
चिकित्सीय वस्त्रादि — कोविड-19 के लिए
कवरआल — विशिष्टि

Medical Textiles — Coveralls for
COVID-19 — Specification

ICS 11.140; 59.080.01

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FOREWORD

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

Coverall is a type of personal protective equipment (PPE) intended to be worn by healthcare personnel for the purpose of isolating all parts of the body from a potential hazard. Coverall for COVID-19 provides protection against various biological agents due to their material sealing arrangements.

This standard is based on guidelines issued by Ministry of Health and Family Welfare on rational use of personal protective equipment and has been developed only as interim arrangements, as an emergency temporary measure in larger public interest, to cater to the present crisis due to COVID-19 and is intended to be used for a limited period. By that time it is expected that a full-fledged standard on coverall will be formulated covering all necessary requirements.

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

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

Indian Standard

MEDICAL TEXTILES — COVERALLS FOR COVID-19 — SPECIFICATION

1 SCOPE

1.1 This standard specifies the requirements for single-use coveralls to meet the urgent need for COVID-19 pandemic.

1.2 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 coverall.

2 REFERENCES

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

3 TERMS AND DEFINITIONS

For the purpose of this standard, the following terms shall apply.

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

3.2 Coverall — Coverall is a type of personal protective equipment (PPE) intended to be worn by healthcare personnel for the purpose of isolating all parts of the body from a potential hazard.

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

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

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

4 MANUFACTURE

4.1 The coverall for COVID-19 shall be made from suitable textile material that is not prohibited for use

for the purpose under any applicable law / regulation in force so that the product made out of this meets the requirements specified in this standard.

4.1.1 The fabric used for the manufacturing of coverall shall be a single or multi-layered textile structure made of woven or non-woven (spunlace or spunbond or combination of spunbond and meltblown) or knitted structure with or without coating / lamination engineered to fulfil the functional requirements.

NOTE — The material used for manufacturing coveralls shall not cause irritation to the user.

4.2 Coverall for COVID-19 consists of an integrated hood with elastic around face opening. It shall be provided with suitable fastening arrangement which shall be covered with a storm flap with provision of self-adhesive sealing. In case of elastic waist, it shall be adhered with glue to minimize the potential entry points.

4.3 Coverall may also be provided with elastic wrists and ankles for convenience and freedom for movement. It shall also be provided with thumb loop for better and secure fit during overhead work.

4.4 Coverall shall be joined by sewing, adhesion, thermally/ultrasonically welding 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 1. The design of the coverall shall be as per the agreement between the buyer and the seller.

4.5 Each coverall shall be provided with a pair of shoe covers with an elastic strip to tighten it with the coverall, so that there is no passage for air through it.

4.6 The coverall shall be manufactured with light colours only, as it is easy to detect possible contamination on light colours.

NOTE — Coveralls shall not be manufactured with black, dark and culturally unacceptable colours.

4.7 The size of coverall shall be as per agreement between the buyer and the seller.

5 REQUIREMENTS

5.1 Workmanship and Finish

The 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.

5.2 Performance Requirements

The coverall for COVID-19 shall conform to the requirements as specified in Table 1.

5.3 The fabric used in the manufacture of shoe cover for coverall shall also conform to the requirements as specified in Table 1.

Table 1 Requirements for Coverall for COVID-19
(Clauses 4.4, 5.2 and 5.3)

Sl No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Blood resistance (see Note) Procedure C (for pressure cycle up to 3.5 kPa)	Pass	IS 16546/ ISO 16603
NOTE — The tests of blood resistance shall also be carried out on samples, covering the seam, in order to test the seam performance. Take atleast 2 samples from seam curvature.			

6 PACKAGING

The coverall shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed between the buyer and the seller. Packaging of the product shall be such as to maintain the integrity of the product.

7 MARKING

7.1 Each pack of the coverall shall be legibly and indelibly marked with following information:

- Name of the product;
- Dimension /Size of the product;
- Manufacturer's name, initials or trademark, if any;
- Month and year of manufacture, batch /lot number;
- No. of coveralls in a package;

- An indication that the device has been specified by the manufacturer for single-use only; and
- Any other statutory requirement as required by the law in force

7.1.1 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 product(s) may be marked with the Standard Mark.

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 Lot

The quantity of the coveralls delivered to the buyer against one despatch note shall constitute a lot.

8.2 The conformity of the lot to the various requirements specified in the standard shall be determined on the basis of tests carried out on the sample selected from the lot.

8.3 Unless otherwise agreed, the number of pieces selected at random for inspection shall be in accordance with Table 2.

8.3.1 For selection of samples at random from the lot, procedure given in IS 4905 may be followed.

8.4 Number of Samples and Criteria for Conformity

It shall be as follows:

Characteristics	Number of Samples	Criteria for Conformity
Workmanship and finish	According to column 3 of Table 2 pieces shall not exceed the	Number of non-conforming corresponding number given in column 4 of Table 2
5.3 and all other requirements as specified in Table 1	According to column 5 of Table 2	Number of non-conforming pieces shall not exceed the corresponding number given in column 6 of Table 2

Table 2 Sample Size and Permissible Number of Non-conforming Coveralls
(*Clauses 8.3 and 8.4*)

SI No.	Lot Size	Sample Size	Permissible Number of Non-Conforming Coveralls	Sub Sample Size	Permissible Number of Non-Conforming Coveralls for Sub Sample
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 50	5	0	3	0
ii)	51 to 150	8	1	5	0
iii)	151 to 280	13	1	8	0
iv)	281 to 500	20	2	8	0
v)	501 to 1 200	32	3	13	0
vi)	1 201 to 3 200	50	5	13	0
vii)	3 201 to 10 000	80	7	20	1
viii)	10 001 to 35 000	125	10	20	1
ix)	35 001 to 150 000	200	14	32	1
x)	150 001 to 500 000	315	21	32	1
xi)	500 001 and above	500	21	50	2

ANNEX A

(*Clause 2*)

LIST OF REFERRED INDIAN STANDARDS

<i>IS No.</i>	<i>Title</i>
4905 : 2015	Random sampling and randomization procedures (<i>first revision</i>)
16546 : 2016/ISO 16603 : 2004	Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood

ANNEX B*(Foreword)***COMMITTEE COMPOSITION**

Technical Textiles for Medtech Applications, TXD 36

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The South India Textile Research Association, Coimbatore	DR PRAKASH VASUDEVAN (Chairman)
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