PRODUCT MANUAL FOR
MEDICAL TEXTILES -COVERALLS FOR COVID-19
ACCORDING TO IS 17423:2020

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.

1.	**Product**	:	IS 17423:2020
	Title	:	Medical Textiles - Coveralls for COVID-19 - Specification
	No. of Amendments	:	Nil
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	As per Clause 4 of the Indian Standard
b)	**Grouping guidelines**	:	Please refer Annex-A
c)	**Sample Size**	:	2 coveralls
3.	**List of Test Equipment**	:	Please refer ANNEX –B
4.	**Scheme of Inspection and Testing**	:	Please refer ANNEX – C
5.	**Hygienic Conditions**	:	During factory inspections, BIS Certification officer shall ensure compliance to Hygienic Conditions as per the Checklist at Appendix-1 to the SIT.
6.	**Possible tests in a day :** Workmanship and Finish		
7.	**Scope of the Licence :**		
	"Licence is granted to use Standard Mark as per IS 17423:2020 with the following scope:"		
	Name of the product	Medical Textiles - Coveralls for COVID-19 for Single Use	
	Fabric	1. Type of Fabric: Polyester Viscose blend, Polyester with OWR etc. 2. Layers: Single or Multi Layered 3. Woven or non-woven (spunlace or spunbond or combination of spunbond and meltblown) or knitted	
	Coating or Lamination	With or Without Coating/Lamination Type of Lamination/Coating: PTFE, PU etc.	

ANNEX A

Grouping Guidelines

Samples of coveralls made of each type of fabric (Polyester Viscose blend, Polyester with OWR etc.), having the same structure (Single or Multi Layered made of: woven or non-woven (spunlace or spunbond or combination of spunbond and meltblown) or knitted structure) shall be required to be tested in order to cover that type of coverall in the scope of licence.

Separate samples of coveralls having different coatings/lamination material (LDPE, PTFE etc.) shall be required to be tested to cover those types of coatings/laminations in the scope of licence.

The above guidelines shall apply for both grant of licence and change in scope of licence.

ANNEX B

List of Test Equipment

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests used in with Clause Reference	Test Equipment
1	Blood Resistance	- Synthetic Blood - Penetration test cell, as specified in ISO 13994 - Air pressure source, capable of providing air at 20 +2/-0 kPa - Stopwatch, or electronic timer - Balance, with a precision of at least 0.01 g - Vessel, or graduated cylinder or vessel, with a precision of 1 ml - Thickness gauge, suitable for measuring thickness to the nearest 0.02 mm - Humidity Chamber for conditioning of sample to a temperature of (21 ± 5) °C and a relative humidity of (60 ± 10) % for 24 h (Reference Test Method as per Procedure C of IS 16546 : 2016/ ISO 16603 : 2004)

The above list is indicative only and may not be treated as exhaustive.

ANNEX C

Scheme of Inspection And Testing

1. LABORATORY - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

1.1 The manufacturer shall prepare a calibration plan for the test equipments.

2. TEST RECORDS – The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. PACKAGING AND MARKING – The Standard Mark as given in the Schedule of the license and shall be marked on each coverall or on its packaging, provided always that the product thus marked and packed conforms to all the requirement of the specification.

3.1 Marking and packaging shall be done as per the provisions of the Indian Standard. In addition, the following details shall be mentioned on each coverall or the packaging or attached label:

a) BIS Licence No. CM/L _____.

b) BIS website details i.e–"For details of BIS certification please visit www.bis.gov.in"

4. CONTROL UNIT – For the purpose of this scheme, entire quantity of coveralls manufactured from the same consignment of material and produced under similar conditions of manufacture in a day, shall constitute a single control unit.

5. LEVELS OF CONTROL - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

5.1 All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

6. HYGIENIC CONDITIONS - Hygienic conditions shall be complied in day to day production and quality control activities. Assessment of hygienic conditions shall be done regularly as per the Checklist enclosed at Appendix-1. Schedule for each activity for this purpose shall be displayed prominently in the factory premises and records of compliance shall be maintained.

7. REJECTIONS – Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016.

TABLE 1: LEVELS OF CONTROL

(1)				(2)	(3)		
Test Details				**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Method**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**				
4	Manufacture	4.1 to 4.7	IS 17423				
4.1	Material	4.1, 4.1.1	-do-	S	One	Each consignment	See Note 3
4.2	Hood	4.2	-do-	R		Each coverall	
4.3	Wrists/Ankles/Thumb loops	4.3	-do-	R		Each coverall	
4.4	Joining and seams, Design	4.4	-do-	R		Each coverall	i. Joining and Design requirements and width of seam shall be checked for each coverall. ii. Compliance of seam to requirements of Table 1 shall be established as per 5.2 below
4.5	Shoe covers	4.5	-do-	R		Each coverall	
4.6	Colour	4.6	-do-	R		Each coverall	
4.7	Size	4.7	-do-	R		Each coverall	Size shall be as agreed to between buyer and seller
5	Requirements						
5.1	Workmanship and Finish	5.1	IS 17423	R	-	Each coverall	

5.2	Performance requirement of Coveralls	5.2	IS 17423				
Table 1 Sl No (i)	Blood Resistance of coveralls		IS 16546	S	See Note 4		
5.3	Fabric used in manufacture of shoe cover	5.3	IS 17423	S	One	Each consignment	See Note 3

Note-1: Whether test equipment is required or sub-contracting is permitted in column 2 shall be decided by the Bureau and shall be mandatory. Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empaneled by the Bureau.

Note-2: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval to BO head.

Note-3: Conformity of the material (for coveralls and shoe covers) to the requirements of the standard may be established through test certificate issued by the manufacturer, or test report issued by a laboratory recognized by the Bureau or Government laboratories empaneled by the Bureau or in-house testing

Note-4:

i) At the beginning of the production run, no. of samples to be drawn for testing shall be based on number of coveralls produced as follows:

No. of samples to be drawn	Number of coveralls produced in a day (from the same consignment of material under similar conditions of manufacture)
One Coverall	0 – 25,000 pcs
Two coveralls	25,001 – 50,000 pcs
Three coveralls	50,001 – and above

Note: During sampling, it shall be ensured that samples are taken from each joining/sealing line by rotation. T

ii) The tests of blood resistance shall also be carried out on samples, covering the seam, in order to test the seam performance. Take at least 2 samples from seam curvature.

iii) If all samples tested as per the above frequency during 10 consecutive days are found conforming to the requirement, the frequency of testing may be reduced to one sample for every 10^{th} control unit.

iv) In case any of the samples tested fail to meet the requirement, all coveralls in that control unit shall not be marked with the BIS Standard Mark. After making necessary rectification, samples shall be tested as per the frequency specified in Sl No (i) of Note 4 and frequency of one sample every 10 control units shall be restored if and when all samples tested as per the above frequency during 10 consecutive days are found conforming to the requirement.

v) In addition, whenever there is a change in the type of material used to make coveralls, marking shall be done only after the material and coveralls made of that material are found conforming to the requirements of the standard.

APPENDIX-1

CHECKLIST FOR HYGIENIC CONDITIONS

S. No.	Aspect	Compliance (C)/Non Compliance (NC)	Remarks
1.	All the operations for manufacturing of finished coveralls (Stitching, heat sealing, marking packing etc) shall be done in closed and dust-free environment		
2.	Manufacturing of coverall should be separated from other activities with proper partition.		
3.	Toilets should not open directly in the manufacturing hall		
4.	Raw materials and finished products shall be stored in closed and damp free rooms having Pucca Floor and pallets should be used for storage		
5.	All the workers engaged in manufacturing and handling of raw materials and finished products should wear masks, gloves and headgears.		
6.	Eating, smoking, chewing tobacco or Gutkha and spitting in the manufacturing premises should be strictly prohibited. Notice to this effect should be displayed at prominent places in Hindi/English and local language.		
7.	Regular medical checkup (At least once in 3 months) for any contagious disease should be done and workers suffering from cough, cold, fever, skin diseases etc shall not be allowed to work and this should be monitored on daily basis.		
8.	Facilities for hand washing and sanitization should be provided at the entrance and hand sanitizers should be provided in shop floor also.		
9.	Entry of unauthorised persons should be strictly prohibited to the manufacturing halls.		

10.	Visitors, if allowed, must wear aprons, headgears and shoe covers etc.		
11.	Workers should be given regular training for following the hygienic conditions		