PM/17423/2
November 2021

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उत्पाद मैनुअल
चिकित्सीय वस्त्रादी – जैव रक्षात्मक कवराल – विशिष्टि

IS 17423:2021 के अनसार

PRODUCT MANUAL
FOR MEDICAL TEXTILES — BIO-PROTECTIVE COVERALLS — SPECIFICATION ACCORDINGTO IS 17423:2021

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना- I के तहत प्रमाणन के संचालन में अभ्यास और पारदर्शिता के संचालन में पारदर्शिता सुनिश्चित करने के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन लाइसेंस/प्रमाणपत्र प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता है।

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.	**उत्पाद** **Product**	:	IS 17423:2021
	शीर्षक **Title**	:	Medical Textiles — Bio-Protective Coveralls — Specification
	संशोधनों की संख्या **No. of amendments**	:	NIL
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	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. 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. (The material used for manufacturing coveralls shall not cause irritation to the user)

			Biocompatibility evaluation for Cytotoxicity and Irritation and skin sensitization shall be done on raw material at design stage (supplier's test certificates or test reports of NABL accredited labs as per IS/ISO 10993-5 and IS/ISO 10993-10 respectively shall be acceptable as evidence of conformity to this requirement)
b)	**समूहीकरण दिशानिर्देश Grouping Guidelines**	:	Please refer Annex-A
c)	**नमूने का आकार Sample Size**	:	2 Coveralls
3.	**परीक्षण उपकरणों की सूची List of Test Equipment**	:	Please refer Annex-B
4.	**निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing**	:	Please refer Annex-C
5.	**स्वास्थ्यकर स्थितियां 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.	**एक दिन में संभावित परीक्षण Possible tests in a day**		
	Construction, Workmanship and Finish		
7.	**लाइसेंस का दायरा /Scope of the Licence:**		
	"Licence is granted to use Standard Mark as per IS 17423:2021 with the following scope:		

	Name of the product	Medical Textiles — Bio-Protective Coveralls
	Fabric	• Type of Fabric: Polyester Viscose blend, Polyester with OWR etc. • Layers: Single or Multi Layered • 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.
	Performance Level	Level 1/Level 2/Level 3/Level 4
	Other	Single Use/Multiple Use (Reusable) (Number of cycles to be mentioned in case of multiple use coveralls)

ANNEX-A

GROUPING GUIDELINES

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

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.

If sample of level 4 tested, coveralls of that level as well as level 3 may be covered in the scope of licence. e.g., if coverall of Performance Level 4 is tested, Performance level 3 may be covered in the license on that basis.

Similarly, if sample of level 2 tested, coveralls of that level as well as level 1 may be covered in the scope of licence. e.g., if coverall of Performance Level 2 is tested, Performance level 1 may be covered in the license on that basis.

If multiple use coveralls are to be covered, one sample of a coverall which has been subjected to the maximum number of sterilization/disinfection cycles shall be tested (**The manufacturer shall declare the number of cycles for reusability/multiple use of coveralls based on authentic documentation and validation of the coveralls**), and multiple use coveralls for that and lower number of cycles may be covered in the scope of licence on that basis e.g. If multiple use coveralls of declared number of cycles: 4 is subjected to the 4 cycles of sterilization/disinfection etc. and then tested, multiple use coveralls of number of cycles: 3, and 2 can also be covered in the licence on that basis.

The scope of the licence shall be restricted based on the manufacturing and testing facilities available.

During surveillance, samples of each variety covered in the scope of licence shall be drawn in rotation

ANNEX – B

LIST OF TEST EQUIPMENTS

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests Used In With Clause Reference	Test Equipment/Chemical
1	Resistance to penetration by blood and body fluids (synthetic blood penetration resistance), procedure d , Cl 5.2, Table 1	-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 d of IS 16546 : 2016/ ISO 16603 : 2004)
2	Resistance to penetration by blood borne pathogens (resistance to viral penetration), procedure d , Cl 5.2, Table 1	Microorganisms and reagents: Bacteriophage Phi-X174 (ATCC 13706-B1), Bacteria E. coli (ATCC 13706), Purified water, grade 3, Nutrient broth, Calcium chloride, Potassium chloride, Sodium hydroxide, Surfactant, Bacto-agar Apparatus and materials: Penetration test cell, as specified in ISO 13994, Retaining screen, Air pressure source, Incubator[(36 ± 1) °C.], Water bath [(45 ± 2) °C**],** Balance, with a precision of 0.001 g, Vortex mixer, Refrigerator, Autoclave, Stopwatch, Orbital shaker, pH meter, sensitive to 0.1 pH, Inoculating loop, Torque wrench, capable of applying a torque of 13,6 N·m., Spectrophotometer, capable of measuring absorbed light at 640 nm, Centrifuge, capable of an acceleration of 10 000 g, Laboratory Glassware (Reference Test Method as per Procedure d of IS 16546 : 2016/ ISO 16603 : 2004)
3	Breathability (water vapour transmission rate), Cl 5.2, Table 1	A test dish which contains water, controlled environment of 27 ± 2°C at 65 ± 2 percent relative humidity, burette, triangular sample support, adhesive, adhesive tape, turntable, Balance, with a precision of 0.001 g

		(Reference Test Method as per Annex F IS 16390:2015)
4	Tensile strength (dry and wet) Cl 5.2, Table 1	For Non Woven: Tensile Testing Machine, Clamps, Cutting implements (Reference Test Method as per IS 15891 (Part 3) :2011) For Woven: Constant-rate-of-extension (CRE) tensile testing machine, cutting and immersion equipment, Nonionic wetting agent, grade 3 water (Reference Test Method as per IS 1969 (Part 1):2018)
5	Seam strength (dry and wet) Cl 5.2, Table 1	For Non Woven: Tensile Testing Machine, Clamps, Cutting implements (Reference Test Method as per IS 15891 (Part 3) :2011) For Woven: Constant-rate-of-extension (CRE) tensile testing machine, Equipment for sewing defined seams, Equipment for cutting test specimens and for fraying them to obtain the required width. (Reference Test Method as IS/ISO 13935-1:2014(E))
6	Bursting strength (dry and wet) Cl 5.2, Table 1	Bursting Tester (Reference Test Method as IS 1966 (Part 1): 2009)
7	Cleanliness-microbial Cl 5.2, Table 1	Apparatus, material and reagents as per ISO 11737-1 : 2018
8	Resistance to dry microbial penetration ,(log cfu) (At challenge concentration 108 CFU/g talcum and 30 min vibration time) Cl 5.2, Table 1	A 10 mm thick stone plate, A pneumatic ball vibrator, A compressed air flow meter, Six stainless steel test containers, A stainless steel plate with 6 retaining holes of suitable dimensions, Laboratory Glassware 50 g ± 0,5 g of talc, Purified spores of Bacillus subtilis ATCC 9372 at a concentration of ≥ 10^9 /ml of ethyl alcohol, TGE agar plates (Reference Test Method IS 16548 : 2016)
9	Biocompatibility evaluation Cl 5.2, Table 1	**Cytotoxicity Test (IS/ISO 10993 Part-5)** - Closed containers for extraction of sample - Extraction vehicle - pH meter - Water bath - Incubator (37±1°C) humidified 5% CO2/air. - Microscope - Laminar flow cabinet (Biological hazard standard). - Shaker for microstate plates. - Cell counter or hemacytometer. Weighing Balance, - Air conditioner - Petri dishes - Pipetting aid. - Pipettes (8-channel pipettes, dilution block)

		- Cryotubes. - Tissue culture flasks (80 cm2, 25 cm2) - 96-Well tissue culture microtitre plates. - Culture medium to prevent absorption -Cell lines -Negative control material (High-density polyethylene) - Positive control material. (Sodium Lauryl Sulphate (SLS) -Reference materials - Dulbecco's Modification of Eagle's Medium (DMEM), without L-glutamine - Newborn calf serum (NBCS). - Phosphate-buffered saline (PBS), without Ca2+ and Mg2+ (for trypsinization). - Phosphate-buffered saline (PBS), with Ca2+ and Mg2+ (for rinsing). - HEPES(4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid) - Dimethyl sulfoxide (AR Grade). - L-glutamine (200 mM), - Trypsin/EDTA solution. - Nutrient agar - Cell culture media - Penicillin/streptomycin solution. - Mouse fibroblasts - Agarose overlay - Neutral red, - Ethanol (AR Grade). - Glacial acetic acid (AR Grade). - Distilled water **Tests for Irritation and Skin Sensitization (IS/ISO 10993 Part-10)** - Rotary evaporator - pH meter - Pipetting aid - Weighing Balance - Shaker, - Flasks - Incubators - Petri dishes - Pipetting aid - Air conditioner - Pulverizing or grinder apparatus - Extraction vial (borosilicate glass tubes with caps) - Absorbent gauze patch (non-occlusive dressing) - Marker with permanent ink. - Extract vehicle

		- Full-spectrum lighting source - Soft catheter or blunt-tipped cannula - Occlusive chamber containing a gauze pad. - Vernier caliper - Non-irritating dressing - Non-irritating tape - Gauze pad - Spectrophotometer - Bandage (semi-occlusive or occlusive) - Water or non-irritant solvent - Methanol - Acetone - Physiological saline -Vegetable oil - Ethylene oxide - Freund's complete adjuvant (FCA) - Cytotoxic marker chemicals (Sodium dodecyl sulphate) -Vital dyes - Tissue culture medium - Distilled or Deionized water - NaCl (0.9 %) - MTT Sol. (0.3 mg/ml to 1 mg/ml) - Isopropanol - Olive oil - Dimethylsulfoxide (DMSO) - n-hexane - Ethanol - Hapten - Lubricant - Positive control (Sodium Lauryl Sulphate (SLS) - Negative control (Non-irritant, Absorbent gauze)
10	Conditioning of Samples	Conditioning Chamber(s) with temperature and relative humidity indicators

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

ANNEX B

SCHEME OF INSPECTION AND TESTING

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

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

2. **TEST RECORD**- The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. **PACKING, STERILIZATION 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.

3.2 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.

3.3 For packaging of the products, requirements as per IS/ISO 11607-1 and 2; and Medical Device Rule, 2017 shall be followed.

3.4 For sterilization, the Medical Device Rule, 2017 shall be followed. Validation of sterilization process shall be done as per IS/ISO 11135, IS/ISO 11137-1 and 2, ISO 11138-7, IS/ISO 10993-7 and ISO 17665-1 standards.

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

a) Name of the product;

b) Dimension/size of the product;

c) Manufacturer’s name, initials or trademark, if any;

d) Month and year of manufacture, batch/lot number;

e) No. of coveralls in a package;

f) Sterilized or un-sterilized;

g) Method of sterilization and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization;

h) An indication that the product has been specified by the manufacturer for single-use only;

j) Declared life cycle/maximum wash cycle, if the product is multiple/reusable;

k) If the product is multiple use, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of reuses. Where products are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the device will still

comply with “the essential principles of safety and performance of medical devices including compliance to all the requirements of this specification and Table 1 at every point of use and methodology of certification before every use ”;
m) Performance level;
n) Shelf life and storage condition; and
p) Any other requirement as per Medical Device Rules, 2017 or as required by the law in force.
q) BIS licence number and “For BIS certification details please visit www.bis.gov.in”

4. **CONTROL UNIT**- For the purpose of this scheme, entire quantity of coveralls of the same performance level, manufactured from the same consignment of material and produced under similar conditions of manufacture in a day, from the same joining/seaming line shall constitute a single control unit..

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

5.1 All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the 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. **STORAGE**: The storage of the coveralls shall be done in a temperature between 2 °C to 30 °C.

8. **REJECTION -** 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.

TABLE1

LEVELS OF CONTROL

(1)				(2)	(3)		
Test Details				**Test equipment requirement** R: required (or)S: Sub-contracting permitted	**Levels of Control**		
Cl.	Requirement	Test Methods Clause Reference			No. of Sample	Frequency	Remarks
4.1,4.1.1	Material/Fabric	4.1, 4.1.1	IS 17423:2021	S	One	Each consignment	No testing is required if material is accompanied by manufacturer's test certificate
4.2 to 4.7	Manufacture	4.2 to 4.7	-do-	R		Each coverall	
4.2	Hood	4.2	-do-	R		-do-	
4.3	Wrists/Ankles/Thumb loops	4.3	-do-	R		-do-	
4.4	Joining and Seams, design	4.4	-do-	R		-do-	
4.5	Shoe Covers	4.5	-do-	R		-do-	
4.6	Colour	4.6	-do-	R		-do-	

4.7	Size	4.7	-do-	R		-do-	
5.1	Workmanship and Finish	5.1	-do-	R		-do-	
5.2, Table 1							
i)	Resistance to penetration by blood and body fluids (synthetic blood penetration resistance), procedure d		IS 16546	S	One	Each Control Unit	The tests of synthetic blood penetration resistance and resistance to viral penetration shall also be carried out on samples, covering the seam, in order to test the seam performance. Take at least 2 specimens from critical/cross or double seam curvatures
ii)	Resistance to penetration by blood borne pathogens (resistance to viral penetration), procedure d		IS 16545	S	-do-	-do-	-do-
iii)	Breathability (water vapour transmission rate),	Annex F	IS 16390	S	-do-	-do-	

iv)	Tensile strength (dry and wet)		Nonwoven: IS 15891 (Part 3), Woven : 1969 (Part 1)	S	-do-	-do-	
v)	Seam strength (dry and wet)		Nonwoven: IS 15891 (Part18), Woven: IS/ISO 13935 (Part 1)	S	-do-	-do-	For determination of seam strength, the seam shall be in the centre of the test sample. The seam strength shall be tested in sample as received with tape
vi)	Bursting strength (dry and wet)		IS 1966 (Part 1)	S	-do-	-do-	
vii)	Cleanliness-microbial (CFU/100 cm2)		ISO 11737 (Part 1)	S	-do-	-do-	
viii)	Resistance to dry microbial penetration ,(log cfu) (At challenge concentration 108 CFU/g talcum and 30 min vibration time)		IS 16548	S	-do-	-do-	
ix)	Biocompatibility evaluation (Cytotoxicity)		IS/ISO 10993-5	S	-do-	Each consignment	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. No testing is required if material is accompanied by manufacturer's test certificate or Test Report issued by NABL Accredited Lab
x)	Biocompatibility evaluation (Irritation and skin sensitization)		IS/ISO 10993-10	S	One	-do-	-do-
5.3	Shoe cover (fabric and seam)	5.3	-do-	S	One	Each Control Unit	If the fabric used in the manufacture of shoe cover is same as that of coverall then only the seam performance shall be tested as given in Table 1 of IS 17423:2021
5.5	Reusability of Multiple Use Coveralls		As above	S	One	Once in 3 months	See Note 3
5.6	Shelf Life		As above	S	One	Once every 2 years	See Note 4

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 empanelled 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 by BO Head.

Note-3: The manufacturer shall declare the number of cycles for reusability/multiple use of coveralls based on authentic documentation and validation of the coveralls. Once in 3 months, a sample of the Multiple Use coveralls with the highest rated number of cycles covered in the scope of licence, shall be subjected to the rated cycles of cleaning, disinfection, etc. and then tested as per requirements of Table 1 (biocompatibility evaluation need not be carried out if there is no change in material)

Note-4: The shelf life of the bio-protective coverall shall be 2 years minimum. Once every two years, one sample of the highest declared shelf life, shall be tested as per requirements of Table 1 (biocompatibility evaluation need not be carried out if there is no change in material)

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		

53917/2021/CMD-II

Email **Central Marks Department II**

Re: Draft product manual for revised IS 17423:2021 - for comments

From : Textiles BIS <txd@bis.gov.in> Thu, Nov 11, 2021 05:53 PM

Subject : Re: Draft product manual for revised IS 17423:2021 - for comments 1 attachment

To : Central Marks Department II <cmd2@bis.gov.in>

Cc : Head Textiles, BIS <htxd@bis.gov.in>

Dear Sir,

The suggestion are highlighted in yellow.

Regards

Dharmbeer
Scientist C, Textiles

From: "Central Marks Department II" <cmd2@bis.gov.in>
To: "Textiles BIS" <txd@bis.gov.in>
Sent: Wednesday, November 10, 2021 12:39:17 PM
Subject: Draft product manual for revised IS 17423:2021 - for comments

Sir

CMD-2 has prepared a draft product manual for IS 17423:2021 which is attached.

It is requested to kindly examine the same and offer your comments, if any, at the earliest as it is intended to circulate the same to BOs along with guidelines for implementation of the revised standard, after approval of CA.

Regards

Aditya Das
Scientist D, CMD-2

CENTRAL MARKS DEPARTMENT-2
Bureau of Indian Standards
9, Bahadur Shah Zafar Marg
NEW DELHI - 110002.
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	Coating or Lamination	With or Without Coating/Lamination Type of Lamination/Coating: PTFE, PU etc.
	Performance Level	Level 1/Level 2/Level 3/Level 4
	Other	Single Use/Multiple Use (Reusable) (Number of cycles to be mentioned in case of multiple use coveralls)

ANNEX-A

GROUPING GUIDELINES

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

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.

~~If sample of highest performance level is tested, coveralls of that level as well as the lower levels may be covered in the scope of licence. e.g. if coverall of Performance Level 4 is tested, Performance levels 3,2, and 1 may be covered in the licence on that basis.~~

If sample of level 4 tested, coveralls of that level as well as level 3 may be covered in the scope of licence. e.g., if coverall of Performance Level 4 is tested, Performance level 3 may be covered in the license on that basis.

Similarly, if sample of level 2 tested, coveralls of that level as well as level 1 may be covered in the scope of licence. e.g., if coverall of Performance Level 2 is tested, Performance level 1 may be covered in the license on that basis.

If multiple use coveralls are to be covered, one sample of a coverall which has been subjected to the maximum number of sterilization/disinfection cycles shall be tested (**The manufacturer shall declare the number of cycles for reusability/multiple use of coveralls based on authentic documentation and validation of the coveralls**), and multiple use coveralls for that and lower number of cycles may be covered in the scope of licence on that basis e.g. If multiple use coveralls of declared number of cycles: 4 is subjected to the 4 cycles of sterilization/disinfection etc. and then tested, multiple use coveralls of number of cycles: 3, and 2 can also be covered in the licence on that basis.

The scope of the licence shall be restricted based on the manufacturing and testing facilities available.

During surveillance, samples of each variety covered in the scope of licence shall be drawn in rotation

ANNEX – B

LIST OF TEST EQUIPMENTS

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests Used In With Clause Reference	Test Equipment/Chemical
1	Resistance to penetration by blood and body fluids (synthetic blood penetration resistance), procedure d , Cl 5.2, Table 1	-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 d of IS 16546 : 2016/ ISO 16603 : 2004)
2	Resistance to penetration by blood borne pathogens (resistance to viral penetration), procedure d , Cl 5.2, Table 1	Microorganisms and reagents: Bacteriophage Phi-X174 (ATCC 13706-B1), Bacteria E. coli (ATCC 13706), Purified water, grade 3, Nutrient broth, Calcium chloride, Potassium chloride, Sodium hydroxide, Surfactant, Bacto-agar Apparatus and materials: Penetration test cell, as specified in ISO 13994, Retaining screen, Air pressure source, Incubator[(36 ± 1) °C.], Water bath [(45 ± 2) °C**],** Balance, with a precision of 0.001 g, Vortex mixer, Refrigerator, Autoclave, Stopwatch, Orbital shaker, pH meter, sensitive to 0.1 pH, Inoculating loop, Torque wrench, capable of applying a torque of 13,6 N·m., Spectrophotometer, capable of measuring absorbed light at 640 nm, Centrifuge, capable of an acceleration of 10 000 g, Laboratory Glassware (Reference Test Method as per Procedure d of IS 16546 : 2016/ ISO 16603 : 2004)
3	Breathability (water vapour transmission rate), Cl 5.2, Table 1	A test dish which contains water, controlled environment of 27 ± 2°C at 65 ± 2 percent relative humidity, burette, triangular sample support, adhesive, adhesive tape, turntable, Balance, with a precision of 0.001 g

		(Reference Test Method as per Annex F IS 16390:2015)
4	Tensile strength (dry and wet) Cl 5.2, Table 1	For Non Woven: Tensile Testing Machine, Clamps, Cutting implements (Reference Test Method as per IS 15891 (Part 3) :2011) For Woven: Constant-rate-of-extension (CRE) tensile testing machine, cutting and immersion equipment, Nonionic wetting agent, grade 3 water (Reference Test Method as per IS 1969 (Part 1):2018)
5	Seam strength (dry and wet) Cl 5.2, Table 1	For Non Woven: Tensile Testing Machine, Clamps, Cutting implements (Reference Test Method as per IS 15891 (Part 3) :2011) For Woven: Constant-rate-of-extension (CRE) tensile testing machine, Equipment for sewing defined seams, Equipment for cutting test specimens and for fraying them to obtain the required width. (Reference Test Method as IS/ISO 13935-1:2014(E))
6	Bursting strength (dry and wet) Cl 5.2, Table 1	Bursting Tester (Reference Test Method as IS 1966 (Part 1): 2009)
7	Cleanliness-microbial Cl 5.2, Table 1	Apparatus, material and reagents as per ISO 11737-1 : 2018
8	Resistance to dry microbial penetration ,(log cfu) (At challenge concentration 108 CFU/g talcum and 30 min vibration time) Cl 5.2, Table 1	A 10 mm thick stone plate, A pneumatic ball vibrator, A compressed air flow meter, Six stainless steel test containers, A stainless steel plate with 6 retaining holes of suitable dimensions, Laboratory Glassware 50 g ± 0,5 g of talc, Purified spores of Bacillus subtilis ATCC 9372 at a concentration of ≥ 10^9 /ml of ethyl alcohol, TGE agar plates (Reference Test Method IS 16548 : 2016)
9	Biocompatibility evaluation Cl 5.2, Table 1	**Cytotoxicity Test (IS/ISO 10993 Part-5)** - Closed containers for extraction of sample - Extraction vehicle - pH meter - Water bath - Incubator (37±1°C) humidified 5% CO2/air. - Microscope - Laminar flow cabinet (Biological hazard standard). - Shaker for microstate plates. - Cell counter or hemacytometer. Weighing Balance, - Air conditioner - Petri dishes - Pipetting aid. - Pipettes (8-channel pipettes, dilution block)

		- Cryotubes. - Tissue culture flasks (80 cm2, 25 cm2) - 96-Well tissue culture microtitre plates. - Culture medium to prevent absorption -Cell lines -Negative control material (High-density polyethylene) - Positive control material. (Sodium Lauryl Sulphate (SLS) -Reference materials - Dulbecco's Modification of Eagle's Medium (DMEM), without L-glutamine - Newborn calf serum (NBCS). - Phosphate-buffered saline (PBS), without Ca2+ and Mg2+ (for trypsinization). - Phosphate-buffered saline (PBS), with Ca2+ and Mg2+ (for rinsing). - HEPES(4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid) - Dimethyl sulfoxide (AR Grade). - L-glutamine (200 mM), - Trypsin/EDTA solution. - Nutrient agar - Cell culture media - Penicillin/streptomycin solution. - Mouse fibroblasts - Agarose overlay - Neutral red, - Ethanol (AR Grade). - Glacial acetic acid (AR Grade). - Distilled water **Tests for Irritation and Skin Sensitization (IS/ISO 10993 Part-10)** - Rotary evaporator - pH meter - Pipetting aid - Weighing Balance - Shaker, - Flasks - Incubators - Petri dishes - Pipetting aid - Air conditioner - Pulverizing or grinder apparatus - Extraction vial (borosilicate glass tubes with caps) - Absorbent gauze patch (non-occlusive dressing) - Marker with permanent ink. - Extract vehicle

		- Full-spectrum lighting source - Soft catheter or blunt-tipped cannula - Occlusive chamber containing a gauze pad. - Vernier caliper - Non-irritating dressing - Non-irritating tape - Gauze pad - Spectrophotometer - Bandage (semi-occlusive or occlusive) - Water or non-irritant solvent - Methanol - Acetone - Physiological saline -Vegetable oil - Ethylene oxide - Freund's complete adjuvant (FCA) - Cytotoxic marker chemicals (Sodium dodecyl sulphate) -Vital dyes - Tissue culture medium - Distilled or Deionized water - NaCl (0.9 %) - MTT Sol. (0.3 mg/ml to 1 mg/ml) - Isopropanol - Olive oil - Dimethylsulfoxide (DMSO) - n-hexane - Ethanol - Hapten - Lubricant - Positive control (Sodium Lauryl Sulphate (SLS) - Negative control (Non-irritant, Absorbent gauze)
10	Conditioning of Samples	Conditioning Chamber(s) with temperature and relative humidity indicators

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

ANNEX B

SCHEME OF INSPECTION AND TESTING

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

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

2. **TEST RECORD**- The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. **PACKING, STERILIZATION 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.

3.2 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.

3.3 For packaging of the products, requirements as per IS/ISO 11607-1 and 2; and Medical Device Rule, 2017 shall be followed.

3.4 For sterilization, the Medical Device Rule, 2017 shall be followed. Validation of sterilization process shall be done as per IS/ISO 11135, IS/ISO 11137-1 and 2, ISO 11138-7, IS/ISO 10993-7 and ISO 17665-1 standards.

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

a) Name of the product;

b) Dimension/size of the product;

c) Manufacturer’s name, initials or trademark, if any;

d) Month and year of manufacture, batch/lot number;

e) No. of coveralls in a package;

f) Sterilized or un-sterilized;

g) Method of sterilization and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization;

h) An indication that the product has been specified by the manufacturer for single-use only;

j) Declared life cycle/maximum wash cycle, if the product is multiple/reusable;

k) If the product is multiple use, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of reuses. Where products are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the device will still

comply with “the essential principles of safety and performance of medical devices including compliance to all the requirements of this specification and Table 1 at every point of use and methodology of certification before every use ”;
m) Performance level;
n) Shelf life and storage condition; and
p) Any other requirement as per Medical Device Rules, 2017 or as required by the law in force.
q) BIS licence number and “For BIS certification details please visit www.bis.gov.in”

4. **CONTROL UNIT**- For the purpose of this scheme, entire quantity of coveralls of the same performance level, manufactured from the same consignment of material and produced under similar conditions of manufacture in a day, from the same joining/seaming line shall constitute a single control unit..

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

5.1 All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the 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. **STORAGE**: The storage of the coveralls shall be done in a temperature between 2 °C to 30 °C.

8. **REJECTION -** 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.

TABLE1

LEVELS OF CONTROL

(1)				(2)	(3)		
Test Details				**Test equipment requirement** R: required (or)S: Sub-contracting permitted	**Levels of Control**		
Cl.	Requirement	Test Methods Clause Reference			No. of Sample	Frequency	Remarks
4.1,4.1.1	Material/Fabric	4.1, 4.1.1	IS 17423:2021	S	One	Each consignment	No testing is required if material is accompanied by manufacturer's test certificate
4.2 to 4.7	Manufacture	4.2 to 4.7	-do-	R		Each coverall	
4.2	Hood	4.2	-do-	R		-do-	
4.3	Wrists/Ankles/Thumb loops	4.3	-do-	R		-do-	
4.4	Joining and Seams, design	4.4	-do-	R		-do-	
4.5	Shoe Covers	4.5	-do-	R		-do-	
4.6	Colour	4.6	-do-	R		-do-	

4.7	Size	4.7	-do-	R		-do-	
5.1	Workmanship and Finish	5.1	-do-	R		-do-	
5.3	Conformity of shoe cover for seam performance as per clause 5.3 needs to be incorporated						
5.2, Table 1							
i)	Resistance to penetration by blood and body fluids (synthetic blood penetration resistance), procedure d		IS 16546	S	One	Each Control Unit	The tests of synthetic blood penetration resistance and resistance to viral penetration shall also be carried out on samples, covering the seam, in order to test the seam performance. Take at least 2 specimens from critical/cross or double seam curvatures
ii)	Resistance to penetration by blood borne pathogens (resistance to viral penetration), procedure d		IS 16545	S	-do-	-do-	-do-

iii)	Breathability (water vapour transmission rate),	Annex F	IS 16390	S	-do-	-do-	
iv)	Tensile strength (dry and wet)		Nonwoven: IS 15891 (Part 3), Woven : 1969 (Part 1)	S	-do-	-do-	
v)	Seam strength (dry and wet)		Nonwoven: IS 15891 (Part18), Woven: IS/ISO 13935 (Part 1)	S	-do-	-do-	For determination of seam strength, the seam shall be in the centre of the test sample. The seam strength shall be tested in sample as received with tape
vi)	Bursting strength (dry and wet)		IS 1966 (Part 1)	S	-do-	-do-	
vii)	Cleanliness-microbial (CFU/100 cm2)		ISO 11737 (Part 1)	S	-do-	-do-	
viii)	Resistance to dry microbial penetration ,(log cfu) (At challenge concentration 108 CFU/g talcum and 30 min vibration time)		IS 16548	S	-do-	-do-	

ix)	Biocompatibility evaluation (Cytotoxicity)		IS/ISO 10993-5	S	-do-	Each consignment	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. No testing is required if material is accompanied by manufacturer's test certificate or Test Report issued by NABL Accredited Lab
x)	Biocompatibility evaluation (Irritation and skin sensitization)		IS/ISO 10993-10	S	One	-do-	-do-
5.5	Reusability of Multiple Use Coveralls		As above	S	One	Once in 3 months	See Note 3
5.6	Shelf Life		As above	S	One	Once every 2 years	See Note 4

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 empanelled 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 by BO Head.

Note-3: The manufacturer shall declare the number of cycles for reusability/multiple use of coveralls based on authentic documentation and validation of the coveralls. Once in 3 months, a sample of the Multiple Use coveralls with the highest rated number of cycles covered in the scope of licence, shall be subjected to the rated cycles of cleaning, disinfection, etc. and then tested as per requirements of Table 1 (biocompatibility evaluation need not be carried out if there is no change in material)

Note-4: The shelf life of the bio-protective coverall shall be 2 years minimum. Once every two years, one sample of the highest declared shelf life, shall be tested as per requirements of Table 1 (biocompatibility evaluation need not be carried out if there is no change in material)

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		