MINUTES

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Venue</th>
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<tbody>
<tr>
<td>03 April 2020</td>
<td>1500 h</td>
<td>Video Conference through CISCO Webex</td>
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</tbody>
</table>

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 Research 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
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
Shri A K Bera, Scientist-F & Head Textiles)  
Bureau of Indian Standards, New Delhi

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)*

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Characteristic</th>
<th>Requirement</th>
<th>Method of test, Ref to</th>
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<tbody>
<tr>
<td>i)</td>
<td>Tensile strength (dry and wet) (N)</td>
<td>≥ 20</td>
<td>Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)</td>
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<tr>
<td>ii)</td>
<td>Bursting strength (dry and wet) (kPa)</td>
<td>≥ 40</td>
<td>IS 1966 (Part 1)</td>
</tr>
<tr>
<td>iii)</td>
<td>Seam strength (dry and wet) (N)</td>
<td>≥ 20</td>
<td>Nonwoven: IS 15891 (Part18)*, Woven: IS/ISO 13935 (Part 1)</td>
</tr>
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<td>iv)</td>
<td>Blood resistance <em>(see note 1)</em>, Class 5, procedure A (for pressure upto 14 kPa)</td>
<td>Pass</td>
<td>IS 16546/ISO 16603</td>
</tr>
<tr>
<td>v)</td>
<td>Viral resistance <em>(see note 1)</em> Class 5, procedure A (for pressure upto 14 kPa)</td>
<td>Pass</td>
<td>IS 16545/ISO 16604</td>
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<tr>
<td>vi)</td>
<td>Cleanliness–microbial (CFU/100 cm²) <em>(see note 1)</em> for non-sterile coverall</td>
<td>≤ 300</td>
<td>ISO 11737-1</td>
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<tr>
<td>vii)</td>
<td>Biocompatibility Evaluation <em>(see note 2)</em> (optional)</td>
<td>None</td>
<td>IS/ISO 10993-5</td>
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<tr>
<td></td>
<td>a) Cytotoxicity</td>
<td>Non</td>
<td>IS/ISO 10993-5</td>
</tr>
<tr>
<td></td>
<td>b) Irritation and skin sensitization</td>
<td>Non-irritant and Non-sensitizer</td>
<td>IS/ISO 10993-10</td>
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*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.