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BUREAU OF INDIAN STANDARDS

MINUTES

Technical Textiles for Medtech Applications Sectional Committee, TXD 36 **12th Meeting**

Date	Time	Venue
03 April 2020 (Friday)	1500 h	Video Conference through CISCO Webex

ATTENDEES:

1. Dr Prakash Vasudevan (Chairman)	The South India Textile Research Association, Coimbatore
2. Shri T Sureshram	The South India Textile Research Association, Coimbatore
3. Dr E Santhini	- do -
4. Dr Prabha Hegde	3 M India Limited, Bangalore
5. Mr. Kulveen Bali	3 M India Limited, Bangalore
6. Shri Sumit Marwah	Dispoline India Private Limited, Bangalore
7. Ms Shivani Swamy	Living Guard, Mumbai
8. Shri V K Patil	The Bombay Textile Resesarch Association, Mumbai
9. Shri Chetan Bijesure	FICCI, New Delhi
10. Ms. Shreya Bansal	FICCI, New Delhi
11. Dr Sanjeev Relhan	FICCI, New Delhi (Shalex Overseas)
12. Shri Rajdeep Singh Grewal	FICCI, New Delhi (Du Pont, India)
13. Shri Manoh Jhaver	FICCI, New Delhi (Du Pont, India)
14. Dr A K Rakshit	Indian Technical Textile Association, Mumbai
15. Prof (Dr) Ashwani Agrawal	Indian Institute of Technology, Delhi
16. Prof (Dr) Bipin Kumar	Indian Institute of Technology, Delhi
17. Ms Shradha Dongre	SASMIRA, Mumbai
18. Shri Sudip Agarwal	Ginni Filaments Ltd, Noida
19. Shri G Joshi	Medline Healthcare Industries Pvt. Ltd, Pune
20. Shri Anthony D'Costa	Medline Healthcare Industries Pvt. Ltd, Pune
21. Shri Siva Vasi Reddi	Vimta Labs Limited, Hyderabad
22. Shri Mukesh Agrawal	Vimta Labs Limited, Hyderabad
23. Shri R Krishna Kumar	Cologenesis Healthcare Pvt Ltd
24. Shri Ravichandran	Textile Committee, Mumbai

25. Shankar G. Aggarwal	NPL, New Delhi
26. Shri Paresh Patel	Surgicot fab, Ahmedabad
27. Dr (Smt) Debarati Bhattacharjee	Terminal Ballistic Research Laboratory (DRDO) Chandigarh
28.Shri Vivek Bansal	Johnson and Johnson, Mumbai
29. Ms Satyaki Banerjee	
30. Shri Mayank Arora	
31. Dr K S Mularidharan	
32. Shri Amit Bhattacharya	
33. Ms Smita Shah	
34. Dr Vijay Shakar Tripathi	
35.Shri Dharmesh Salot	
36.Shri Santosh Malke	

BIS DIRECTORATE GENERAL:

37. Shri A K Bera, Scientist-F & Head Textiles)	Bureau of Indian Standards, New Delhi
38. Shri J.K. Gupta Scientist D (Textiles)	- do –
39. Shri Dharmbeer Scientist C (Textiles) & (Member Secretary)	- do -
40. Shri Sourabh Awasthi Young Professional (Textiles)	- do -

Item 0 WELCOME & INTRODUCTORY REMARKS

Shri A K Bera, Scientist F & Head (Textiles) while welcoming the participants explained the need of holding this urgent meeting in view of the Novel Corona virus (COVID 19) crisis and directives received from Government of India on the need of formulation of National Standard on 'Coveralls' among other items. He further stated that the draft standard has already been circulated to all the members of the Sectional Committee and some comments have also been received. He further emphasized that the Committee may consider finalizing this document under Rule 22 (4) of BIS Rules 2018 notified vide GSR 584(E) dated 25 June 2018 which states 'Provided that the wide circulation may be waived of, if the Sectional Committee is satisfied that the matter is urgent or non-controversial'.

Dr Prakash Vasudevan, Chairman also extended a hearty welcome to the members of TXD 36 and stated that only a specific item will be discussed in this meeting and all other regular items may be left for discussion in the next meeting of TXD 36. He highlighted the importance of this meeting in this critical situation and called for active participation from the members and requested for the precise inputs so the right document is finalized.

Item 1 DRAFT STANDARDS FOR FINALIZATION

1.1 Doc: TXD 36 (15526), Medical Textiles — Bio-Protective Coverall — Specification

The Committee considered the draft specification and the comments received thereon and after deliberation, the committee decided that due to urgent need to have appropriate standards on PPEs for healthcare workers due to Novel Corona virus (COVID 19) pandemic and for uniform product requirements and test methods to be followed by stakeholder, the wide circulation of the draft standard be waived off under Rule 22 (4) of BIS Rules 2018 notified vide GSR 584(E) dated 25 June 2018 draft standard be held to have been FINALIZED for publication with the following changes:

1) (*Foreword, first sentence*) and (*Definition in Clause* **3.1**) — Substitute the following for the existing:

   'Bio-protective coverall is a type of personal protective equipment (PPE) intended to be worn by healthcare personals for the purpose of isolating all parts of the body from a potential hazard.'

2) (*Scope, Clause* **1.3**) — Substitute the following for the existing:

   'This standard does not address the overall construction and components, or interfaces of garments or other factors during actual use which can affect the overall protection offered by bioprotective coverall.'

3) (*Terms and definition, Clause* **3**) — Delete the definition of dry microbial penetration, microbial penetration, wet microbial penetration.

4) (*Manufacture, Clause* **4.4**) — Substitute the following for the existing:

   'Bio-protective coverall shall be joined by sewing, adhesion, welding, thermally, ultrasonically or any other suitable technique. The seams shall be sealed with a tape of suitable material of medical grade of minimum 16 mm width or any other sealing arrangement that ensure that the seam shall pass the same tests as the body specified in Table 2. The design of the suit shall be as per the agreement between the buyer and the seller.'

5) (*Manufacture, Clause* **4.7**) — Substitute the following for the existing:

   'The size of bio-protective coverall shall be as per the agreement between buyer and seller.'

6) (*Workmanship and Finish, Clause* **5.1**) — Substitute the following for the existing:

The bio-protective coverall shall be clean and free from substances liable to cause tendering during storage. The manufacture and preparation of the coverall shall be conducted under proper hygienic conditions and in clean room as specified in ISO 14644-1 (Class 9).

7) (*Performance Requirement*, *Clause* **5.2**, *Table 2*) — Substitute the following for the existing:

Table 2 Requirements for Bio-Protective Coverall
(*Clauses* 4.4, 5.2 *and* 5.3)

Sl. No.	**Characteristic**	**Requirement**	**Method of test, Ref to**
(1)	*(2)*	*(3)*	*(4)*
i)	Tensile strength (dry and wet) (N)	≥ 20	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)
ii)	Bursting strength (dry and wet) (kPa)	≥ 40	IS 1966 (Part 1)
iii)	Seam strength (dry and wet) (N)	≥ 20	Nonwoven: IS 15891 (Part18)*, Woven: IS/ISO 13935 (Part 1)
iv)	Blood resistance (*see* note 1), Class 5, procedure A (for pressure upto 14 kPa)	Pass	IS 16546/ISO 16603
v)	Viral resistance (*see* note 1) Class 5, procedure A (for pressure upto 14 kPa)	Pass	IS 16545/ISO 16604
vi)	Cleanliness–microbial (CFU/100 cm^2) (for non-sterile coverall)	≤ 300	ISO 11737-1
vii)	Biocompatibility Evaluation (*see* note 2) (optional)		
	a) Cytotoxicity	None	IS/ISO 10993- 5
	b) Irritation and skin sensitization	Non-irritant and Non-sensitizer	IS/ISO 10993- 10

*****For determination of seam strength, the seam shall be in the centre of the test sample.

NOTE 1 — The tests of blood resistance and viral resistance shall also be carried out on samples, covering the seam, in order to test the seam performance.

NOTE 2 — Confirm the biocompatibility of raw material at designed stage. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product.

8) (*Performance Requirement*, *Clause* **5.4**,) — Substitute the following for the existing:

   The performance requirements of reusable products shall have to be met after declared wash and sterilization cycle. The manufacturer shall provide the washing, drying, handling, storage and sterilization instruction for reusable bioprotective coveralls to ensure proper use and care.

9) (*Annex A, Clause* **2**) — References to be updated accordingly.

10) (*Lot, Clause* **8.1**) — Substitute the following for the existing:

    All the bio-protective coverall of the same material produced under similar conditions of manufacture and/or sterilization shall constitute a lot.

The Committee further decided that any editorial changes, if required, may be carried out by BIS as per their procedure.

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