*Biocompatibility and toxicological attributes of the Packaging Materials and/or components (including printing inks) should be evaluated*	Biocompatibility tests are not performing for packaging material as they are not directly impacting suture products
Regulation (EC) No 1272/2008	Classification, labelling and packaging of substances and mixtures (CLP)	ISO15223:2021 IS being followed which is enough for suture and in compliance to EUMDR
ISO 5832-1	Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel	Not followed for suture (used for titanium metal implants)
ISO 10334	Implants for Surgery - Malleable Wires for Use as Sutures and Other Surgical Applications	Pacing wire need to implement the conductivity test
EN 62570	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	Not required for suture
EN 62366-1:2015 / A1	Application of Usability Engineering to Medical Devices	These are legacy devices already in the market. Can be used in case of a completely new type of suture coming for registration
Triclosan content	Additional test performing for antibacterial coated sutures	Supplier technical file should be enough
Section 4.2 Performance test	*Breaking strength of suture*	BSR (breaking strength retention test should be performed.
Beeswax	European Pharmacopeia, *Monograph for Beeswax*	Bees wax is a raw material and not a suture product and hence required for bonewax to be made known

TECHNICAL INPUTS SHRI DHAVAL GHUGE ON STERILIZATION WRAP

Sterilization wrap

Introduction:

The EN ISO 11607- series consists of two parts under the general title "Packaging for terminally sterilized medical devices". Part 1 of this series specifies general requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use. Part 2 of this series specifies validation requirements for forming, sealing and assembly processes.

Scope:

While materials specified in 4.2.2.1 to 4.2.2.3 of this part of EN 868 are intended for single use, the materials specified in 4.2.2.4 are intended for reuse.

4.2 Performance Requirements and test methods

4.2.1 General

4.2.1.1 No colour shall leach out of the wrap. Compliance shall be tested by visual examination of a hot aqueous extract prepared in accordance with the method given in ISO 6588-2.

4.2.1.2 The average mass of 1 m2 of the conditioned wrap when tested in accordance with EN ISO 536 shall be within ± 5 % of the nominal value stated by the manufacturer.

4.2.1.3 The pH of an aqueous extract of the wraps shall be not less than 5 or greater than 8 when tested in accordance with ISO 6588-2, hot extraction method.

4.2.1.4 The chloride content of the wrap, calculated as sodium chloride, shall not exceed 0,05 % when tested in accordance with ISO 9197 using a hot extract prepared in accordance with ISO 6588-2:2012, 7.2 except that 2 ml of potassium chloride solution is not added.

4.2.1.5 The sulphate content of the wrap, calculated as sodium sulphate, shall not exceed 0,25 % when tested in accordance with ISO 9198, using a hot extract prepared in accordance with ISO 6588-2:2012, 7.2 except that 2 ml of potassium chloride solution is not added.

4.2.1.6 When tested in accordance with ISO 2470-2 the material shall not exhibit an increase in D65 brightness, due to the optical brightener agents, of more than 1 %; calculated as the ratio of the D65 brightness measured with the 420 nm UV-cut-off filter in place to the D65 brightness measured without 420 nm UV-cut-off filter.

4.2.1.7 When exposed at 25 cm from a UV light source, the material shall not have per 0,01 m2 more than five fluorescent spots, each having an axis greater than 1 mm. NOTE The UV light to be used is the one described as per Annex C.

4.2.1.8 The manufacturer shall provide drapeability results and associated test method on request. NOTE For test method, see e.g. EN ISO 9073-9 and Annex B.

4.2.2 Specific requirements:

4.2.2.1 Wrap made of plain paper

4.2.2.1.1 The internal tearing resistance of the conditioned wrap shall be not less than 500 mN in both machine and cross direction when tested in accordance with EN ISO 1974.

4.2.2.1.2 The air permeance of the conditioned wrap shall be not less than 1,7 µm/Pa · s at an air pressure of 1,47 kPa when tested in accordance with ISO 5636-3.
4.2.2.1.3 The bursting strength of the conditioned wrap shall be not less than 110 kPa when tested in accordance with EN ISO 2758.
4.2.2.1.4 The wet bursting strength of the wrap shall be not less than 35 kPa when tested in accordance with ISO 3689 using an immersion time of 10 min.
4.2.2.1.5 The water repellency of the wrap shall be such that the penetration time is not less than 20 s when tested in accordance with Annex C.
4.2.2.1.6 When tested in accordance with Annex D, the average of the pore diameters of the ten test pieces shall be lower than or equal to 35 µm. No value shall be greater than 50 µm.
4.2.2.1.7 The tensile strength of the conditioned wrap shall be not less than 1,33 kN/m in machine direction and not less than 0,67 kN/m in cross direction when tested in accordance with EN ISO 1924-2.
4.2.2.1.8 The wet tensile strength of the wrap shall be not less than 0,33 kN/m in machine direction and not less than 0,27 kN/m in cross direction when tested in accordance with ISO 3781.
4.2.2.1.9 The surface absorbency of each side of the paper shall be not more than 20 g/m2 when tested in accordance with EN ISO 535 using a 60 s exposure time (Cobb test).

4.2.2.2 Wrap made of creped paper:

4.2.2.2.1 The wrap shall be creped to give increased flexibility.
4.2.2.2.2 The elongation at break of the conditioned wrap shall be not less than 10 % in the machine direction and not less than 2 % in the cross direction when tested by measurement of the elongation in conjunction with the test for tensile strength in accordance with EN ISO 1924-2.
4.2.2.2.3 The water repellency of the wrap shall be such that the penetration time is not less than 20 s when tested in accordance with Annex C.
4.2.2.2.4 When tested in accordance with Annex D, the average of the pore diameters of the ten test pieces shall be lower than or equal to 35 µm. No value shall be greater than 50 µm.
4.2.2.2.5 The tensile strength of the conditioned wrap shall be not less than 1,33 kN/m in machine direction and not less than 0,67 kN/m in cross direction when tested in accordance with EN ISO 1924-2.
4.2.2.2.6 The wet tensile strength of the wrap shall be not less than 0,33 kN/m in machine direction and not less than 0,27 kN/m in cross direction when tested in accordance with ISO 3781.

4.2.2.3 Wrap made of nonwoven material

NOTE For the purpose of this specification, a nonwoven for sterile barrier systems can be described as a bonded web made of textile and/or non-textile fibres.
4.2.2.3.1 The internal tearing resistance of the conditioned nonwoven wrap shall be not less than 750 mN in the machine direction and 1 000 mN in the cross direction when tested in accordance with EN ISO 1974.
4.2.2.3.2 The bursting strength of the conditioned nonwoven wrap shall be not less than 130 kPa when tested in accordance with EN ISO 2758.
4.2.2.3.3 The wet bursting strength of the nonwoven wrap shall be not less than 90 kPa when tested in accordance with ISO 3689 using an immersion time of 10 min.
4.2.2.3.4 The elongation at break of the conditioned nonwoven wrap shall be not less than 5 % in the machine direction and not less than 7 % in the cross direction when tested in accordance with EN ISO 1924-2.

4.2.2.3.5 The resistance to water penetration of the nonwoven wrap shall be determined using the hydrostatic head test based on EN 20811. Test results shall be documented.
4.2.2.3.6 The tensile strength of the conditioned nonwoven wrap shall be not less than 1,00 kN/m in machine direction and not less than 0,65 kN/m in cross direction when tested in accordance with EN ISO 1924-2
4.2.2.3.7 The wet tensile strength of the nonwoven wrap shall be not less than 0,75 kN/m in machine direction and not less than 0,50 kN/m in cross direction when tested in accordance with ISO 3781.

4.2.2.4 Wrap made of woven textile material:

4.2.2.4.1 When the woven textile material is to be used to manufacture packaging intended to be irradiation sterilized only, it is not necessary for it to be permeable to air, so 4.2.2.4.6 need not to apply.

4.2.2.4.2 Requirements for the processing of reusable fabrics as given in EN ISO 11607-1:2009, 5.1.11 and 5.1.12 apply and shall include the means to quantify and control the number of processing cycles.

4.2.2.4.3 The tensile strength, dry and wet, of the wrap shall be not less than 300 N in the warp and weft directions when tested in accordance with strip method of EN 29073-3.

4.2.2.4.4 The tear strength, dry and wet, of the wrap shall be not less than 6 N in the warp and weft directions when tested in accordance with EN ISO 13937-1. The samples for the “wet” test shall be prepared according to EN 29073-3.

4.2.2.4.5 The bursting strength “dry” and “wet” of the wraps shall not be less than 100 kPa when tested in accordance with EN ISO 13938-1. The preparation of samples for wet state testing shall be performed according to EN 29073-3.

4.2.2.4.6 The air permeability of the wrap shall be not more than 20 mm/s when tested in accordance with EN ISO 9237.

4.2.2.4.7 The resistance to water penetration of the woven textile material shall be determined using the hydrostatic head test based on EN 20811. Test conditions and test results shall be documented.

4.3 Marking

4.3.1 Transport packaging

The transport packaging shall be legibly and durably marked with the following information:

a) reference, stock or catalogue number;

b) quantity;

c) name/company and address of the manufacturer; address shall include: street/road, number/house/floor, postal code, city, state/region and country;

d) name and address of authorized representative within the European Community in the case where the manufacturer does not have a registered place of business in the community; address shall include: street/road, number/house/floor, postal code city, state/region and country;

e) date of manufacture in accordance with ISO 8601;

f) lot number1);

g) nominal sheet size or nominal width of rolls in millimetres and length in metres;

h) the recommended storage conditions;

i) whether sterilization wrap is intended for single use only.

NOTE 1 Regulatory requirements apply to marking and can change in the future, e.g. Unique Device Identification (UDI).

NOTE 2 Symbols for marking can be used see EN ISO 15223-1.

4.3.2 Inner package

The inner package with sheets or inner label with reels shall be legibly and durably marked with the information a), b), e), f) and g) according to 4.3.1.

5 Information to be supplied by the manufacturer

a) Recommendations for particular applications of sterilization wrap (e.g. sterile barrier system, transport packaging, packaging system);

b) The nature and extent of any identified risks associated with the use of the packaging material and/or system;

c) Any information pertinent to the packaged medical device as may be required (see EN 1041).
NOTE For requirements on information to be provided by the manufacturer national or regional legislation can apply, see in particular Directive 93/42/EEC, Annex I, Section 13 [10].

Annex A (informative) Details of significant technical changes between this European Standard and the previous edition

Changes between this European Standard and EN 868-2:2009 are the following:

a) changes in order to align this European Standard with the EN ISO 11607 series, in particular by:

1. adopting terms and definitions of EN ISO 11607 series without additional elements, i.e. deleting “sterile field” and “surgical drape” which are covered by the EN 13795 series;
2. elucidating the requirements given by EN ISO 11607-1 as general requirements for this standard;
3. formulating the significance and limits of the requirements of this standard with respect to the requirements given by EN ISO 11607-1;
4. linking the test methods with regard to information on statement of precision and bias, repeatability and reproducibility to EN ISO 11607-1:2009+A1:2014, Table B.1;

b) the test method on fluorescence is in accordance with ISO 2470-2. The test method according Annex B has been deleted;

c) updating of the following test methods by a statement of repeatability and reproducibility:

1. method for the determination of water repellency as per Annex C;
2. method for the determination of pore size as per Annex D;

d) providing of informative data for repeatability and reproducibility of the following test methods as per Annex E:

1. method for the determination of water repellency as per Annex C;
2. method for the determination of pore size as per Annex D;
3. chloride content;
4. sulphate content;
5. updating of the bibliography.

NOTE This list is not exhaustive.

Annex B (informative) Method for the determination of drape

B.1 Apparatus

B.1.1 Softness tester

Softness tester comprising a clamp formed by a pair of flat jaws or rollers, designed to grip the end of a 25 mm wide strip of paper along a horizontal axis at right angles to its length, and mounted on a spindle to enable the clamped end of the strip to be rotated about the spindle axis. The edges of the clamping surfaces shall be coincident and means provided for indicating when the clamp has rotated through 90° from any initial position.

B.1.2 Rule

Rule, graduated in millimetres.

B.2 Procedure

Condition the specimen at (23 ± 1) °C and (50 ± 2) % relative humidity for not less than 24 h. Cut 10 test pieces, each 25 mm in width and 200 mm in length, five with the length in the machine direction of the sample and five with the length in the cross direction.

Level the machine so that the axis of the clamping edges is horizontal and place the end of the test piece between them. Arrange the protruding length such that on rotating the spindle clockwise at a speed of 1 r/min (15 s for a 90° turn) with the strip to the left, the strip falls through the vertical to the right and on rotating the spindle counter clockwise, the strip does not fall back to the left when turned through 90° from that point.

Reduce the protruding length until a rotation of (90 ± 2)° clockwise and counter clockwise causes the end of the strip to fall from one side to the other.

Measure the effective protruding length (critical length) from the line where the edges of the jaws or rollers grip the test piece to the end of the strip.

B.3 Test report

The test report shall include the following information:

a) the mean critical length (in mm) for both machine and cross directions of the paper;

b) on request, the identification of the product under test, the identification of the test-house and the date;

c) the normative reference of the test method.

Annex C (normative) Method for the determination of water repellency

C.1 Apparatus

C.1.1 An ultraviolet light source and light meter with a range of wavelength of 315 nm to 390 nm.

C.1.2 Flat dish, approximately 200 mm x 150 mm x 15 mm.

C.1.3 Desiccator.

C.1.4 Stopwatch.

C.1.5 Powder dispenser, with a sieve of nominal aperture size between 0,125 mm and 0,150 mm at one end and closed at the other.

C.2 Reagent

Dry indicator powder prepared as described below.

Grind 20 g of sucrose in a mortar and pass through a sieve of nominal aperture size 0,063 mm to 0,075 mm. Dry the sieved sucrose in a desiccator over silica gel or in an oven at 105 °C to 110 °C. Mix 10 g of the dry sucrose with 10 mg of sodium fluorescein and pass the mixture 5 times through a sieve of nominal aperture size 0,063 mm to 0,075 mm and finally transfer the dry indicator powder to the powder dispenser.
The dry indicator powder in the powder dispenser should be stored either in a desiccator or in an oven at 105 °C to 110 °C.

C.3 Procedure

Take 10 test pieces of conditioned paper, each of size 60 mm x 60 mm. Separate the samples into two groups of five, one group with the 'wire-side' uppermost and the other with the 'top-side' uppermost. For each sample make two folds, each 10 mm high at right angles along two edges. Fill the flat dish with purified water at the conditioning temperature to a depth of 10 mm. Switch on the UV lamp and allow it to develop full output and adjust the distance of the lamp so that the irradiance at the level of the water in the dish is (300 ± 20) μW/cm2. Sprinkle the upper surface of a test piece thinly with indicator powder from the dispenser. Float the test piece on the water under the UV light source and note the time taken for a general fluorescence to appear. Repeat the procedure with the remaining nine test pieces.

The water repellency of the paper is considerably influenced by the temperature of the water which shall be maintained within the specified limits (23 ± 1) °C.

C.4 Repeatability and reproducibility

See Annex E for repeatability and reproducibility of the test method.

C.5 Test report
The test report shall include the following information:
a) the mean penetration time in seconds for each side of the paper;

b) on request, the identification of the product under test, the identification of the test-house and the date; c)
the normative reference of the test method.

Annex D (normative) Method for the determination of pore size

D.1 Principle
The pressure required to force air bubbles through the interstices of a material, wetted by a liquid and having a film of the same liquid applied to its upper surface, is observed. This pressure, together with the known surface tension of the liquid, is used to estimate the size of the interstices in the material.

D.2 Test liquid

The test liquid used should allow the paper to be wetted completely, have low solvent power for proofing materials, cause no swelling of the fibres, have constancy of surface tension, non-toxicity, low flammability, freedom from foaming, and moderate cost.
NOTE Ethanol R has been found to be suitable.

D.3 Apparatus

D.3.1

The apparatus is shown diagrammatically in Figure D.1. The principal parts are as follows:

a) the testing head “1”: a cylindrical vessel of an appropriate material (e.g. brass) over which the specimen “a” can be clamped by a clamping ring “b” and screw “c”. It is fitted with a synthetic rubber gasket “d” of 50 mm internal diameter to make a seal against the specimen;

b) pressure measuring device;

c) a stop-valve which serves to direct air to the testing head;

d) a variable flow valve set to give the required rate of rise of pressure in “1”;

e) a stop-valve which directs air to the pressure measuring device;

f) air reservoir of about 2,5 l capacity connected to “1”; this ensures that the rate of flow of air necessary to maintain the required rise of pressure is so large that the loss of air through the material when bubbling begins will not reduce the rate of rise of pressure;

g) the air supply.

D.3.2

Using the apparatus shown in Figure D.1 the test is conducted as follows:

Turn on the air supply. Open valve “3” to direct air to the test head via reservoir “6”, and adjust valve “4” to give the required rate of pressure rise. Leave stop-valve “5” open during testing. When the first bubble appears in the test material, “5” is closed to allow the pressure reached to be read from the measuring device “2”.

Figure D.1 Diagrammatic representation of the apparatus for the determination of the pore size

	Number of Laboratories	Number of test runs	Replication	Number of sample materials	Type of materilas
Pore size	7	9	10	4	Plain paper, creped paper
Water repellency	3	16	10	3	Fine creped paper, Plain

					paper, creped paper
Chloride content	3	7	2	4	Plain paper
Sulfate content	3	7	2	4	Plain paper

D.3.3
Apparatus for measurement of the equivalent pore size, having the following characteristics:

a) Means shall be provided for clamping the specimen of material in such a manner that:
1. it is horizontal;
2. a circular area of the material 50 mm in diameter will be subjected to steadily increasing air pressure on the lower face;
3. no leakage of the test liquid occurs during the test period;
4. the specimen does not slip in the clamps.

NOTE 1 The clamps need to be faced with resilient material which is resistant to the test liquid. With some forms of apparatus, it has been found that the correct conditions of clamping can be attained if the clamps are faced with a suitable grade of synthetic rubber.

b) The rate of increase in air pressure shall be 2 kPa/min to 2,5 kPa/min (200 mm head of water per minute to 250 mm head of water per minute).2)

c) A pressure measuring device connected to the test head shall be calibrated in kilopascals (or millimetres head of water).

d) The pressure measuring device shall have a suitable range

NOTE 2 A pressure measuring device which provides for pressure up to 6 kPa (600 mm head of water) is suitable for most materials. A pressure measuring device providing pressures of up to 10 kPa (1 m head of water) is used for measurements on close materials, e.g. ventiles, clean room overalls, theatre clothing and drapes.

D.7 Repeatability and reproducibility

See Annex E for repeatability and reproducibility of the test method.

D.8 Test report

The test report shall include the following information:

a) the equivalent pore diameter in micrometres for each specimen and the mean pore diameter in micrometres for the sample;
b) details of any deviation from the specified procedure;

c) on request, the identification of the product under test, the identification of the test-house and the date;

d) the normative reference of the test method.

Annex E (informative) Repeatability and reproducibility of test methods

The precision of the following test methods have been assessed by a Round Robin Test protocol in 2010 and 2011, conducting a precision experiment as described in ISO 5725-2: —

- pore size;
- water repellency;
- chloride content;
- sulfate content.

Standards	Protocol
ASTM 5034-95: Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	Machine Direction (MD) Grab Tensile
ASTM 5034-95: Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	Cross Machine Direction (CD) Grab Tensile
ASTM 5034-95: Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	MD Elongation @ Break
ASTM 5034-95: Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	CD Elongation @ Break
ASTM 5587-96: Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	MD Trap Tear
ASTM 5587-96: Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	CD Trap Tear
AATCC 127-2008: Water Resistance: Hydrostatic Pressure Test	Hydrostatic Head
ASTM D 737-96: Test Method for Air Permeability of Textile Fabrics	Air Permeability

Tensile breaking strength and elongation (ASTM D5034)
Tear Strength (ASTM D5587)
Hydrostatic Pressure (AATCC 127)
Burst Pressure (ASTM D3786)
Air Permeability (ASTM D737)

Standard Test Method for
Breaking Strength and Elongation of Textile Fabrics (Grab Test) D5034 − 21

TABLE 1 Breaking Strength Grab Test
Components of Variance, Coefficient of Variation, %

Fabric Type and Test Atmosphere	Type Machine	Grand Average Pounds	Single-Operator Component	Within-Laboratory Component	L
Filter Fabric					
72F, 65 % RH	CRE	61.4	4.1	3.8	0
72F, 50 % RH	CRE	63.4	3.9	1.1	0
72F, 65 % RH	CRT	64.6	2.1	0	0
Plain Weave Fabric					
72F, 65 % RH	CRE	112	3.7	1.4	0
72F, 50 % RH	CRE	116	4.0	2.8	0
72F, 65 % RH	CRT	118	4.0	2.3	0
Sateen Fabric					
72F, 65 % RH	CRE	240	3.1	1.3	2
72F, 50 % RH	CRE	241	4.6	5.6	0
72F, 65 % RH	CRT	247	2.4	0.7	1

TABLE 2 Breaking Strength Grab Test Critical Difference for Conditions Noted, % of Average

Fabric Type and Test Atmosphere	Type Machine	Number of Observations in Each Average	Single-Operator Precision	Within-Laboratory Precision	Between Laboratory Precision
Filter Fabric					
72F, 65 % RH	CRE	2	8.1	13.3	13.3
		5	5.1	11.7	11.7
		10	3.6	11.2	11.2
72F, 50 % RH	CRE	2	7.6	8.1	8.1
		5	4.8	5.6	5.6
		10	3.4	4.5	4.5
72F, 65 % RH	CRT	2	11.1	11.1	11.1
		5	7.0	7.0	7.0
		10	5.0	5.0	5.0
Plain Weave Fabric					
72F, 65 % RH	CRE	2	7.4	8.3	8.3
		5	4.7	6.0	6.0
		10	3.3	5.0	5.0
72F, 50 % RH	CRE	2	7.9	11.1	11.1
		5	4.5	9.3	9.3
		10	3.5	8.7	8.7
72F, 65 % RH	CRT	2	7.9	7.9	10.1
		5	5.0	5.0	8.1
		10	3.5	3.5	7.3

Sateen Fabric					
72F, 65 % RH	CRE	2	6.0	7.0	9.1
		5	3.8	5.2	7.8
		10	2.7	4.4	7.3
72F, 50 % RH	CRE	2	9.0	17.7	17.7
		5	5.7	16.3	16.3
		10	4.0	15.8	15.8
72F, 65 % RH	CRT	2	4.6	5.0	6.6
		5	2.9	3.5	5.5
		10	2.1	2.8	5.1

AATCC Test Method 127-2018
Water Resistance: Hydrostatic Pressure Test

Table I—Components of Variance for Two Fabrics (Option 1 Tester)

Component	Variance Fabric 1	Variance Fabric 2
Laboratory	13.450	7.323
Operator	3.127	2.145
Specimen	30.253	5.382

Table II—Fabric 1—Critical Differences—95% Confidence (Option 1 Tester)

Det in Avg (*N*)	Single Operator	Within Laboratory	Between Laboratory
1	15.25	16.02	18.97
2	10.78	11.84	15.61
3	8.80	10.08	14.31
4	7.62	9.06	13.62
5	6.82	8.04	13.19

Table III—Fabric 2—Critical Differences—95% Confidence (Option 1 Tester)

Det in Avg (*N*)	Single Operator	Within Laboratory	Between Laboratory
1	6.43	7.61	10.68
2	4.55	6.10	9.67
3	3.71	5.50	9.30
4	3.22	5.18	9.12
5	2.88	4.98	9.00

Table IV—Material A—Critical Differences—95% Confidence (Option 2 Tester)

Det in Avg (*N*)	Single Operator	Within Laboratory
1	72.49	72.49
2	51.26	51.26
3	41.85	41.85
4	36.25	36.25
5	32.42	32.42

Table V—Material B—Critical Differences—95% Confidence (Option 2 Tester)

Det in Avg (*N*)	Single Operator	Within Laboratory
1	10.08	12.85
2	7.13	9.09
3	5.82	7.42
4	5.04	6.43
5	4.51	5.75

Table VI—Material C—Critical Differences—95% Confidence (Option 2 Tester)

Det in Avg (*N*)	Single Operator	Within Laboratory
1	16.13	16.13
2	11.40	11.40
3	9.31	9.31
4	8.06	8.06
5	7.21	7.21

Table VII—Material D—Critical Differences—95% Confidence (Option 2 Tester)

Det in Avg (*N*)	Single Operator	Within Laboratory
1	2.88	3.50
2	2.04	2.47
3	1.66	2.02
4	1.44	1.75
5	1.29	1.57

Table VIII—Material E—Critical Differences—95% Confidence (Option 2 Tester)

Det in Avg (*N*)	**Single Operator**	**Within Laboratory**
1	15.04	16.55
2	10.63	11.70
3	8.68	9.55
4	7.52	8.27
5	6.72	7.40

Standard Test Method for
Air Permeability of Textile Fabrics D 737 – 04 (Reapproved 2008)

Materials	Number of Observations in Each Average	Single- Operator Precision	Within-Laboratory Precision	Between-Laboratory precision
Woven Fabrics Plain, Oxford spun yarns, Material 5	1	28.8	34.1	59.3
	2	20.3	27.4	55.7
	5	12.9	22.4	53.4
	10	9.1	20.5	52.6
Plain, spun yarns, Material 6	1	9.7	13.0	30.4
	2	6.9	11.0	29.6
	5	4.3	9.6	29.1
	10	3.1	9.1	29.0
Plain, continuous, filament yarns, Material 7	1	2.8	2.8	4.4
	2	2.0	2.0	3.8
	5	1.3	1.3	3.5
	10	0.9	0.9	3.4
Nonwoven Fabrics Hydroentangled	1	27.6	33.9	52.0
	2	19.5	27.7	48.2
	5	12.3	23.3	45.8
	10	8.7	21.6	45.0

Dry-laid	1	51.3	55.6	73.4
	2	36.3	42.1	63.8
	5	23.0	31.3	57.2
	10	16.2	26.8	54.9
Meltblown	1	8.8	9.3	21.5
	2	6.2	6.9	20.6
	5	4.0	4.9	20.0
	10	2.8	4.0	19.8
Needlepunch	1	100.7	112.4	113.4
	2	71.2	87.0	88.2
	5	45.0	67.3	68.8
	10	31.8	59.2	61.0
Resin-bonded	1	162.7	179.8	189.2
	2	115.1	138.1	150.1
	5	72.8	105.4	120.8
	10	51.5	92.0	109.3
Spun-bonded	1	234.6	234.6	251.2
	2	165.9	165.9	188.7
	5	104.9	104.9	138.1
	10	74.2	74.2	116.5
Thermal	1	206.2	232.3	232.2
	2	145.8	180.8	180.8
	5	92.2	141.2	141.2
	10	65.2	125.2	125.2
Wet-laid	1	1.34	2.80	3.24
	2	0.95	2.63	3.10
	5	0.60	2.52	3.01
	10	0.43	2.49	2.98

TABLE 3 Air Permeability, ft3/min/ft2

Component	Component	Component		
Woven Fabrics				
Plain, Oxford spun yarns Mat 5	217.0	10.4	6.6	17.5
Plain, spun yarns Mat 6	90.0	3.5	3.1	9.9
Plain, continuous filament yarns Mat 7	8.3	1.0	0.0	1.2
Nonwoven Fabrics Hydroentangled	220.0	9.9	7.1	14.2
Dry-laid	402.0	18.5	7.7	17.3
Meltblown	72.7	3.2	1.0	7.0
Needlepunch	278.	36.0	18.	5.3

	0		0	
Resin-bonded	948.0	58.7	27.5	21.3
Spun-bonded	474.0	84.6	0.0	32.4
Thermal	564.0	74.4	38.6	0.0
Wet-laid	17.2	0.5	0.9	0.6

[A] The square roots of the components of variance are being reported to express the variability in the appropriate units of measure rather than as the squares of those units of measure.

Standard Test Method for
Bursting Strength of Textile Fabrics—Diaphragm Bursting Strength Tester Method1
Burst Pressure (ASTM D3786)
TABLE 1 Components of Variance for Hydraulic Bursting
Strength Expressed as Standard Deviations, Percentage Points

	Single-Operator Component	Within-Laboratory Component	Between-Laboratory Component
Spun yarns in circular knit	6.8	1.1	2.5
Filament yarns in tricot knit	2.3	3.1	2.6

Critical Differences—For the components of variance reported in 14.2, two averages of observed values should be considered significantly different at the 95 % probability level if the difference equals or exceeds the critical differences listed in Table 2

TABLE 2 Critical Differences for Bursting-Pressure for the Conditions Noted, psi*A*

	Number of Observations in Each Average	Single-Operator Precision	Within-Laboratory Precision	Between-Laboratory Precision
Spun yarns in circular knit	5	8.4	9.0	11.3
	10	6.0	6.7	9.6
	20	4.2	5.2	8.7
	40	3.0	4.3	8.1
Filament yarns in tricot knit	5	2.9	9.1	11.6
	10	2.0	8.8	11.4
	20	1.4	8.7	11.3
	40	1.0	8.7	11.3

Standard Test Method for Tearing strength of Fabrics by Trapezoid Procedure
Tear Strength (ASTM D5587) 2019

Materials	Number of Observations in Each Average	Single- Operator Precision	Within-Laboratory Precision	Between-Laboratory Precision
S/1008H	1	7.27	7.27	7.27
	2	5.14	5.14	5.14
	5	3.25	3.25	3.25
	10	2.30	2.30	2.30
S/28305	1	27.5	27.5	43.9
	2	19.5	19.5	39.3
	5	12.3	12.3	35.2
	10	8.7	8.7	34.9
S/9408R	1	7.9	7.9	12.2
	2	5.6	5.6	10.9
	5	3.5	3.5	10.0
	10	2.5	2.5	9.7

Table 3 Trapezoid Tear Strength, lb

		Components of Variance expressed as Standard deviation		
Materials	Grand Average	Single- Operator Precision	Within-Laboratory Precision	Between-Laboratory Precision
Woven Fabrics				
S/1008H	14.3	2.6	0.0	0.0
S/28305	101.9	9.9	0.0	12.3
S/9408R	34.4	2.8	0.0	3.4

Sterilization wrap:

Standard #	Standard Name	Relevant ISO
AATCC 127	Water Resistance: Hydrostatic Pressure Test	ISO 811
D 737 – 04	Standard Test Method for Air Permeability of Textile Fabrics	ISO 9237:1995
D3786/D3786M − 18	Standard Test Method for Bursting Strength of Textile Fabrics—Diaphragm Bursting Strength Tester Method	ISO 13938-2:2019
D5034 − 21	Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	ISO 13934-1:2013
D5587-15	Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	Not Available

TECHNICAL INPUTS FROM MS. SHIVANI SWAMY ON SCRUB SUIT

Draft Indian Standard

Scrub suit/patients gowns — Specification

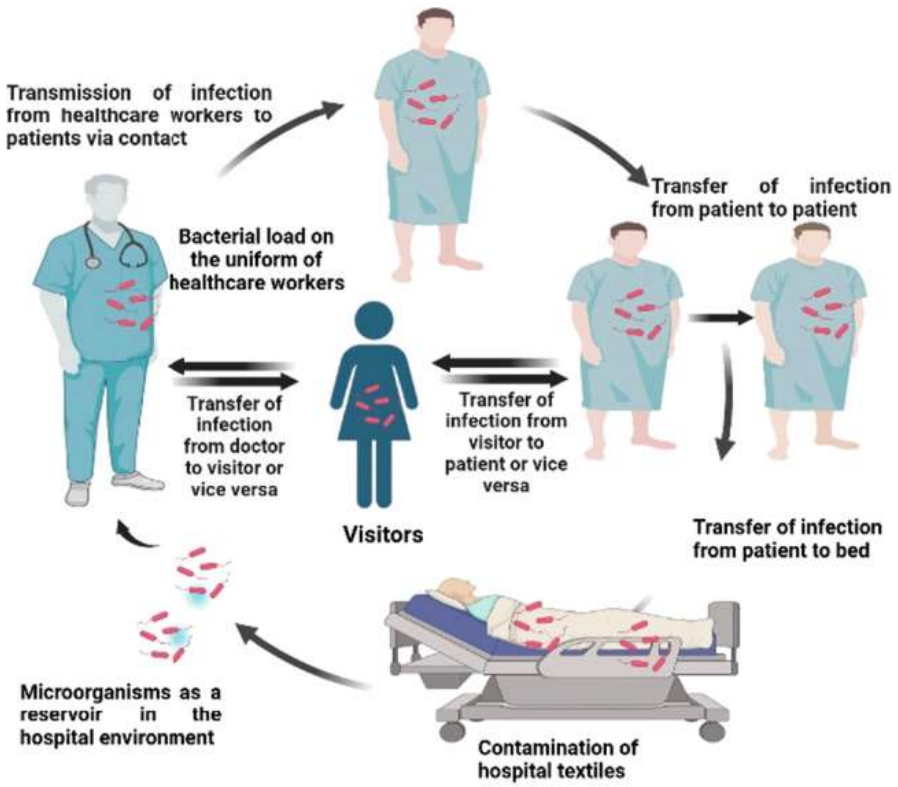
FOREWORD

A scrub suit is a type of clothing that medical professionals wear to protect their bodies from blood, other fluids and contamination in healthcare and clinical settings.
A patient gown is a type of clothing that medical patients wear in healthcare and clinical settings. For the purposes of this standard, both scrub suits and patient gowns will be considered as medical apparel/ the product/the garment/ the apparel. Both types of medical apparel act as a barrier layer between the wearer and contaminants found in healthcare/ clinical settings.

Hospital acquired infections (HAIs) are a major challenge in healthcare settings; textiles, especially healthcare providers' and patients' clothes, play a role in the spread of these infections by becoming carriers of bacteria, viruses and fungi.[1] The spread of these germs within a hospital

[1] https://www.expresshealthcare.in/interviews/hospital-acquired-infection-a-high-risk-for-patients-in-india/411904/

environment is further explained below.[2] [3] Ensuring that medical apparel is designed to limit the spread of HAIs and cross-contamination in healthcare settings is of vital importance.



1 SCOPE

This standard covers the requirements for scrub suits and patient clothing for external use in healthcare and clinical settings.

2 REFERENCES

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

3 MATERIALS

Scrub suits and patient gowns are clothing typically made from good quality cotton, polyester, polyester/cotton blended fabric, viscose, polyester/viscose blended fabric or any other suitable materials as agreed mutually between the buyer and seller. It is recommended that the fabrics used for scrubs and patient gowns are manufactured with coatings and/or finishes to enhance the user experience and ensure improved safety and hygiene of the wearer, and reduce the chances of cross contamination between and among patients and healthcare provides - eg. fluid/ water and blood repellant and environmentally friendly, metal-free antimicrobial finishes. The final fabrics must be breathable and provide odor-protection for their anticipated long durations of wear.

[2] https://europepmc.org/article/pmc/pmc10193315#CR64

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3499872/

4 MANUFACTURE, WORKMANSHIP AND FINISH

4. 1 *Manufacture*

Manufacturing of these products must be done by companies holding IS 9001 and IS 13485 licenses and must be done following GMP practices.

4. 2 *Workmanship and finish*

The material used in the fabrication of these kinds of medical apparel must be free from lumps and stains, safe for skin contact, and shall not leach harmful chemicals, metal salts and dyes or bleed colour. When visually examined, apparel shall be free from defects, tears or loose stitching. The materials shall be free from odour, smooth to the touch and when worn, shall not chafe or be uncomfortable for the user.

5 SIZES

Size and style of the apparel shall be as agreed to between the buyer and the seller. It is recommended that manufacturers offer a range of sizes from XS - XL to account for different user requirements.

6 WASHING, DRYING AND HANDLING INSTRUCTION

The manufacturer shall provide the washing, drying, handling and storage instruction on every packet to ensure proper use and care by the wearer and/or hospitals/ laundry. All medical apparel shall be able to withstand autoclaving.

7 GENERAL REQUIREMENTS

The raw material/fabric used for manufacturing the product shall meet the following requirements as specified in Table 1:

Table 1 Colour Fastness and Dimensional Stability Requirement of Raw Material/Fabric
(*Clause* 8.1)

Sl No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Colorfastness to rubbing		IS 766
	Dry	4 or better	
	Wet	4 or better	
ii)	Colorfastness to perspiration (acidic and alkaline)		
	Color Change	4 or better	IS/ISO 105 E04
	Staining	4 or better	
iii)	Colorfastness to washing		
	Color Change	4 or better	IS/ISO 105 C06
	Staining	4 or better	
iv)	Dimensional stability to washing, percentage Max		Annex C, IS 16394
	Warp and Weft Way	$\pm$ 3 %	

8 PERFORMANCE REQUIREMENTS

The scrub suits and patient gowns shall meet the requirements specified herein when supplied in packaged condition.

8.1 Hygiene Testing Requirement

Total viable count (total number of bacteria and fungi) shall not be more than 10 cfu/gm and *Staphylococcus aureus* shall be absent

8.1.1 *Bacterial and Fungal Bioburden*

Medical apparel must be tested for bacterial and fungal bioburden using the method described below. For selecting sample item portion (SIP), appropriate eluent and methods of extraction; ISO 11737 (Part 1) shall be referred.

8.1.1.1 *Test method*

A sample of 5 gm cut from the centre portion of the garment shall be checked for its absorbency in eluent such as 0.85 percent sodium chloride or equivalent medium till it reaches saturation limit. Add eluent either ten times the absorbent quantity of the garment or the quantity in which the garment completely immerse. The garment shall be shaken vigorously in the eluent and the liquid shall be extracted from it. Report the quantity of the eluent used for extraction, time and frequency of shaking in the test report. The extract shall be serially diluted and plated out on respective mediums, that is, plate count agar (PCA) for bacterial bioburden and sabouraud chloramphenicol agar (SCA) for fungal bioburden. Incubate PCA plates at 30 - 35^{0}C for 24 h and count colonies.

Continue incubation upto 72 h, re-examine the plates after 48 h and 72 h, and report the results that have not resulted in overgrowth. Similarly incubate SCA plates at 20 - 25^{0}C for 3 days and count the fungi. Re-examine after incubation for 5 and 7 days. Report the results from incubation time that does not result in over growth. The typical colony characteristics are shown in Fig.1.

(A) **(B)**

FIG 1 TYPICAL COLONY CHARACTERISTICS OF BACTERIAL BIOBURDEN (A) AND FUNGAL BIOBURDEN (B)

8.1.2 *Test for Common Skin Pathogen — Staphylococcus Aureus*

The apparel shall be tested for the presence of *Staphylococcus aureus* in accordance with the method given below. For the preparation of medium such as cooked salt medium, baird-parker medium and method for coagulase test; IS 5887 (Part 2) shall be referred.

8.1.2.1 *Test method*

A sample of 5 gm cut from the centre portion of the garment shall be completely immersed in appropriate volume of enrichment medium like cooked salt medium or equivalent medium. Incubate for enrichment purpose at 37^{0}C for 24 h. Report the quantity of the medium used for enrichment in the test report. The incubated sample shall be shaken vigorously in the medium and the liquid shall be extracted from the garment. The extract shall be streaked onto a *Staphylococcal* isolation medium, such as Baird-Parker medium or equivalent and incubated at 37°C for 24-48 h and examine for growth. The result is considered positive if black colonies with a narrow white margin, surrounded by a zone of clearance are seen. Suspect colonies must show coagulase activity to confirm presence of *Staphylococcus aureus*. The typical colony characteristic is shown in Fig. 2.

FIG. 2 TYPICAL COLONY CHARACTERISTICS OF *STAPHYLOCOCCUS AUREUS*

8.2 Biocompatibility Evaluation– Cytotoxicity, Irritation and Skin Sensitization

The manufacturer shall ensure that raw materials used for manufacturing the final products are safe for the user based on its known toxicological characteristics at intended use. The biocompatibility of the material shall be detected by evaluating cytotoxicity, irritation and skin sensitization test as per IS/ISO 10993 Part 5 and IS/ISO 10993 Part 10 respectively.

For cytotoxicity, the material shall show reactivity as "None" when tested as per IS/ISO 10995 Part 5. Similarly, the material shall be "Non-irritant and Non-sensitizing" when tested as per IS/ISO 10993 Part 10. For preparation of samples for these tests, ISO 10993 Part 12 shall be referred.

8.3 Antibacterial treatment & activity Value (Recommended)

If agreed between the buyer and seller, the raw material/fabric used for the apparel shall have an antibacterial treatment that is metal-free, proven non-toxic, non-leaching and an anti-bacterial activity value greater than or equal to 2 when tested by the absorption method prescribed in IS/ISO 20743.

8.4 Antifungal treatment & activity Value (Recommended)

If agreed between the buyer and seller, the raw material/fabric used for the apparel shall have an antifungal treatment that is metal-free, proven non-toxic, non-leaching and an antifungal activity value greater than or equal to 2 when tested by ISO 13629-2:2014.

8.4 Antiviral treatment & activity Value (Optional - relevant at time of viral outbreak)

If agreed between the buyer and seller, the raw material/fabric used for the apparel shall have an antiviral treatment that is metal-free, proven non-toxic, non-leaching and an antiviral activity value greater than or equal to 2 when tested by the absorption method prescribed in IS/ISO 18184

8.4 Hydrophobic coating (Recommended)

If agreed between the buyer and seller, the raw material/fabric used for the apparel shall have a PFAS-free hydrophobic coating when tested as per IS 390.

9 SAMPLING AND CRITERIA FOR CONFORMITY

9.1 Lot

All the products of the same material produced under similar conditions of manufacture shall constitute a lot.

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

9.1.2 The number of products to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, column 3 and column 5 of Table 2.

9.1.3 These products shall be selected at random from the lot. Guidance for the selection process shall be taken from IS 4905.

Table 2 Number of Scrub Suits/ Patient Gowns to be Selected
(*Clause* 11.1.2)

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

Note — for colourfastness and dimensional stability, hygiene testing, biocompatibility evaluation , antibacterial activity refer clauses 7 and 8.

9.2 Number of Tests and Criteria for Conformity

9.2.1 All products to be selected as per column 3 of Table 2 shall be examined for workmanship and finish.

9.2.1.1 Any products failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 4 of Table 2. Otherwise, the lot shall be rejected.

9.2.2 Out of the sample already found satisfactory according to **9.2.1.1**, a sub-sample as per column 5 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

9.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective products found in the sample (*see* **9.2.2**) is less than or equal to the acceptance number as given in column 6 of Table 2.

9.2.4 The manufacturer shall perform the colour fastness and dimensional stability once for existing products and whenever there is a change in the raw material for manufacturing the product.

9.2.5 The manufacturer shall perform the hygiene testing for the final product every quarter for monitoring purposes and whenever there is a change in the raw material used, manufacturing premises, and the supplier of the raw material.

9.2.6 The biocompatibility evaluation shall be carried out once every 5 years for existing raw material and whenever there is a change in the raw material used for manufacturing of the product.

9.2.7 The anti-bacterial activity testing shall be carried out once every 2 years for existing products and whenever there is a change in the raw material used for manufacturing the product.

10 MARKING

10.1 Each package shall be legibly and indelibly marked with the manufacturer's name or trademark, number of products contained in it, and size designation in addition to the following:

a) Use and care instructions;
b) Storage instructions
c) Batch/Lot no. and date of manufacturing;
d) Country of origin, and
e) Additional features of antibacterial or strain repellant, and
f) Any other information required by law in force or agreed between the buyer and the seller.

10.2 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.

11 PACKING

Scrub Suits and Patient Gowns shall be supplied in rigid or flexible packages made of suitable materials which are sealed so as to protect the product from moisture, soiling and contamination during storage and transportation. The package should be free of any torn or damaged areas.

ANNEX A

(*Clause 2.1*)

IS No.	*Title*
766 : 1988	Method for determination of colour fastness of textile materials to rubbing (first revision)

4905 : 2015 Random sampling and randomization procedures (*first revision*)

5887 (Part 2) : 1976 Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of *staphylococcus aureus* and *faecal streptococci* (*first revision*)

16394 Textiles — Woven shirting made of cotton, man-made fibres/filaments and their blend — Specification

IS/ISO 105-C06 :1994 Textiles — Tests for colour fastness Part C06 Colour fastness to domestic and commercial laundering

IS/ISO 105-E04 : 2008 Textiles — Tests for colour fastness: Part E04 Colour fastness to perspiration

IS/ISO 10993 (Part 5) : 2009 Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity

IS/ISO 10993 (Part 10) : 2010 Biological evaluation of medical devices: Part 10 Tests for irritation and skin sensitization

IS/ISO 20743 : 2013 Textiles — Determination of antibacterial activity of textile products

IS/ISO 13629-2: 2014 Textiles - Determination of antifungal activity of textile products - Part 2: Plate count method
IS/ISO 18184:2019 Textiles - Determination of antiviral activity of textile products

ISO 10993-12 : 2012 Biological evaluation of medical devices Part 12 Sample preparation and reference materials

IS 390: Method for determining the water repellency of fabrics by water spray test

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

ANNEX 8

(Item 7.1)

COMMENTS ON PUBLISHED STANDARDS

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

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	Note on rising to be mentioned as 60 Cmwc/min	

			AAMI standard (where rate of rising is mbar as per AATCC 127), the rate of rising is performed at **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 for medical gown wearers' environment exposure, the particulate size range of 3 micrometer to 25 micrometer is appropriate to be considered.	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 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	1. If method of test is ISO 11092, then test performance requirement to be named as	

			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.	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)	

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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	• Moderate to significantly invasive procedure

	• Arthroscopic orthopaedic procedures • Endoscopic urological procedures (for example, transurethral prostate resections) • Open gastrointestinal and genito-urinary procedures	• 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 9

(Item 7.2)

COMMENTS ON PUBLISHED STANDARDS

IS 17351 : 2020, MEDICAL TEXTILES – DRESSING, SHELL COMPRESSED – SPECIFICATION

PROPOSALS FROM DIRECTORATE OF STANDARDIZATION (DOS), MINISTRY OF DEFENCE ON COMPRESSED DRESSING CELL FOR CONSIDERING AS INDIAN STANDARDS

भारतीयमानक **IS _____**

Indian Standard

ड्रेसिंग सेल कम्प्रेस्ड

DRESSING SHELL COMPRESSED

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FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by……. had been approved by …….

This standard was first published in 2022. This standard was formulated by referring JSS 6510-20 : 2020 (Second Revision).

This standard shall be used as a guide during procurement, manufacturer & Quality Assurance of the store for which it is intended. This standard is a live document and is, therefore, likely to undergo changes.

Non-registered users can obtain the following on payment:

Copies of IS from:

Bureau of Indian Standards,
Manak Bhawan,
9, Bahadur Shah Zafar Marg,
New Delhi-110002.
or
their regional offices.

Indian Standard

DRESSING SHELL COMPRESSSED

1. SCOPE

1.1 This standard covers the requirements of Dressing Shell Compressed.

1.2 The dressing shall essentially consists of a pad of cotton wool absorbent enclosed in a medicated gauge cloth and is meant for dressing wounds. The pad is provided with bandage cloth for wrapping and is supplied in a compressed form in air tight waterproof cover.

2. REFERENCES

2.1 Reference are made in this standard to:

IS	*Title*
IS 280 : 2006	Mild Steel Wire for General Engineering Purposes
IS 758 : 1988	Specification for Handloom Cotton Gauze, Absorbent, Non-Sterilized
IS 863 : 1988	Specification for Handloom Cotton Bandage Cloth, Non-Sterilized
IS 1029 : 1970	*Specification for Hot Rolled Steel Strips (Baling)*
IS 1503 : 1988	Specification for Wooden Packing Cases
IS 1720 : 1978	*Specification for Cotton Sewing Threads*
IS 2508 : 2016	Polyethylene Films and Sheets Specification
IS 2674 : 1988	Specification for Battened Plywood Cases
IS 2771 (Part 1) : 1990	Corrugated Fibreboard Boxes-Specification Part 1 General Requirements
IS 4905 : 2015/ ISO 24153	Random Sampling and Randomization
IS 4905:2015 ISQ 24153 : 2009	Random Sampling and Randomization Procedures
IS 5012 : 1987	Specification for Cellulose Film
IS 10106 (Part 3/Sec 1) : 1984	Packaging Code Part 3 Ancillary materials Section 1 Cushioning Materials
IPC/IS	Cotton Wool Absorbent

2.2 All specification/Drawing referred to in this standard for any tender or contract shall mean the edition current on the date of such tender or contract.

3. STANDARD PATTERN

3.1 The Standard Pattern of the item quality assurance authority shall constitute the standard as regards any characteristics or properties not noted/defined in this standard.

3.2 This item has been codified and assigned NSN 6510016311886 under the HSN Code 30059040.

4. MATERIAL

The following materials shall be used in the manufacture, of dressing shell Compressed.

Table No. 1

Material	*Confirming to*
Handloom Cotton Gauge Absorbent Non Sterilized	IS 758
Handloom Cotton Bandage Cloth Non Sterilized	IS 863
Cotton Sewing Threads 100 d tex x 6 Variety No. 31	IS 1720
Low density polyethylene film	IS 2508
Cellulose Film moisture proof 0.02 mm thick	IS 5012
Cotton Wool Absorbent	IPC/IS
Pin Safety 5 cm	Best Trade Quality approved by the Inspection Authority
Standard Corrugated Carton (Boxes Fibre Board Corrugated)	IS 2771 (Part 1)

5. MANUFACTURE

5.1 The basic material, Cotton wool absorbent. Bandage loose wove Gauze Surgical Medicated and

polythene bags shall be of dimensions shown in clause 6.

5.2 The cotton wool shall be wrapped neatly with the piece of gauge surgical giving an overlap of 10 cm at the centre along the length to form a pad, the free end of the overlap being turned in by about 1 cm. The ends of the pad shall be closed by turning over the sides of the gauge cloth by 1 cm on the side of the overlap and neatly stitched with sewing cotton.

5.3 The bandage cloth piece shall then be placed on the back of the pad (over the overlapped portion of the gauge cloth) and stitched neatly with sewing cotton 20 cm apart and equidistant from the end of the pad, the first row of stitching being at a distance of 60 cm from one end of the bandage.

5.4 The two free ends of the pad shall be folded inside one cover the other at the stitches so that the bandage lies on the outside. The outer folds of the pad shall be secured by one stitch of black thread at each of two corners to prevent opening. The thread shall be such that it can be broken easily without tearing the gauze cloth when the folded pad is pulled open by hand if so required during use.

5.5 The pad shall finally be folded again at the centre once upon itself so that the bandage lies on the outside. The short end of the bandage shall be plaited neatly on the back of the pad. The long end rolled loosely on itself within a distance of 45 cm of the pad and secured by a light stitch. The stitching shall be such that it is easily broken without tearing be bandage. There after the remaining 45 cm of the bandage shall be folded on the back of the pad.

5.6 The pad shall then be compressed to reduce its thickness to approximately 2.5 cm and placed in paper cellulose film or other approved material and effectively with a suitable adhesive at the two sides as well as the two ends, to form a packet.

5.7 The packet shall be placed in a polythene bag made from 0.08 mm thick polythene laminates free from pin holes and sealed hermetically using impulse sealing machine providing a 2 to 3 mm wide seal. The package shall again be placed in an outer bag made from polythene sheet (0.08 mm) and sealed hermetically in the manner as for the inner bag.

5.8 Suitable number of such packets (in multiple of ten) shall be packed in a standard corrugated fibreboard boxes.

5.9 A product labelled marked with details shown in Appx 'A' alongwith a safety pin free from corroding effect enclosed in a polythene film, shall be placed in between the cut and inner polythene bag.

5.10 The lid of the carton shall be closed and secured by suitable adhesive tape. A product label as per details given at Appx 'B' shall be fixed with an indicator disc shall be pasted over the outside of the packed carton.

5.11 The Dressing packed in the Standard Corrugated fibreboard boxes Cardboard Cartons shall be sterilized by Gamma radiation, giving a minimum dose of 2.5 MRADS at any radiation sterilization plant approved by Drug Control Authority.

5.12 The sterilization authorities will issue a certificate to the effect that the products have been duly irradiated to a minimum dose of 2.5 MRADS.

NOTES

1. The gross mass of the carton in the packed condition should not exceed 14 kg.

2. After packing adequate number of Dressing Shell Compressed inside the carton, the empty spaces left must be filled with cushioning materials.

3. Corrugated fibreboard boxes shall be approved by Quality Assurance Authorities prior to use.

6. DIMENSIONS

Dimensions of components materials of the dressing:

Table No. 2

Cotton wool Absorbent(cm)	*Gauge Surgical (cm)*	*Bandage (cm)*	*Polythene Bag (cm approx)*
60 x 15 x 1Mass not less than30 g not more than 45 g	60 x 40	275 x 10	13.5 x 20 (Inner bag) 15.25/15.75 x 22.5/23.0 (outer bag)

7. WORKMANSHIP AND FINISH

7.1 The components of dressing conforming to the dimensions given in clause **6** shall be packed in

polythene bags and neatly sealed as described in clause **5**.

7.2 In appearance, general workmanship and finish and in all other respects not defined in this standard, the Dressing Shell Compressed shall conform to the sealed pattern held with Quality Assurance authority.

8. MARKING

Details as given in Appx 'A' shall clearly be printed on the product label (to be placed between the inner and outer polythene bag). An outer label with red cross showing the details given in Appx 'B' shall also be pasted outside the corrugated cardboard carton.

9. QUALITY ASSURANCE

9.1 Sterility (Laboratory) Test

When tested by the method given in BPC all the dressing shall be immersed in water at 27ºC to a depth of about 15 cm minutes after which the polythene bags shall be opened and the dressing examined. No part of the dressing or the wrapping material shall have become wet. This test shall be carried out on samples in the proportion shown below:

a) 10 samples for supplies upto - 1000

b) 15 samples for supplies from - 1001 to 2000

c) 0.5% of the lot as samples on supplies - over 2000 but not less than 30 samples

9.2 Euflavine Content

When tested in accordance with the method described in BPC, the Euflavine content of the gauge surgical used in the dressing shall be 0.08% to 0.2%.

10. *PRE-INSPECTION OF STORES/ CONSIGNMENT*

10.1 Manufacturers/contractors must satisfy themselves that the stores are in accordance with the terms of the contact and fully conform to the required standard by carrying out a thorough pre-inspection of each lot before actually tendering the same for inspection to the Quality Assurance Officer nominated under the terms of the contract. A declaration by the contractors that a necessary pre-inspection has been carried out on the stores tendered will be submitted along with the challan. The declaration will also indicate the method followed in carrying out pre-inspection showing the features checked/tested and will have the test certificate attached to the challan/declaration.

11. SCALE OF SAMPLING

11.1 The supplier shall offer the stores serially numbered and arranged in such a way that the entire lot is accessible to the Quality Assurance Officer.

11.2 The number of sample units shall be drawn by the Quality Assurance Officer for preliminary examination as per column 2 of the Table. The sampling shall be done adopting any one appropriate sampling method as per IS 4905, the samples units so drawn shall be visually examined for the following details:

a) Constructional and dimensional details of packet.

b) Packing and Marking

c) Color change of Indicator disc.

11.3 Samples shall be drawn as per column 2 and 3 of Table 3, shall be subjected to details inspection for following:

a) Dimensional/Constructional details of dressing.

b) Leakage Test.

c) Internet packing of the pad.

11.4 If the conditions of acceptance as give under column 4 of Table 3 are fulfilled, the samples for Lab tests/examination shall be drawn as per column 5 of Table 3 from the sample units drawn as per column 2 of Table 3.

Table 3

Lot Size	*Sample Size for Visual Examination*	*Sample Size for Details Inspection*	*Permissible No. of Non Conforming Units*	*Samples for Lab Test*
(1)	(2)	(3)	(4)	(5)
Up to 500	21	8	2	13
501 to 1000	33	13	3	20
1001 to 3000	50	13	5	32
3001 to 10000	80	20	7	32
10001 to 35000	125	20	10	50
35001 to 50000	200	25	14	80

12. CRITERIA FOR CONFORMITY

12.1 On examination, those units which are found not conforming to this standard shall be rejected.

12.2 The rejected stores shall be marked in such a way that the same cannot be reoffered/ mixed with accepted stores.

13. WARRANTY

13.1 "Except as otherwise provided in the invitation to the tender, the contractor/seller hereby declare that the goods, stores, articles sold/supplied to the purchaser under this contract shall be of the best quality and workmanship and new in all respect and shall be strictly in accordance with the standards and particulars contained/mentioned in the contract.

13.2 The contractor/seller hereby guarantees that the said goods/stores articles would continue to conform to the description and quality aforesaid for a period of twelve months from the date of delivery of the said goods/stores/articles to the purchaser or 15 months from the date of shipment/ dispatch from the contractors works whichever is earlier and notwithstanding the fact that the purchaser (Inspector) may have inspected and/or approved the said goods/stores/articles, if during the aforesaid period of 12/15 months the said goods/stores/articles, be discovered not to conform to the description and quality aforesaid or not giving satisfactory performance or have deteriorated and the decision of the purchaser in the behalf shall be final and binding on the contractor/seller to rectify/replace by acceptable goods/stores/articles, or such portion or portion thereof as is found to be defective by the purchaser within a reasonable period not exceeding 3 months or as may be allowed by the purchaser in his discretion on the application made thereof by the contractor/seller, and in such an event the above mentioned warranty period shall apply to the goods/stores/articles rectified/replaced from the date of rectification/replacement thereof, otherwise the contractor/seller shall pay to the purchaser such compensations as determined by the purchaser as may arise by reason of the breach of the warranty herein contained".

14. PACKAGING

14.1 Packaging Material

Table 4 Packaging Material

S. No.	*Specified Packing Material*	*Standard No.*
a)	Low density polythene Film 0.04 mm thick	IS 2508
b)	Corrugated fireboard boxes 5 ply (double walled)	IS 2771 (Part 1)
c)	Cushioning material	IS 10106 (Part 3/Sec 1)
d)	Pressure Sensitive Adhesive tape with plastic base	IS 13262
e)	Boxes rigid collapsible cover Type 'D'	Best Trade Quality approved by the Inspection Authority
f)	Polypropylene strapping 0.05 mm Thick x 12 mm wide	Best Trade Quality approved by the Inspection Authority

14.2 Suitable number of such packs (in multiple of ten) shall then be kept in a box, rigid, collapsible, covered Type 'D' which shall be closed and secured by adhesive tape.

14.3 Two boxes, rigid, collapsible, covered type 'D' with sterilized shall be packed in a 5 ply corrugated fibreboard box of suitable size. Empty spaces if any shall be filled with suitable cushioning material to prevent movement of the contents during transit.

14.4 The boxes packed above shall be bound with two bands of polypropylene strapping in each direction along length and width. Each strapping shall be sealed with machine using steel seals of suitable sizes.

14.5 The gross mass of a corrugated fibreboard box shall not exceed 40 kg.

NOTE - Storage period should generally not exceed 10 to 15 days after irradiation at ISOMED premises if post. Sterilization inspection is to be carried out at ISOMED.

14.6 Marking of Package

Before dispatch each Corrugated fibreboard boxes shall be legibly and indelibly marked showing the following details:

a) Nomenclature with Catalogue No.

b) Quantity packed.

c) Serial Number of Corrugated fibreboard boxes.

d) Month and year of packing.

e) Name and trade mark of the supplier.

f) Name and address of Consignee.

g) Gross Mass in kg.

h) SO/contract Number and date.

j) Red Cross mark on a white circular background at two sides of the package.

15. SUGGESTION FOR IMPROVEMENT

Any suggestions for improvement of this document may be forward to:

The Director,
Directorate of Standardisation,
Ministry of Defence,
6th Floor, 'A' Block,
Defence Offices Complex,
KG Marg, New Delhi-110001.

APPX 'A'
(*Clause* 5.9)

A-1. DRESSING SHELL COMPRESSED

A-1.1 Sterlised by Exposure to Ionizing Radiation

To open-Tear out the polythene bags.

A-1.2 Directionfor Use

Take the folded ends of the bandage in each band and keeping the bandage tight apply surface of pad to wound and fix with safety pin.

A-1.2.1 To make dressing cover large area break both black threads with thumb nail and flip open tie the ends to secure the dressing.

A-1.2.2 In case of head wounds when respirators have to be warp, care should be taken to adjust the pad so that it does not interfere with the fit of the face piece.

A-1.2.3 *Caution*

a) Do not handle wound or pad.

b) No attempt should be made to re-sterilize the dressing.

A-1.3 Manufacturer's Name

Indicator Disc (**NOTE** - the Original yellow color of disc change to Red/Orange on exposure to Gamma Radiation).

APPX 'B'
(*Clause* 5.10)

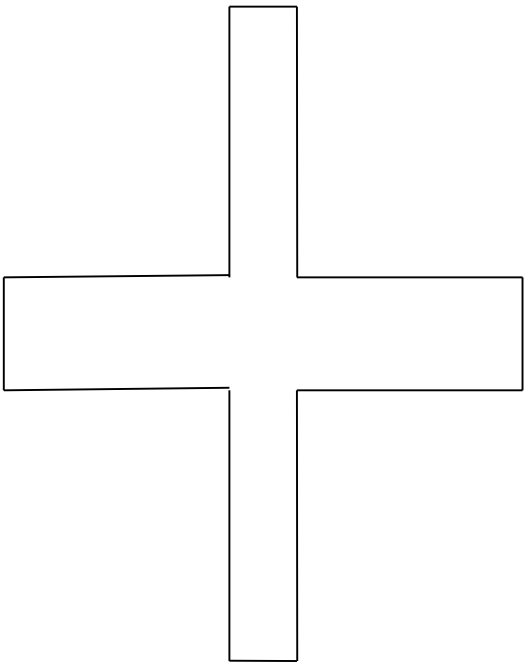
DRESSING SHELL COMPRESSED

Quantity Packed

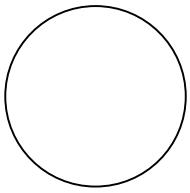
Month & Year

Gross Mass

Mfg
Packed on



Indicator Disc



The original Yellow colour of the disc changes to Red/Orange on exposure to Gamma Radiation.

Date of sterilisation.

ANNEX 10

(Item 8.1)

INTERNATIONAL ACTIVITIES

Committee Internal Ballot (CIB) - ISO TC 338 N 38 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

[SOURCE: ISO 13629 – 2: 2014,3.3]

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 adevice, 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 likelocal 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 arereleased 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 orinfirmity, 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 levelof 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 microbiotaVMB
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)

Bibliography

[1] ISO 3071:2020 *Textiles — Determination of pH of aqueous extract*

[2] ISO 4833-1:2013 *Microbiology of the food chain — Horizontal method for the enumeration of microorganisms — Part 1: Colony count at 30 °C by the pour plate technique*

[3] ISO 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testingwithin a risk manage*

[4] ISO 10993-5:2009 *Biological evaluation of medical devices — Part 5: Tests for in vitrocytotoxicity process*

[5] ISO 10993-18:2020 *Biological evaluation of medical devices — Part 18: Chemicalcharacterization of medical device materials within a risk management process*

[6] ISO 11139:2018 *Sterilization of health care products — Vocabulary of terms used insterilization and related equipment and process standards*

[7] ISO 13629-2:2014 *Textiles — Determination of antifungal activity of textile products — Part2: Plate count method*

[8] ISO 16929:2021 *Plastics — Determination of the degree of disintegration of plastic materialsunder defined composting conditions in a pilot-scale test*

[9] ISO 18606:2013, *Packaging and the environment — Organic recycling*

[10] ISO 20743:2021 *Textiles — Determination of antibacterial activity of textile products*

[11] ISO/DIS 5157 Textiles — Environmental aspects — Vocabulary

[12] Better Health Channel
https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/menstrual-cycle

[13] Menstrual health: a definition for policy, practice, and research. 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.

[14] Glossary for the Global Menstrual Movement MH Hub, Period. 2022. Glossary for the Global Menstrual Movement

[15] Mind your bloody language Bloody Good Period. A factsheet on language associated withperiod products

[16] FDA, *https://www.fda.gov/medical-devices/biocompatibility-assessment-resource-center/glossary-biocompatibility-terms*

[17] GENERAL PRINCIPLES OF FOOD HYGIENE CXC 1-1969

[18] Pawel Laniewski, Melissa Herbst-Kralovetz, in Encyclopedia of Reproduction (SecondEdition), 2018]

[19] International Federation of Gynecology and Obstetrics; b). Sonya et al., Menstrual BleedingPatterns Among Regularly Menstruating Women, American Journal of Epidemiology, 2012;175(6):536–545

[20] Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP), September 18,2016

[21] Glossary for the Global Menstrual Movement. MH Hub, Period. 2022. Glossary for the GlobalMenstrual Movement.

ANNEX 12

(Item 8.3)

INTERNATIONAL ACTIVITIES

MINUTES OF THE PANEL MEETING FOR STRATEGIC BUSINESS PLAN (TG 1) AND THE FINAL DOCUMENTS OF STRATEGIC BUSINESS PLAN

ISO/TC 338/TG 1 **N 19**

ISO/TC 338/TG 1 "Strategic Business Plan"
Convenorship: **BIS**
Convenor: **Santhini E. Ms**

Meeting report TG 1 (2)

Document type	Related content	Document date	Expected action
Meeting / Minutes	Meeting: VIRTUAL 20 Jun 2023	2023-06-19	**INFO** by 2023-06-20

Meeting report ISO/TC 338 TG 1 Strategic Business Plan

2023-06-01, at 9.00- 11.30 (CET)

1. Opening of the meeting

Convenor Dr. E Santhini opened the meeting and welcomed all. The convenor gave a brief report on the background and what was done at the previous meetings, that asubgroup was created to work on the document that now has been out for a commenting period.

2. Roll call of delegates

Dr. E Santhini, Louise Klintner, Marie Gunnlert, Dharmbeer, Junjie Liu, Qiu Wenlun,Wang Wenjun, Jenny Acaralp.

3. Adoption of the agenda

The agenda was adopted.

Louise asked if there were any changes made to the draft after the latest meeting, that wasn't up for discussion at the meeting? Dr. E Santhini explained that the document was revised according to the discussions after the subgroup meeting andthat document was sent out for the wider group.

It was further discussed that its´s difficult to identify the places where changes weremade and we didn't agree on, to ensure that it´s clear to everyone we should from now on use Track changes.

Few members had signed up for today's meeting therefor it was further discussed that meetings all planned well in advance and that relevant meeting documents areshared with the members and circulated in good time before a meeting so that the members can prepare and able to participate.

4. Revise the working document/resolve remaining issues, questions

The meeting reviewed the draft and looked at the comments received from CharlottePersson. All comments were accepted, discussed and included in the draft.

The following Chinese standards was included in the list of national standardsavailable:

- 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).

It was decided for everyone to submit their comments to the convenor, for the convenor to include them in the draft and circulate the draft for a 4-week commentingperiod.

Jenny to ask Maho Takahashi (ISO TMP) about the deadline for submitting the draftto her for comments.

5. Any other business

No other business.

6. Future meetings

The next meeting takes place on June 20 at 9.00-11.30 (CET).

7. Closure of the meeting

The convenor thanked all present members for today´s fruitful discussions.

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

EXECUTIVE SUMMARY

The strategic business plan for ISO/TC 338 Menstrual Products outlines the need for international standards in the menstrual product industry. The document emphasizes the importance of aligning ISO's work with business environment needs and trends, ensuring prioritization and adequate resources for projects.

The business environment of the ISO/TC 338 is characterized by the importance of menstrual health and the need for products that support physical, mental, and social well-being. It is described in terms of qualitative and quantitative factors. Qualitatively, the focus is on achieving menstrual health for women, girls, and all people who menstruate. Quantitatively, the document presents demographic considerations, market size, distribution, and pressures on margins. Menstrual products play a crucial role in allowing individuals who menstruate to participate fully in society. However, there is a lack of harmonized international standards for menstrual products, which can hinder their availability and safety.

The market for menstrual products is significant, with 300 million people menstruating daily. The market size is projected to reach USD 33.1 billion by 2030, driven by both mature and growth markets. The demand for environmentally sustainable products and the emergence of reusable alternatives also impact the industry. However, the industry faces challenges such as margin pressures, pricing pressures, distribution costs, import dependence, and high competition.

The establishment of international standards for menstrual products can address these challenges by ensuring product safety, quality, and performance while promoting innovation and sustainability. Standards can also contribute to achieving various Sustainable Development Goals related to poverty, health, education, gender equality, water and sanitation, reduced inequalities, and responsible consumption and production.

In conclusion, the strategic business plan highlights the need for international standards in the menstrual product industry to improve access, ensure safety, and support sustainable development.

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 the globally accepted definition of menstrual health, achieving menstrual health implies that women, girls, and all people who menstruate 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[4]. 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 barriers to availability and accessibility of products in different regions.
- contributing to a positive and constructive global narrative around menstruation and making it easier for consumers to access information about menstruation and menstrual products

Everyday 300 million people menstruate, 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 fluid 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[5]. 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. Standardization in the area of menstrual products 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) pose very different challenges than those of growth markets in low- and middle-income countries (LMICs).

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 1) market penetration due to urbanization, 2) gender equality and 3) 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[6] but preliminary evidence indicates

[4] 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.

[5] 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.

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

that both external and internal reusable products have good acceptability amongst consumers in growth[7,8,9,10] and mature markets. As innovations in existing product categories and the advent of new 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 behaviour, consumers continuously search for more sustainable alternatives including in menstrual products. In contexts, where waste management infrastructure is still evolving, there are also environmental concerns regarding disposable menstrual products, which hold around 97 percent of the world market. The impact on wastewater infrastructure in HIC settings has also been noted. The lack of appropriate waste management systems and the variety of the different waste management systems places different demands on suitable product solutions[11]. This standard can provide guidance to policy makers and referral to already existing and accepted standards in the area (e.g. ISO 14040, ISO 17088 and any others) for
- Appropriate handling of existing products and
- innovation of more sustainable menstrual products-both disposable and reusable

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 measures needed to place a safe product on the market[12].

Increasing consumer demand for environmentally sustainable products has also led to the emergence of products that falsely claim to be compostable and are oxo-degradable in some regions. Standards can also safeguard consumers against such products by providing reference to existing standards that define biodegradability and compostability e.g. ISO 17088.

Standards for menstrual products can also help governments achieve various 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 to menstrual products 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)[13]. Ensuring that all people who menstruate have access to safe menstrual products 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:

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[7] 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.

[8] 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.

[9] 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

[10] 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.

[11] Reproductive Health Supplies Coalition. (2022). Webinar series on menstrual management

[12] 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.

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

1. Demographic considerations (consumer)

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 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[14].

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 compound annual growth rate (CAGR) of 4.9 percent from 2023 to 2030[15].

The continuing importance of mature markets in the segment of menstrual products is demonstrated by its projected market growth. According to the Annual & Sustainability Report published in 2022 by Essity AB, a leading hygiene products manufacturer, the highest usage of menstrual products was witnessed in Western Europe, followed by North America and Eastern Europe 2020[16]. 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. As discussed in the section on qualitative factors, these statistics indicate that while mature markets have achieved saturation in terms of market penetration, there is significant growth potential from innovations across existing product categories like disposable pads and tampons and new consumer categories like reusable pads and menstrual cups.

The increasing importance of growth markets is reflected in both the potential for increasing market penetration and product innovations. The growing overall potential market size due to increase in menstruating population is also a contributor. In LMICs, the largest manufacturers are experiencing double-digit growth in market size annually, led by manufacturers in 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 menstrual products.[17] Ethiopia, the Democratic Republic of the Congo, Uganda and Sudan account for 51 percent of all menstruators among all low income countries..

[14] Ibid. Klinter, L. (2021).

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

[16] Essity AB. (2022). Annual and Sustainability Report. https://www.essity.com/sustainability/sustainability-reporting-governance-and-data/annual-and-sustainability-report/

[17] Weinberger M, Eva G, Gold J, Bellows N, Reidy M, Sanders R, and Skibiak J. LEAP: Landscape and Projection of Reproductive Health Supply Needs. Reproductive Health Supplies Coalition. (2021). https://leap.rhsupplies.org/#/menstrual-hygiene

The total Asia Pacific market stood at USD 11.96 billion in 2020[18]. In 2023 by comparison, the market size of menstrual products in China alone was approximately USD 11.37 billion with a five year projected CAGR of 6.16 percent[19] and in India, it was estimated at USD 6.2 billion with a five year projected CAGR of 4.76 percent[20].

3. Pressures on margins

With changing dynamics of the menstrual product market globally and efforts to improve access and affordability, there are increasing pressures on margins. Many of these pressures were exacerbated during the COVID19 crisis that impacted supply chains globally[21]. 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 at price points which are 2.3 times that of the lowest price per pack and in India, the range is up to 9.4 times the lowest price per pack.[22] This indicates efforts on the part of manufacturers to expand the price range and reach across wealth quintiles. Another study states that 46 percent of all consumers are from lower-middle income countries while they contribute only 32 percent of overall global spend on menstrual products[23]. 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. They include but are not limited to menstrual product dispensers and pads dispensed in the form of rolls at the point of use, last mile distribution models that include menstrual products as part of a basket of health products and services e.g. Kasha, Triggerise and many others. Other distribution strategies include leveraging traditional fast moving consumer goods (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 menstrual pad raw materials in terms of number of import shipments, followed by Bangladesh and Vietnam[24]. 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 menstrual pads globally (in terms of number of shipments) and India, China and South Africa are the

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18 https://www.fortunebusinessinsights.com/feminine-hygiene-products-market-103530

19 https://www.statista.com/outlook/cmo/tissue-hygiene-paper/feminine-hygiene/china

20 https://www.statista.com/outlook/cmo/tissue-hygiene-paper/feminine-hygiene/india

21 Access to menstrual health supplies during COVID-19-What have we learnt. (2021). https://medium.com/its-about-supplies/access-to-menstrual-health-supplies-during-covid-19-what-have-we-learnt-%C2%B9-ec8b55e5f390

22 Landscaping Supply Side Factors to Menstrual Health Access. (2021). Mann Global Health. https://www.rhsupplies.org/uploads/tx_rhscpublications/Landscaping_Supply_Side_Factors_to_Menstrual_Health_Access.pdf

23 Ibid. Weinberger et al. (2021). LEAP Report.

24 https://www.volza.com/p/sanitary-napkin-raw-material/import/

largest exporters[25]. 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 the COVID19 crisis, 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 competition in the industry manifold. For example, India has at least 20 disposable menstrual pad brands, 16 reusable menstrual pad brands, 5 tampon brands and 24 menstrual cup brands. Similarly, Kenya, Nigeria and Tanzania have 25, 19 and 13 disposable menstrual pad 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 of small and medium sized players have led to increased access to affordable products. However, without clarity on safety requirements for menstrual products, it has also led to unregulated products with unsubstantiated claims coming into the market, especially in the case of LMICs. Standardization can help ensure that while access is increased, quality is assured simultaneously. In higher income countries, sustainability related innovation is one of the key drivers of growth in disposable and reusable menstrual product categories.[26] In this context, research and development costs in a highly competitive market can put additional pressures on margins. Standards can ensure that quality is prioritized as part of such development efforts, as we see innovation across product categories.

4. Existing regulations[27],[28]

Many countries have standards for disposable menstrual pads but only a few countries in Africa and India have developed standards for reusable menstrual pads. Some 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 EU Ecolabel. In Europe there is also an association of the nonwovens and related industries (EDANA) which 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.

Regulatory and economic 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

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

[26] Ibid. Essity AB Annual and Sustainability Report. (2022).

[27] 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

[28] Original proposal for TC 338

products are included in the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. A list of known national and/or regional regulations and standards on menstrual products (not comprehensive) is given in Annexure A.

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

An international standard in the area of menstrual products 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, performance and fitness to purpose. These matters should be addressed on a global level, since they apply to all consumers of these products, globally.[29]

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 menstrual products. The standard is expected to benefit all stakeholder categories including consumers, manufacturers, other supply chain stakeholders, 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

[29] Ibid. Klinter, L. (2021).

- 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 25 Participating members and 18 Observing members (as of [date of publication]). 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

ISO/TC 338 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

Existing liaison relationships are:

- UNFPA - United Nations Population Fund
- EDANA 'European Disposables and Nonwovens Association – EDANA'
- These ISO committees have been identified as collaboration partners, however not overlapping in scope.
- Liaison Committees to ISO/TC 338:
- ISO/TC 6 Paper, board and pulps
- ISO/TC 6/SC 2 Test methods and quality specifications for paper and board
- ISO/TC 173/SC 3 Aids for ostomy and incontinence
- Liaison Committees from ISO/TC 338:
- ISO/TC 38 Textiles ISO
- ISO/TC 133 Clothing sizing systems - size designation, size measurement methods and digital fittings ISO
- ISO/TC 157 Non-systemic contraceptives and STI barrier prophylactics ISO
- ISO/TC 173/SC 3 Aids for ostomy and incontinence ISO
- ISO/TC 194 Biological and clinical evaluation of medical devices ISO

- ISO/TC 210 Quality management and corresponding general aspects for products with a health purpose including medical devices

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 reference to existing guidelines on manufacturing processes.
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.
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 is:

AHG 1 Terminology

TG 1 Strategic Business Plan

WG 1 General Requirements

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

Annexure A

S.No	Country	Standard	Authority
1.	Australia	AS 2869:2008 Tampons - Menstrual	Standards Australia
		Therapeutic Goods (Standard for Menstrual Cups) Order 2018 (Therapeutic Goods Order 99)	
2.	ARSO**	DARS 653:2017 for disposable sanitary napkins	African Organization for Standardization
		DARS 1575:2017 for reusable sanitary napkins	
3.	Bangladesh	BDS 1261:2016 Sanitary Towels Mandatory	Bangladesh Standards and Testing Institute
4.	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).	Standardization Administration of the People's Republic ofChina
5.	East African Community*	EAS 96-1: Sanitary towels Specification- Disposable (2008)	East African Standards Committee
		FDEAS:96- Sanitary towels- Specification- Reusable (2019)	
6.	European Union	EU Ecolable for Absorbent hygiene produts and reusable menstrual cups)	EU Ecolabel
7.	Egypt	ES :2023 TAMPONS	Egyptian Organization for Standardization and Quality
8.	Ethiopia	ES: 6345- Sanitary Pads- Specification- Disposable (2018)	Ethiopian Standards Agency
		ES: 6346- Sanitary Pads- Specification- Reusable (2018)	

9.	Ghana	GS 1248:2019: Specification for single-use disposable sanitary towels (pads) for external use	
10.	Indonesia	SNI 16-6363-2000: Sanitary Pads (2000, was taken under revision in 2015)	National Standardization Agency of Indonesia (Badan National Standardisasi - BSN)
11.	India	IS 5405:2019 for disposable sanitary napkins (1980, revised in 2019)	Bureau of Indian Standards
		IS 17514:2021 for reusable sanitary napkins	
12.	Japan	PFSB No. 0325-17: Standards for Approval of Sanitary Napkins (2015)	Japanese Industrial Standards
13.	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)	
14.	Malawi	MS 890:2013 SANITARY TOWELS – SPECIFICATION (2013)	Malawi Bureau of Standards
		MS 1445:2018- Reusable sanitary towels-Specification (2018)	
15.	Nigeria	NIS 291 (2018) Disposable Sanitary Pads	
16.	Pakistan	PS: 1449-1979 for disposable sanitary napkins	Pakistan Standards and Quality Control Authority
17.	South Africa	SANS: 1043 for disposable sanitary napkins (2010)	South Africa Bureau of Standards (SABS)
		SANS: 1812 for reusable sanitary napkins (2019)	
18.	South Korea	MFDS Quasi-drugs Group 1 (A) (2009)	Korean Ministry of Food and Drug Safety
19.	Tanzania	TZS: 1659- Disposable Sanitary Towels - Specifications (2014)	Tanzania Bureau of Standards
		TBS: 6136- Reusable Sanitary Towels – Specifications (2nd Edition - 2019)	
20.	United States of America	Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) (2005)	US FDA
21.	UNGM	Technical Specifications for Disposable Sanitary pads, Reusable Menstrual Pads and Menstrual cups (2021)	UNICEF, UNFPA, UNHCR

22.	Uganda	UBS: 1782- Disposable Sanitary Towels - Specifications (2017)	Uganda National Bureau of Standards
		US: 1782- Reusable sanitary towels — Specification (2017)	
23.	Vietnam	TCVN 10585:2014 Sanitary Pads for Women	Directorate for Standards, Metrology and Quality (TCVN)
24.	Zambia	*HS Code: 4818.40 (import guidelines 2011)* for sanitary napkins	Zambia Bureau of Standards
25.	Zimbabwe	ZWS: 730- Manufacture of Sanitary Pads (2015)	Standards Association of Zimbabwe
		ZWS 1023: Reusable sanitary pads (2019)	

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

ANNEX 13

(Item 8.3)

INTERNATIONAL ACTIVITIES

MINUTES OF THE PANEL MEETING FOR WORKING GROUP WG 1 'GENERAL REQUIREMENT' AND THE OUTLINE OF THE DOCUMENT

ISO/TC 338/WG 1 **N 11**

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

Minutes of the 2nd meeting of WG1

Document type	Related content	Document date	Expected action
Meeting / Minutes	Meeting: VIRTUAL 29 May 2023	2023-06-29	**INFO** by 2023-05-29

Description

Minutes of the 2nd meeting of WG 1 held in virtual mode on 29.05.23 and 30.05.23 is attached herewith.

Meeting minutes 2nd meeting of ISO/TC 338 Menstrual products – General safety requirements, Working Group 1

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)

DAY 1 (29th May 2023 10.00 hours CET)

1. Opening of the meeting

Convenor, S. Sivakumar opened the meeting and welcomed all attendees to the second WG1 meeting. Further, he has also briefed on the outcome of the 1st meeting of WG1 and the plenary meeting held at SIS, Sweden on 20th and 21st April 2023.

2.Roll call of delegates

The convenor S. Sivakumar and committee manager, Jenny Acaralp presented themselves.

All participants presented and introduced themselves. There were a few members in the committee and they have also introduced themselves. The new members have also been apprised of the developments in this working group so far.

See attendance list below.

3. Code of conduct

The members were given a brief insight about the "ISO code of conduct – PUB100011" and the convenor requested all the members to adhere to these guidelines.

Presentation ISO Code of Ethics and Conduct.

ISO - ISO Code of Ethics and Conduct

4.Adoption of the agenda

The members agreed to proceed with the meeting as per the N 08 Meeting agenda.

5. Review of discussions held during ISO/TC 338 plenary meeting held on 20th and21st April 2023

At the plenary meeting S. Sivakumar presented the status report of WG 1, presentationmade at the plenary meeting of ISO TC 338, N 9.

The following points were discussed at the plenary meeting:

- There are products which are used both internally and externally
- The Indian delegation suggested to decide the scope of this Working Group 1 as there was no such document available. This would help WG1 to plan their accordingly.
- It was also suggested to change the title of the working group to make it relevant to the work being carried out by the group.
- The way forward for preparing the standards was discussed whether to prepare product-wise or based on the types of menstrual products was discussed in detail. Many of the plenary members suggested that it will be better to have product-wise standards formulated.
- It was also suggested to decide the title of the preliminary work item to be prepared. Project leaders may be decided for them to prepare the preliminary work item and take it forward.
- The Plenary committee finally suggested that all the above points may be deliberatedat the Working Group 1 and the recommendations may be approved by ISO/TC 338 either in plenary meeting or by way of Committee Internal Balloting (CIB).

Details may be referred in "Points to be discussed at the meeting N 10".

6.Discussion on scope of ISO/TC338/ WG1

i. The title of WG1 is to be modified to make it relevant and inclusive. The members deliberated on the title and recommended the below title:

Title of WG 1- Safety, Performance and General Requirements of menstrual products.

The recommendation to change the WG 1 title is to be approved by ISO/TC 338, by Committee Internal Balloting (CIB).

ii. The meeting started with discussing the WG 1 scope.

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.

- The members felt as the terminology is covered by AHG1, the AHG1 may continue until the terminology document is finalized and a new work item proposal is given by that group after necessary Committee Internal Balloting (CIB).
- It was further discussed that the general requirements standard should be kept product neutral and with a user perspective in focus. The first part could be a generalrequirement standard, the

other parts can also be included in the work programme for WG 1.

- Performance requirements or test methods should not be included in the general standard; these are topics for separate standards. The committee also observed that there are different requirements for different products.

- Some of the members suggested that the scope as presented in the first initial draft included in ISO/TC 338 N 4 may be adopted as the scope of WG 1 as it seems to cover the broad outline of this working group. The scope of working document ISO/TC 338 N 4 was reviewed for adoption under WG1. Consensus was reached to keep the scope of WG1 as given below:

Scope of WG1

This document specifies safety, performance, and health requirements for menstrual products from a user perspective covering products intended both for single and multiple use, regardless of material.

7.Roadmap for WG1 – Options for categorizing the standards

The two options for categorizing the standards presented at the plenary were discussed:

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, etc)

The members decided to go forward with a third option:

General requirements and safety requirements

1. Chemical safety
2. Biological safety.
3. Physical safety – shouldn't hurt or damage skin

A menstrual product should be safe to use during a lifetime of menstruations. Then we can describe the different aspects above.

Ms. Tanya proposed the following categorization:

Part 1: Classification/categorization document

Part 2: General and safety requirements

Part 3: Performance requirements

For now, we´ll start work on part 2 and 3 at a general level. The classification may be added at a later point of time.

Another proposal was to draft internally used products as standard 2 and externally used products as part 3.

Menstrual products are categorized in different ways, either as medical device, therapeutic goods or consumer products in different countries and regions. In European countries they fall under the General Product Safety Directive. In the US menstrual products are considereda medical device, with additional testing requirements. In Japan menstrual products are regulated by the Pharmaceuticals and medical act.

It was concluded that it doesn't matter what regulations there are in different countries.

- Another proposal was that the Performance requirements could be divided by use type (rather than product type):
  - Performance requirements of External Reusable Menstrual products
  - Performance requirements of External Disposable Menstrual products
  - Performance requirements of Internal Reusable Menstrual products
  - Performance requirements of Internal Disposable Menstrual products

Start very general but when we come to specific task break that out into a work item.

Biological safety:

Adverse tissue reaction, vaginal injury, vaginal infection, toxic shock syndrome should be covered under biological safety.

Table A.1 in ISO 10993-1:2018 lists the specific endpoints to be considered for the biological safety according to the type of device.

After all the deliberations as above, the working group suggested to move forward with one standard as per the topic given below and then decide about other topics:

ISO XXXXX: General and safety requirements of menstrual products

It is decided to prepare the working document for deliberation in the next meeting of the Working Group 1. After the scrutiny by the members, the draft may be proposed as a new work item at ISO TC 338.

8. Review of working document / existing resources

The following examples of umbrella standards were mentioned:

- ISO 20002 general requirements- part 1 applies, simpler way to standard.
- More complex standards IEC 60601-1-1, IEC 60601-2-24
- Reference to be added in the Bibliography: ISO 10993-3 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO/IEC Guide 51:2014 Safety aspects — Guidelines for their inclusion in standards.

The Day 1 meeting ended with the vote of thanks from the convenor S. Sivakumar and he has requested the members to join the Day 2 meeting to discuss on the outline of working document.

DAY 2 (30th May 2023 10.00 hours CET)

Convenor S. Sivakumar opened the meeting, welcomed all, and thanked the participants for their valuable input and engagement at the previous day's meeting.

The convenor gave a recap of previous day's meeting which are listed in Day 1 minutes.

S. Sivakumar especially thanked and applauded the AHG 1 members lead by the convenor Ms. Tanya Mahajan for their excellent work with the terminology document for menstrual products. He also informed the members that the terminology document that currently is out for comments may be proposed as a NWIP in the near future after addressing the commentsfrom the internal committee members. Since the terms and definitions have already been handled, the WG 1 need not spend much time on them.

Discussion on the outline - ISO XXXXX: General and safety requirements of menstrualproducts

The convenor has from earlier discussion prepared a proposal for a draft outline, themeeting deliberated the headings and what to be included in every section with the ambition to finalize the outlines during this meeting. Later on smaller groups can work on the text.

The meeting started to work on with the main headings, documented in N 012. The following deliberations were made.

- Proposal for text under General requirements:

Menstrual product should be safe to use during the menstruation and during all years of menstruation. They should not cause discomfort or any harmful impact on the health of the user during short or long term use.

- Discussions were held as to use which terminology (i.e) health or safety. The members suggested keeping safety requirements in the standard's outline.

- With regard to the workmanship, it was suggested to refer to GMP, GoodManufacturing practices in clause 5.2.

- 5.1.1 Chemical safety
  Materials in the menstrual products should be inert or contain chemicals with minimal risk for health effects. Raw material suppliers and product converters should take the utmost care to when selecting sub-suppliers and chemicals/components for use in menstrual products.

- 5.1.2 Biological safety

  Biocompatibility

  Menstrual products must be produced using materials and production conditions to be biocompatible with the intended use. Materials and production must assure high hygiene standards to assure that the materials and products meet the requirements onbacteria content.

- 5.1.3 Physical safety

  Menstrual products should be physically fit for purpose (suitable for the intended use) and should not harm or penetrate the skin or mucus of the user or break during use.

- 6.6 Environmental safety

  Deliberations were also made regarding the environmental safety as most of the menstrual products are made from synthetic materials which are not easily bio-degradable. Some members opined that Safety is the main priority and in a subsequent stage we may deal with environmental questions. We might need to invite environmental experts to the work. Further, it was informed that the environmental aspects may be covered in broad details not getting very specific into the requirements.

  The working group decided to keep environmental safety as one of the headings to cover in brief about the requirements of raw materials and the end product.

The working group has finalized the outline of the working document as given in Point no. 10.

9. Any other businessWay of working

- It was proposed that Google docs could be used for commenting; The Committee manager informed that it is to be noted that the document should also need to be circulated through ISO documents and that comments can be included directly in the document (publish the document as a WORD document not PDF if possible) or by using the ISO commenting template.

- It was also suggested to use “Track Changes” mode from now on when updating the

document.

- Presentations to be made at a meeting may be notified in advance before themeeting, wherever possible.

10. Summing up / resolutions for further progress

i. Title of the working group to be changed as "***Safety, Performance and General requirements of menstrual products".***

ii. Scope of ISO/TC 338 N 4 to be adopted as the scope of WG 1 which is given below:

This document specifies safety, performance, and health requirements for menstrual products from a user perspective covering products intended both for single and multiple use, regardless of material.

iii. Options to prepare standards

The working group, after detailed discussions, has decided to work on one umbrella standard covering the General and safety requirements of menstrual products and then decide later on work on product specific standards. The title of the draft working document is decided as follow:

ISO XXXXX: General and safety requirements of menstrual products

iv. Outline of the working document

After detailed deliberations, the revised outline of the document was prepared by this working group, N 013 General and safety requirements of menstrual products – Rev. 30.05.23.

ISO XXXXX: General and safety requirements of menstrual productsForeword

1 Scope
2 Normative references
3 Terms and definitions

4 Classification of menstrual products
4.1 Types of Menstrual products
4.2 Size and shape of products

5 General requirements5.1 General
5.2 Manufacture, workmanship and finish5.3 Hygiene requirements
5.4 Materials used and design

- Disposable and reusable materials

6 Safety requirements

6.1 Material and product safety

6.2 Physical safety

6.3 Chemical assessment and safety

6.4 Biological

6.4.1 Cytotoxicity
6.4.2 Skin irritation and Sensitization
6.4.3 Carcinogenicity
6.4.4 Reproductive and developmental
toxicity6.4.5 alteration in normal vaginal flora
6.4.6 Pyrogenicity

6.5 Exposure assessment
6.5.1 Materials with direct skin contact 6.5.2
Materials with indirect skin contact
6.5.3 Materials with negligible skin contact
6.5.4 Materials with direct vaginal contact

6.6 Environmental safety
6.7 Risk Management – Informative annex

7 Packaging and labeling

8 User information
8.1 General
8.2 Marking
8.3 Instructions of use, handling and storage
8.4 Ingredient disclosure
8.5 Cleaning and maintenance of multi-use products
8.6 Instructions for disposal
8.7 Shelf life of the product

9 Bibliography

The convenor informed that the above outline will be circulated to the WG 1 members for giving their inputs for each of the headings and the inputs will be consolidated into a working draft by the convenor. The working draft thus prepared may be taken up for discussion in the next WG1 meeting.

11. Closure of the meeting

- The revised outline of the document (N 013) as finalized by this working group will besent for a 4 week commenting period. The next meeting date will be intimated after the commenting period has ended. The convenor requested all the members toshare their valuable inputs either through Google docs or through e-mail on each of the headings of the working draft.

- At the next meeting, we will review the drafting process, NWIP ballot and projectplan.

The convenor thanked all attendees for their great work and summarized the day's meeting and presented the action plan for subsequent meetings.

Attendance list

S. No.	Name of the attendee	
	29.05.23	30.05.23
1.	Jenny Acaralp	Jenny Acaralp
2.	S. Sivakumar	S. Sivakumar
3.	Monica Cameo	Monica Cameo
4.	Monica Lundervold	Monica Lundervold
5.	E. Santhini	E. Santhini
6.	Viscovich Veronica	Viscovich Veronica
7.	Satoru Numata	Satoru Numata
8.	Louise Klintner	Louise Klintner
9.	Henning Roettger	-
10.	Nirav Mehta	-
11.	Dharmbeer	Dharmbeer
12.	Liu Junjie	Liu Junjie
13.	Marie Gunnlert	Marie Gunnlert
14.	Charlotte Persson	Charlotte Persson
15.	Kristin Lorenz	Kristin Lorenz
16.	Elisa Gusberti	Elisa Gusberti
17.	Farré Eduard	Farré Eduard
18.	Míriam Carrero	Míriam Carrero
19.	Aki Yuyama	Aki Yuyama
20.	Jane Wainaina	Jane Wainaina
21.	Seto Hirokazu	Seto Hirokazu
22.	Tanya Mahajan	Tanya Mahajan
23.	-	Armelle Bevilacqua
24.	Iina Kurjanen	Iina Kurjanen
25.	-	Eckard Jantzen
26.	Hideki Kondo	Hideki Kondo
27.	Kawasaki Hironori	Kawasaki Hironori
28.	Kiyoshi Miyazawa	Kiyoshi Miyazawa
29.	Mariko Matsue (interpreter)	Mariko Matsue (interpreter)

**
**
*

ISO/TC 338/WG 1 **N 14**

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

N 013 Outline of working document finalised on 30.05.23

Document type	Related content	Document date	Expected action
~~Recommendation~~ **2023**	Meeting: VIRTUAL 29 May 2023	2023-06-29	**INFO** by 2023-05-30

Description

Detailed deliberations were held during the meeting on 30.05.23 on the draft outline of working draft N 012 and the revised outline of working document was prepared. Please find attached herewith the revised outline of the working document, N 013. The members are requested to share their inputs for each of the headings in this draft outline and forward to the convenor for consolidation and discussionin the next meeting of WG 1.

Menstrual products — General and safety requirements of menstrual products

Element introductive — Element central — Element complementaire

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Contents **Page**

6.5.3 Materials with negligible skin contact

6.5.4 Materials with direct vaginal contact

6.6 Environmental safety

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member of body interested in a subject for whicha technical committee has been established has the right to be represented on that committee.International organizations, governmental and non-governmental, in liaison with ISO also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on the matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directive, Part 2 (see www.iso.org/directives).

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This document was prepared by the Technical Committee ISO/TC 338, *Menstrual Products*, Subcommittee SC WG1, *General Requirements.*

A list of all parts in the ISO #### series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body.A complete listing of these bodies can be found at www.iso.org/members.html.

Menstrual products — General and safety requirements of menstrual products

ANNEX 14

(Item 9.1)

REVIEW OF PUBLISHED STANDARDS - PRE-2000 STANDARDS

REVIEW ANALYSIS OF INDIAN STANDARD
(To be submitted to the Sectional Committee)

1. *Sectional Committee No. & Title: TXD 36, (Technical Textiles for Medtech Applications Sectional Committee)*
2. **IS No:** 1681 : 1998
3. **Title:** Textiles — Hospital Blankets, Woollen, Dyed — Specification (Third Revision)
4. **Date of review:** 28 July 2023

5. Review Analysis

i) Status of standard(s), if any from which assistance had been drawn in the formulation of this IS.

Standard (No. & Title)	Whether the standard has since been revised	Major changes	Action proposed
NIL	NIL	NIL	NIL

ii) Status of standards referred in the IS

Referred standards (No. & Title)	IS No. of this standards since revised	Changes that are of affecting the standard under review	Action proposed
IS 187 1978	Same version	NA	NA

Cotton long cloth (second revision)			
IS 665 : 1989 Method for determination of dimensional changes of fabrics containing wool on soaking in water (first revision)	Same version	NA	NA
IS 686 1985 Methods for determination of colour fastness of textile materials to daylight (first revision)	Same version	NA	NA
IS 741 : 1971 Code for inland packaging of woollen and worsted yarn and cloth (first revision)	Same version	NA	NA
IS 1390 1983 Methods for determination of pH value of aqueous extracts of textiles materials (first revision)	**IS 1390 : 2022** **ISO 3071 : 2020** Textiles — Determination of pH of Aqueous Extract (Third Revision)	—	Latest version of the standard i.e. IS 1390 : 2022 ISO 3071 : 2020 shall be referred in the revision and accordingly other changes will be made wherever required.

IS 1720 1978 Cotton sewing threads (second revision)	Same version	NA	NA
IS 1793 1973 Guide for marking textile materials made of wool (first revision)	**IS 1793 : 2023** Requirements for Marking Textiles Materials Made of Wool (Second Revision)	—	Latest version of the standard i.e IS 1793 : 2023shall be referred in the revision and accordingly other changes will be made wherever required.
IS 1954 : 1969 Methods for determination of length and width of fabrics (first revision)	**IS 1954 : 1990** Determination Of Length And Width Of Woven Fabrics - Methods (Second Revision)	—	Latest version of the standard i.e. IS 1954 :1990 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 1963 : 1981 Method for determination of threads per unit length in woven fabrics (second revision)	Same Version	NA	NA
IS 1964 : 1970 Methods for determination of weight per square metre and weight per linear metre of fabrics (first revision)	**IS 1964:2001** Textiles — Methods For Determination Of Mass Per Unit Length And Mass Per Unit Area Of Fabrics (Second Revision)	—	Latest version of the standard i.e. IS 1964 :2001 shall be referred in the revision and accordingly other changes will be made wherever required.

IS 1969 : 1985 Methods for determination of breaking load and elongation of woven textile fabrics (second revision)	**IS 1969 (Part 1) : 2018** **ISO 13934-1:2013** Textiles — Tensile Properties of Fabrics Part 1 Determination of Maximum force and Elongation at Maximum Force Using the Strip Method (Fourth Revision)	—	Latest version of the standard i.e. IS 1969 (Part 1) : 2018 ISO 13934-1:2013shall be referred in the revision and accordingly other changes will be made wherever required.
IS 2006 : 1988 Quantitative chemical analysis of binary mixtures of protein fibre and certain other fibres (second revision)	Same version	NA	NA
IS 2454 : 1985 Method for determination of colour fastness of textile materials to artificial light (xenon lamp) (first revision)	**IS/ISO 105-B02 : 2014** Textiles – Tests for colour fastness – Part B02 Colour fastness to artificial light: Xenon arc fading lamp test	—	Latest version of the standard i.e. IS/ISO 105-B02 : 2014shall be referred in the revision and accordingly other changes will be made wherever required.
IS 3161 : 1979 Method for determination of colour fastness of textile materials to washing : Test 2 (first revision)	**IS/ISO 105-C10 : 2006** Textiles - Tests For Colour Fastness Part C10 Colour Fastness To Washing With Soap Or Soap And Soda	—	Latest version of the standard i.e. IS/ISO 105-C10 : 2006 shall be referred in the revision and accordingly other changes will be made wherever required.

IS 4125 : 1987 Glossary of terms pertaining to defects in fabrics (first revision)	withdrawn	NA	NA
IS 4905 : 1968 Methods for random sampling	**IS 4905 : 2015** **ISO 24153: 2009** Random Sampling and Randomization Procedures (First Revision)	—	Latest version of the standard i.e IS 4905 : 2015 ISO 24153: 2009shall be referred in the revision and accordingly other changes will be made wherever required.
IS 5910: 1977 Fineness grades of wool (first revision)	**IS 5910 : 2023** Fineness Grades of Wool (Second Revision)	—	Latest version of the standard i.e. IS 5910 :2023 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 7702 : 1975 Method for determination of thickness of woven and knitted fabrics	**IS 7702 : 2012** **ISO 5084:1996** Textiles — Determination Of Thickness Of Textiles And Textile Products (First Revision)	—	Latest version of the standard i.e IS 7702 : 2012 ISO 5084:1996 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 10014 (Part 1) : 1984 Methods Of Tests For Man-Made Staple Fibres Part 1 Determination Of Length	Same version	NA	NA

IS 10014 (Part 2) : 1981 Methods Of Tests For Man-Made Staple Fibres Part Ii Determination Of Linear Density	Same version	NA	NA
IS 11206 : 1984 Glossary of textile terms — wool and other animal fibres, their processing and products	Same version	NA	NA

iii) Any other standards available related to the subject& scope of the standard being reviewed(International/regional/other national/association/consortia, etc or of new or revision of existing Indian Standard)

Standard **(No. & Title)**	**Provisions that could be relevant while reviewing the IS**	**Action proposed**
NIL	NIL	NIL

iv) Technical comments on the standard received, if any

Source	Clause of IS	Comment	Action proposed
NIL	NIL	NIL	NIL

v) Information available on technical developments that have taken place (on product/processes/practices/use or application/testing/input materials, etc)

Source	Development	Relevant clause of the IS under review that is likely to be impacted (Clause & IS No.)	Action proposed
NIL	NIL	NIL	NIL

vi) Issues arising out of changes in any related IS or due to formulation of new Indian Standard

Related IS and its Title (revised or new)	Provision in the IS under review that would be impacted & the clause no. or addition of new clause/provision	Changes that may be necessary in the Standards under review	Action proposed
NIL	NIL	NIL	NIL

vii) Any consequential changes to be considered in other IS

Related IS to get impacted	Requirements to be impacted
NIL	NIL

6. Any other observation:

i) IS 2:1960 should be updated in the latest version of the standard.

7. Recommendations:

i) BIS certification clause should be incorporated in the latest version of the standard.
ii) Packing and marking clause should be incorporated in the latest version of the standard.
iii) Latest sampling clause should be in corporate in the latest version of the standard.
iv) ICS number should be incorporated in place of udc number in the latest version of the standard.
v) References to Indian standards may be updated
vi) Format of the standard is to be updated to A-4

REVIEW ANALYSIS OF INDIAN STANDARD
(To be submitted to the Sectional Committee)

8. *Sectional Committee No. & Title: TXD 36, (Technical Textiles for Medtech Applications Sectional Committee)*

9. IS No: 10829:1993

10. Title: X-Ray Detectable Gauze Swabs And Laparotomy Sponges- Specification (First Revision)

11. Date of review: 28 July 2023

12. Review Analysis

viii) Status of standard(s), if any from which assistance had been drawn in the formulation of this IS.

Standard (No. & Title)	Whether the standard has since been revised	Major changes	Action proposed
NIL	NIL	NIL	NIL

ix) Status ofstandards referred in the IS

Referred standards (No. & Title)	IS No. of this standards since revised	Changes that are of affecting the standard under review	Action proposed
IS : 1963-1981 Methods for determination of threads per unit length in woven fabrics (second revision)	Same version	NA	NA
IS: 1964-1970 Methods for determination of weight per square metre and weight per linear metre of fabrics (*first revision*).	**IS 1964 : 2001** Textiles – Methods for determination of mass per unit length and mass per unit area of fabrics (*second revision*)	This standard has now been revised again to provide for removal of selvedge in case the fabric mass is different than that of selvedge. The method based on determining the moisture present by moisture metre and then correcting the mass to commercial moisture regain has been deleted as the result obtained by moisture metre is not accurate	Latest version of the standard i.e. IS 1964: 2001 shall be referred in the revision and accordingly other changes will be made wherever required.

IS 10150 : 1981 Guide for sterilization of medical products	Same version	NA	NA

x) Any other standards available related to the subject& scope of the standard being reviewed(International/regional/other national/association/consortia, etc or of new or revision of existing Indian Standard)

Standard **(No. & Title)**	**Provisions that could be relevant while reviewing the IS**	**Action proposed**
NIL	NIL	NIL

xi) Technical comments on the standard received, if any

Source	**Clause of IS**	**Comment**	**Action proposed**
NIL	NIL	NIL	NIL

xii) Information available on technical developments that have taken place (on product/processes/practices/use or application/testing/input materials, etc)

Source	Development	Relevant clause of the IS under review that is likely to be impacted (Clause & IS No.)	Action proposed
NIL	NIL	NIL	NIL

xiii) Issues arising out of changes in any related IS or due to formulation of new Indian Standard

Related IS and its Title (revised or new)	Provision in the IS under reviewthat would be impacted & the clause no. or addition of new clause/provision	Changes that may be necessary in the Standards under review	Action proposed
NIL	NIL	NIL	NIL

xiv) Any consequential changes to be considered in other IS

Related IS to get impacted	Requirements to be impacted
NIL	NIL

13. Any other observation:

ii) IS 2:1960 should be updated in the latest version of the standard.

14. Recommendations:

vii) BIS certification clause should be incorporated in the latest version of the standard.
viii) Packing and marking clause should be incorporated in the latest version of the standard.
ix) Latest sampling clause should be in corporate in the latest version of the standard.
x) ICS number should be incorporated in place of udc number in the latest version of the standard.
xi) References to Indian standards may be updated
xii) Format of the standard is to be updated to A-4

REVIEW ANALYSIS OF INDIAN STANDARD
(To be submitted to the Sectional Committee)

15. *Sectional Committee No. & Title: TXD 36, (Technical Textiles for Medtech Applications Sectional Committee)*

16. IS No: 11046 - 1984
17. Title: Specification For Towel, Operating
18. Date of review: 28 July 2023

19. Review Analysis

xv) Status of standard(s), if any from which assistance had been drawn in the formulation of this IS.

Standard (No. & Title)	Whether the standard has since been revised	Major changes	Action proposed

JSS 7210-8	JSS 7210-08-2019 (Second Revision) Towel Operating, Opaline Green	NIL	NIL

xvi) Status ofstandards referred in the IS

Referred standards **(No. & Title)**	**IS No. of this standards since revised**	**Changes that are of affecting the standard under review**	**Action proposed**
IS 179-1977 Cotton Dosuti (second revision)	**IS 179 : 2009** Textiles — Cotton Dosuti — Specification (Third Revision)	—	Latest version of the standard i.e. IS 179:2009 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 756-1955 Handloom cotton dosuti grey, scoured, bleached or dyed.	**IS 756 : 1984** Specification For Handloom Cotton Dosuti And Ded-Suti, Grey, Scoured, (First Bleached Or Dyed(First Revision)	—	Latest version of the standard i.e. IS 756:1984 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 1720-1978 Specification For Cotton Sewing Threads (First Revision)	Same version	NA	NA

IS : 394 – 1963 Specification for ink, cloth marking (revised).	**IS : 394 - 1985** Specification For Ink, Cloth Marking (Second Revision)	—	Latest version of the standard i.e. IS 394:1985 shall be referred in the revision and accordingly other changes will be made wherever required.
IS : 2500 (Part 1)-1973 Sampling inspection tables: Part 1 Inspection by attributes and by count of defects.	**IS 2500 (Part 1) : 2000** **ISO 2859-1:1999** Sampling Procedure For Inspection By Attributes Part 1 Sampling Schemes Indexed By Acceptance Quality Limit (Aql) For Lot-By-Lot Inspection (Third Revision)	—	Latest version of the standard i.e. IS 2500 (Part 1) : 2000 ISO 2859-1:1999 shall be referred in the revision and accordingly other changes will be made wherever required.

xvii) Any other standards available related to the subject& scope of the standard being reviewed(International/regional/other national/association/consortia, etc or of new or revision of existing Indian Standard)

Standard **(No. & Title)**	**Provisions that could be relevant while reviewing the IS**	**Action proposed**
NIL	NIL	NIL

xviii) Technical comments on the standard received, if any

Source	Clause of IS	Comment	Action proposed
NIL	NIL	NIL	NIL

xix) Information available on technical developments that have taken place (on product/processes/practices/use or application/testing/input materials, etc)

Source	Development	Relevant clause of the IS under review that is likely to be impacted (Clause & IS No.)	Action proposed
NIL	NIL	NIL	NIL

xx) Issues arising out of changes in any related IS or due to formulation of new Indian Standard

Related IS and its Title (revised or new)	Provision in the IS under reviewthat would be impacted & the clause no. or addition of new clause/provision	Changes that may be necessary in the Standards under review	Action proposed

NIL	NIL	NIL	NIL

xxi) Any consequential changes to be considered in other IS

Related IS to get impacted	Requirements to be impacted
NIL	NIL

20. Any other observation:

iii) IS 2:1960 should be updated in the latest version of the standard.

21. Recommendations:

xiii) BIS certification clause should be incorporated in the latest version of the standard.

xiv) Packing and marking clause should be incorporated in the latest version of the standard.

xv) Latest sampling clause should be in corporate in the latest version of the standard.

xvi) ICS number should be incorporated in place of udc number in the latest version of the standard.

xvii) References to Indian standards may be updated

xviii) Format of the standard is to be updated to A-4

REVIEW ANALYSIS OF INDIAN STANDARD
(To be submitted to the Sectional Committee)

22. Sectional Committee No. & Title: TXD 36, (Technical Textiles for Medtech Applications Sectional Committee)

23. IS No: 12839 : 1989

24. Title: Wool/Polyamide Blended Flannel, Hospital, Grey — Specification

25. Date of review: 28 July 2023

26. Review Analysis

xxii) Status of standard(s), if any from which assistance had been drawn in the formulation of this IS.

Standard (No. & Title)	Whether the standard has since been revised	Major changes	Action proposed
DMSRDE/T	NIL	NIL	NIL
GS/86/332	NIL	NIL	NIL

xxiii) Status of standards referred in the IS

Referred standards (No. & Title)	IS No. of this standards since revised	Changes that are of affecting the standard under review	Action proposed
IS 32 : 1971 Code for seaworthy packaging of woollen and worsted yarn and cloth (second revision)	Same version	NA	NA

IS 665 : 1989 Method for determination of dimensional changes of fabrics containing wool on soaking in water (first revision)	Same version	NA	NA
IS 686 : 1985 Method for determination of colour fastness of textile materials to daylight *(first revision*)	**IS/ISO 105-B01 : 2014** Textiles — Tests for Colour Fastness Part B01 Colour Fastness to Light : Daylight	—	Latest version of the standard i.e. IS/ISO 105-B01 : 2014 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 741 : 1971 Code for inland packaging of woollen and worsted yarn and cloth (first revision)	Same version	NA	NA
IS 1954 : 1969 Methods for determination of length and width of fabrics (first revision)	**IS 1954 : 1990** Determination Of Length And Width Of Woven Fabrics - Methods (Second Revision)	—	Latest version of the standard i.e. IS 1954 :1990 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 1963 : 1981 Method for determination of threads per unit length in woven fabrics (second revision)	Same Version	NA	NA

IS 1964 : 1970 Methods for determination of weight per square metre and weight per linear metre of fabrics (first revision)	**IS 1964:2001** Textiles — Methods For Determination Of Mass Per Unit Length And Mass Per Unit Area Of Fabrics (Second Revision)	—	Latest version of the standard i.e. IS 1964 :2001 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 1969 : 1985 Methods for determination of breaking load and elongation of woven textile fabrics (second revision)	**IS 1969 (Part 1) : 2018** **ISO 13934-1:2013** Textiles — Tensile Properties of Fabrics Part 1 Determination of Maximum force and Elongation at Maximum Force Using the Strip Method (Fourth Revision)	—	Latest version of the standard i.e. IS 1969 (Part 1) : 2018 ISO 13934-1:2013shall be referred in the revision and accordingly other changes will be made wherever required.
IS 2006 : 1988 Quantitative chemical analysis of binary mixtures of protein fibre and certain other fibres (second revision)	Same version	NA	NA
IS 2454 : 1985 Method for determination of colour fastness of textile materials to artificial light (xenon lamp) (first revision)	**IS/ISO 105-B02 : 2014** Textiles – Tests for colour fastness – Part B02 Colour fastness to artificial light: Xenon arc fading lamp test	—	Latest version of the standard i.e. IS/ISO 105-B02 : 2014shall be referred in the revision and accordingly other changes will be made wherever required.

IS 3361 : 1979 Method for determination of colour fastness of textile materials to washing : Test 2 (first revision)	**IS/ISO 105-C10 : 2006** Textiles - Tests For Colour Fastness Part C10 Colour Fastness To Washing With Soap Or Soap And Soda	—	Latest version of the standard i.e. IS/ISO 105-C10 : 2006 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 3522 (Part 3) : 1983 Methods of estimation of common preservatives used in textile industry	Same version	NA	NA
IS 3751 : 1966 Specification for heavy cee cloth	**IS 3751 : 1993** Textiles — Heavy Cee Jute Cloth — Specification (First Revision)	—	Latest version of the standard i.e. IS 3751 :1993 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 4125 : 1987 Glossary of terms pertaining to defects in fabrics (first revision)	withdrawn	NA	NA
IS 4802 : 1988 Method for determination of colour fastness of textile material to drycleaning (first revision)	withdrawn	NA	NA
IS 4905 : 1968 Methods for random sampling	**IS 4905 : 2015** **ISO 24153: 2009** Random Sampling and Randomization	—	Latest version of the standard i.e IS 4905 : 2015 ISO 24153: 2009shall be referred

	Procedures (First Revision)		in the revision and accordingly other changes will be made wherever required.
IS 5910: 1977 Fineness grades of wool (first revision)	**IS 5910 : 2023** Fineness Grades of Wool (Second Revision)	—	Latest version of the standard i.e. IS 5910 :2023 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 5911 : 1977 Fineness grades of wool tops (first revision)	**IS 5911 : 2023** Fineness Grades of Wool Tops (Second Revision)	—	Latest version of the standard i.e. IS 5911:2023 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 10971 : 1984 Method for determining pilling resistance of fabrics	**IS 10971 (Part 1) : 2022** **ISO 12945-1:2020** Textiles — Determination of Fabric Propensity to Surface Pilling, Fuzzing or Matting Part 1 Pilling Box Method (Second Revision)	—	Latest version of the standard i.e IS 10971 (Part 1) : 2022 ISO 12945-1:2020shall be referred in the revision and accordingly other changes will be made wherever required.
IS 11206 : 1984 Glossary of textile terms — wool and other animal fibres, their processing and products	Same version	NA	NA

IS 11662 : 1986 Preservative treatment of textiles	Same version	NA	NA

xxiv) Any other standards available related to the subject& scope of the standard being reviewed(International/regional/other national/association/consortia, etc or of new or revision of existing Indian Standard)

Standard **(No. & Title)**	**Provisions that could be relevant while reviewing the IS**	**Action proposed**
NIL	NIL	NIL

xxv) Technical comments on the standard received, if any

Source	**Clause of IS**	**Comment**	**Action proposed**
NIL	NIL	NIL	NIL

xxvi) Information available on technical developments that have taken place (on product/processes/practices/use or application/testing/input materials, etc)

Source	Development	Relevant clause of the IS under review that is likely to be impacted (Clause & IS No.)	Action proposed
NIL	NIL	NIL	NIL

xxvii) Issues arising out of changes in any related IS or due to formulation of new Indian Standard

Related IS and its Title (revised or new)	Provision in the IS under review that would be impacted & the clause no. or addition of new clause/provision	Changes that may be necessary in the Standards under review	Action proposed
NIL	NIL	NIL	NIL

xxviii) Any consequential changes to be considered in other IS

Related IS to get impacted	Requirements to be impacted

NIL	NIL

27. Any other observation:

iv) IS 2:1960 should be updated in the latest version of the standard.

28. Recommendations:

xix) BIS certification clause should be incorporated in the latest version of the standard.

xx) Packing and marking clause should be incorporated in the latest version of the standard.

xxi) Latest sampling clause should be in corporate in the latest version of the standard.

xxii) ICS number should be incorporated in place of udc number in the latest version of the standard.

xxiii) References to Indian standards may be updated

xxiv) Format of the standard is to be updated to A-4

REVIEW ANALYSIS OF INDIAN STANDARD
(To be submitted to the Sectional Committee)

29. *Sectional Committee No. & Title: TXD 36, (Technical Textiles for Medtech Applications Sectional Committee)*

30. IS No: 14274:1995

31. Title: Bandage, T-Shaped, Calico - Specification

32. Date of review: 28 July 2023

33. Review Analysis

xxix) Status of standard(s), if any from which assistance had been drawn in the formulation of this IS.

Standard (No. & Title)	Whether the standard has since been revised	Major changes	Action proposed
JSS: 6510-07 (Feb 1981) 'Bandage, T-shaped, calico	6510-07 : 2020 (Sixth Revision) BANDAGE, 'T' SHAPED, CALICO	NIL	NIL

xxx) Status of standards referred in the IS

Referred standards (No. & Title)	IS No. of this standards since revised	Changes that are of affecting the standard under review	Action proposed
IS1397 : 1990 Kraft paper (second revision)	**IS 1397 : 2020** Kraft Paper for Packing and Wrapping — Specification (Third Revision)	—	Latest version of the standard i.e IS 1397 : 2020shall be referred in the revision and accordingly other changes will be made wherever required.
IS1544 : 1973 Cotton Calico (second revision)	**IS 1544 : 2022** Textiles — Cotton Calico — Specification (Second Revision)	—	Latest version of the standard i.e IS 1544 : 2022shall be referred in the revision and accordingly other changes will be made wherever required.
IS 1670 : 1991 Textile - Yarn – Determination of breaking load and elongation at break	Same version	NA	NA

of single strand (second revision)			
IS 1720 1978 Cotton sewing threads (second revision)	Same version	NA	NA
IS 1963 : 1981 Method for determination of threads per unit length in woven fabrics (second revision)	Same Version	NA	NA
IS 1964 : 1970 Methods for determination of weight per square metre and weight per linear metre of fabrics (first revision)	**IS 1964:2001** Textiles — Methods For Determination Of Mass Per Unit Length And Mass Per Unit Area Of Fabrics (Second Revision)	—	Latest version of the standard i.e. IS 1964 :2001 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 1969 : 1985 Methods for determination of breaking load and elongation of woven textile fabrics (second revision)	**IS 1969 (Part 1) : 2018** **ISO 13934-1:2013** Textiles — Tensile Properties of Fabrics Part 1 Determination of Maximum force and Elongation at Maximum Force Using the Strip Method (Fourth Revision)	—	Latest version of the standard i.e. IS 1969 (Part 1) : 2018 ISO 13934-1:2013shall be referred in the revision and accordingly other changes will be made wherever required.

IS 3442. 1980 Method for determination of crimp and count of yarn removed from fabrics (first revision)	**IS 3442 : 2023** Textiles — Method for Determination of Crimp and Linear Density of Yarn Removed from Fabric (Second Revision)	—	Latest version of the standard i.e. IS 3442 : 2023shall be referred in the revision and accordingly other changes will be made wherever required.
IS 4905 : 1968 Methods for random sampling	**IS 4905 : 2015** **ISO 24153: 2009** Random Sampling and Randomization Procedures (First Revision)	—	Latest version of the standard i.e IS 4905 : 2015 ISO 24153: 2009shall be referred in the revision and accordingly other changes will be made wherever required.
IS 6615: 1972 General purpose packing/wrapping paper	**IS 6615 : 2021** General Purpose Packing/Wrapping Paper — Specification (First Revision)	—	Latest version of the standard i.e IS 6615 : 2021 shall be referred in the revision and accordingly other changes will be made wherever required.

xxxi) Any other standards available related to the subject& scope of the standard being reviewed(International/regional/other national/association/consortia, etc or of new or revision of existing Indian Standard)

Standard **(No. & Title)**	**Provisions that could be relevant while reviewing the IS**	**Action proposed**
NIL	NIL	NIL

xxxii) Technical comments on the standard received, if any

Source	Clause of IS	Comment	Action proposed
NIL	NIL	NIL	NIL

xxxiii) Information available on technical developments that have taken place (on product/processes/practices/use or application/testing/input materials, etc)

Source	Development	Relevant clause of the IS under review that is likely to be impacted (Clause & IS No.)	Action proposed
NIL	NIL	NIL	NIL

xxxiv) Issues arising out of changes in any related IS or due to formulation of new Indian Standard

Related IS and its Title (revised or new)	Provision in the IS under review that would be impacted & the clause no. or addition of new clause/provision	Changes that may be necessary in the Standards under review	Action proposed
NIL	NIL	NIL	NIL

xxxv) Any consequential changes to be considered in other IS

Related IS to get impacted	Requirements to be impacted
NIL	NIL

34. Any other observation:

v) IS 2:1960 should be updated in the latest version of the standard.

35. Recommendations:

xxv) BIS certification clause should be incorporated in the latest version of the standard.

xxvi) Packing and marking clause should be incorporated in the latest version of the standard.

xxvii) Latest sampling clause should be in corporate in the latest version of the standard.

xxviii) ICS number should be incorporated in place of udc number in the latest version of the standard.

xxix) References to Indian standards may be updated

xxx) Format of the standard is to be updated to A-4

REVIEW ANALYSIS OF INDIAN STANDARD
(To be submitted to the Sectional Committee)

36. *Sectional Committee No. & Title:* ***TXD 36, (****Technical Textiles for Medtech Applications Sectional Committee)*

37. IS No: 14306:1995

38. Title: Bandage, Triangular ,Calico — specification

39. Date of review: 28 July 2023

40. Review Analysis

xxxvi) Status of standard(s), if any from which assistance had been drawn in the formulation of this IS.

Standard **(No. & Title)**	**Whether the standard has since been revised**	**Major changes**	**Action proposed**
JSS : 6510-02(Aug 1980) 'Bandage, triangular, calico',	6510-02 : 2020 (Seventh Revision) BANDAGE TRIANGULAR	NIL	NIL

xxxvii) Status of standards referred in the IS

Referred standards **(No. & Title)**	**IS No. of this standards since revised**	**Changes that are of affecting the standard under review**	**Action proposed**

IS 1383 : 1977 Methods for determination of scouring loss in grey and finished cotton textile materials (first revision)	Same Version	NA	NA
IS 1390 : 1983 Methods for determination of pH value of aqueous extracts of textile materials (First revision)	**IS 1390 : 2022** **ISO 3071 : 2020** Textiles — Determination of pH of Aqueous Extract (Third Revision)	—	Latest version of the standard i. IS 1390 : 2022 ISO 3071 : 2020shall be referred in the revision and accordingly other changes will be made wherever required.
IS 1397 : 1990 Kraft paper (second revision)	**IS 1397 : 2020** Kraft Paper for Packing and Wrapping — Specification (Third Revision)	—	Latest version of the standard i.e IS 1397 : 2020shall be referred in the revision and accordingly other changes will be made wherever required.
IS 1954 : 1969 Methods for determination of length and width of fabrics (first revision)	**IS 1954 : 1990** Determination Of Length And Width Of Woven Fabrics - Methods (Second Revision)	—	Latest version of the standard i.e. IS 1954 :1990 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 1963 : 1981 Method for determination of threads per unit length in woven fabrics (second revision)	Same Version	NA	NA

IS 1964 : 1970 Methods for determination of weight per square metre and weight per linear metre of fabrics (first revision)	**IS 1964:2001** Textiles — Methods For Determination Of Mass Per Unit Length And Mass Per Unit Area Of Fabrics (Second Revision)	—	Latest version of the standard i.e. IS 1964 :2001 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 1969 : 1985 Methods for determination of breaking load and elongation of woven textile fabrics (second revision)	**IS 1969 (Part 1) : 2018** **ISO 13934-1:2013** Textiles — Tensile Properties of Fabrics Part 1 Determination of Maximum force and Elongation at Maximum Force Using the Strip Method (Fourth Revision)	—	Latest version of the standard i.e. IS 1969 (Part 1) : 2018 ISO 13934-1:2013shall be referred in the revision and accordingly other changes will be made wherever required.
IS 2454 : 1985 Method for determination of colour fastness of textile materials to artificial light (xenon lamp) (first revision)	**IS/ISO 105-B02 : 2014** Textiles – Tests for colour fastness – Part B02 Colour fastness to artificial light: Xenon arc fading lamp test	—	Latest version of the standard i.e. IS/ISO 105-B02 : 2014shall be referred in the revision and accordingly other changes will be made wherever required.
IS 3361 : 1979 Method for determination of colour fastness of textile materials to washing : Test 2 (first revision)	**IS/ISO 105-C10 : 2006** Textiles - Tests For Colour Fastness Part C10 Colour Fastness To Washing With Soap Or Soap And Soda	—	Latest version of the standard i.e. IS/ISO 105-C10 : 2006 shall be referred in the revision and accordingly other changes will be made wherever required.

IS 4905 : 1968 Methods for random sampling	**IS 4905 : 2015** **ISO 24153: 2009** Random Sampling and Randomization Procedures (First Revision)	—	Latest version of the standard i.e IS 4905 : 2015 ISO 24153: 2009shall be referred in the revision and accordingly other changes will be made wherever required.
IS 6615: 1972 General purpose packing/wrapping paper	**IS 6615 : 2021** General Purpose Packing/Wrapping Paper — Specification (First Revision)	—	Latest version of the standard i.e IS 6615 : 2021 shall be referred in the revision and accordingly other changes will be made wherever required.

xxxviii) Any other standards available related to the subject& scope of the standard being reviewed(International/regional/other national/association/consortia, etc or of new or revision of existing Indian Standard)

Standard **(No. & Title)**	**Provisions that could be relevant while reviewing the IS**	**Action proposed**
NIL	NIL	NIL

xxxix) Technical comments on the standard received, if any

Source	Clause of IS	Comment	Action proposed
NIL	NIL	NIL	NIL

xl) Information available on technical developments that have taken place (on product/processes/practices/use or application/testing/input materials, etc)

Source	Development	Relevant clause of the IS under review that is likely to be impacted (Clause & IS No.)	Action proposed
NIL	NIL	NIL	NIL

xli) Issues arising out of changes in any related IS or due to formulation of new Indian Standard

Related IS and its Title (revised or new)	Provision in the IS under review that would be impacted & the clause no. or addition of new clause/provision	Changes that may be necessary in the Standards under review	Action proposed
NIL	NIL	NIL	NIL

xlii) Any consequential changes to be considered in other IS

Related IS to get impacted	Requirements to be impacted
NIL	NIL

41. Any other observation:

vi) IS 2:1960 should be updated in the latest version of the standard.

42. Recommendations:

xxxi) BIS certification clause should be incorporated in the latest version of the standard.

xxxii) Packing and marking clause should be incorporated in the latest version of the standard.

xxxiii) Latest sampling clause should be in corporate in the latest version of the standard.

xxxiv) ICS number should be incorporated in place of udc number in the latest version of the standard.

xxxv) References to Indian standards may be updated

xxxvi) Format of the standard is to be updated to A-4

REVIEW ANALYSIS OF INDIAN STANDARD
(To be submitted to the Sectional Committee)

43. *Sectional Committee No. & Title: TXD 36, (Technical Textiles for Medtech Applications Sectional Committee)*

44. IS No: 14316:1995

45. Title: Swabs, Small, In Bag Of 50 - Specification

46. Date of review: 28 July 2023

47. Review Analysis

xliii) Status of standard(s), if any from which assistance had been drawn in the formulation of this IS.

Standard (No. & Title)	Whether the standard has since been revised	Major changes	Action proposed
JSS : 6510-10 (Oct 1981) 'Swab, cotton wool, dental, box of 100 and Swab, small, in bag of SO	6510-10-2018 (Sixth Revision) Pad, cotton wool, Dental, box of 100 and Pad, small in bag of 50	NIL	NIL

xliv) Status of standards referred in the IS

Referred standards (No. & Title)	IS No. of this standards since revised	Changes that are of affecting the standard under review	Action proposed
IS 199 : 1989 Estimation of moisture, total size or finish, ash and fatty matter in grey and finished cotton textile material(third revision)	Same version	NA	NA
IS 684 : 1962 Method for determination of nep count in cotton	Same version	NA	NA

IS 758 : 1988 Handloom. cotton gauze, absorbent, non-sterilized (fourth revision)	Same version	NA	NA
1390 : 1983 Methods for determination of pH value of aqueous extracts of textile materials (First revision)	**IS 1390 : 2022** **ISO 3071 : 2020** Textiles — Determination of pH of Aqueous Extract (Third Revision)	—	Latest version of the standard i.e. IS 1390 : 2022 ISO 3071 : 2020shall be referred in the revision and accordingly other changes will be made wherever required.
IS 1720-1978 Specification For Cotton Sewing Threads (First Revision)	Same version	NA	NA
IS : 2500 (Part 1)-1973 Sampling inspection tables: Part 1 Inspection by attributes and by count of defects.	**IS 2500 (Part 1) : 2000** **ISO 2859-1:1999** Sampling Procedure For Inspection By Attributes Part 1 Sampling Schemes Indexed By Acceptance Quality Limit (Aql) For Lot-By-Lot Inspection (Third Revision)	—	Latest version of the standard i.e. IS 2500 (Part 1) : 2000 ISO 2859-1:1999 shall be referred in the revision and accordingly other changes will be made wherever required.
IS 3456 : 1966 Method for determination of water soluble matter of textile materials	**IS 3456 : 2022** Method for Determination of Water-Soluble Matter of Textile Materials (First Revision)	—	Latest version of the standard i.e. IS 3456 : 2022shall be referred in the revision and accordingly other changes will be made wherever required.

xlv) Any other standards available related to the subject& scope of the standard being reviewed(International/regional/other national/association/consortia, etc or of new or revision of existing Indian Standard)

Standard **(No. & Title)**	**Provisions that could be relevant while reviewing the IS**	**Action proposed**
NIL	NIL	NIL

xlvi) Technical comments on the standard received, if any

Source	**Clause of IS**	**Comment**	**Action proposed**
NIL	NIL	NIL	NIL

xlvii) Information available on technical developments that have taken place (on product/processes/practices/use or application/testing/input materials, etc)

Source	Development	Relevant clause of the IS under review that is likely to be impacted (Clause & IS No.)	Action proposed
NIL	NIL	NIL	NIL

xlviii) Issues arising out of changes in any related IS or due to formulation of new Indian Standard

Related IS and its Title (revised or new)	Provision in the IS under review that would be impacted & the clause no. or addition of new clause/provision	Changes that may be necessary in the Standards under review	Action proposed
NIL	NIL	NIL	NIL

xlix) Any consequential changes to be considered in other IS

Related IS to get impacted	Requirements to be impacted
NIL	NIL

48. Any other observation:

vii) IS 2:1960 should be updated in the latest version of the standard.

49. Recommendations:

xxxvii) BIS certification clause should be incorporated in the latest version of the standard.

xxxviii) Packing and marking clause should be incorporated in the latest version of the standard.

xxxix) Latest sampling clause should be in corporate in the latest version of the standard.

xl) ICS number should be incorporated in place of udc number in the latest version of the standard.

xli) References to Indian standards may be updated

xlii) Format of the standard is to be updated to A-4