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Bio-Protective Coveralls — Specification

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Bio-Protective Coveralls — Specification

1 Scope

This standard specifies the requirements for single use and reusable bio-protective coveralls intended for medical use. 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 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9073-3, *Textiles — Test methods for nonwovens: Part 3 Determination of tensile strength and elongation*

ISO 9073-18, *Textiles — Test methods for nonwovens: Part 18 Determination of breaking strength and elongation of nonwoven materials using the grab tensile test*

ISO 10993-5, *Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity*

ISO 10993-7, *Biological evaluation of medical devices: Part 7 Ethylene oxide sterilization residuals*

ISO 10993-10, *Biological evaluation of medical devices: Part 10 Tests for irritation and skin sensitization*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation: Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation: Part 2 Establishing the sterilization dose*

ISO 11138-7, *Sterilization of health care products — indicators Biological — Part 7: Guidance for the selection, use and interpretation of results*

ISO 11607-1, *Packaging for terminally sterilized medical devices: Part 1 Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices: Part 2 Validation requirements for forming, sealing and assembly processes*

ISO 11737-1, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ISO 13934-1, *Textiles — Tensile properties of fabrics: Part 1 Determination of maximum force and elongation at maximum force using the strip method*

ISO 13935-1, *Textiles — Seam tensile properties of fabrics and made-up textile articles: Part 1 Determination of maximum force to seam rupture using the strip method*

ISO 13938-1, *Textiles — Bursting properties of fabrics — Determination of bursting strength and bursting distension: Part 1 Hydraulic method*

ISO 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

ISO 14698-1, *Cleanrooms and associated controlled environments — Bio-contamination control — Part 1: General principles and methods*

ISO 16603, *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*

ISO 16604, *Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X174 bacteriophage*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process medical devices*

ISO 22612-2, *Clothing for protection against infectious agents— Test method for resistance to dry microbial penetration*

ISO 24153, *Random sampling and randomization procedures*

3 Terms and definitions

For the purpose of this standard the following definitions apply.

3.1
barrier properties
ability of a protective material to resist the penetration of liquids and resistance to airborne and liquid borne microorganisms at different state (*see* **3.8**)

3.2
bio-protective coverall
bio-protective 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
biocompatibility
the ability to be in contact with a living system without producing an adverse effect

3.4
blood-borne pathogen
Infectious microorganisms including virus carried in blood or other body fluids

3.5
body fluids
any liquid produced (secreted/excreted) by body

3.6
colony Forming Unit (CFU)
unit by which culturable number of microorganisms is expressed

3.7
cleanliness–microbial
freedom from population of viable microorganism on a product and/or a package

3.8
dry microbial penetration
migration of microorganisms through a barrier material in dry state

3.9
infective agent
microorganism that has been shown to potentially cause infections

3.10
lot
the quantity of the coveralls of same material and performance level delivered to the buyer against one dispatch note

3.11
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

3.12
performance level
discrete standard defined to classify products according to the performance requirements of this standard

3.13
reusable product
product intended by the manufacturer to be reprocessed and reused

3.14
single-use product
product intended by the manufacturer to be used only once

3.15
synthetic blood
mixture of red dye/surfactant, thickening agent, and distilled water having a surface tension and viscosity representative of blood and other body fluids and the colour of blood

4 Requirements

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

4.2 The bio-protective coveralls shall be made from suitable 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.

4.3 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.

4.4 The bio-protective coveralls consist 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 provided with suitable self-adhesive sealing arrangement such as a double-sided tape etc. In case of elastic waist, it shall be adhered with glue to minimize the potential entry points.

4.5 Coverall shall also be provided with elastic wrists and ankles. It shall also be provided with thumb loop for better and secure fit during overhead work.

4.6 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.

4.7 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.

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

4.9 The size of coverall shall be as per agreement between the buyer and the seller. The size shall be designated based on the measurement of height and chest.

4.10 Workmanship and Finish

The bio-protective coveralls 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.

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

4.12 Performance requirement

The bio-protective coveralls shall conform to the requirements as specified in Table 1.

Table 1 – Performance requirements for Bio-protective Coveralls

Characteristics	Requirements				Method of test
	Level 1	Level 2	Level 3	Leve l4	
Resistance to penetration by blood and body fluids (synthetic blood penetration resistance), procedure d (see note 1)	Pass (for pressure cycle up to 1.75 kPa)	Pass (for pressure cycle up to 3.5 kPa)	Pass (for pressure cycle up to 7 kPa)	Pass (for pressure cycle up to 14 kPa)	ISO 16603
Resistance to penetration by blood borne pathogens (resistance to viral penetration), procedure d (see note 1)	-	-	Pass (for pressure cycle up to 3.5 kPa)	Pass (for pressure cycle up to 7 kPa)	ISO 16604
Breathability (water vapour transmission rate), g/m^2/day, Max	1200	1200	800	800	Annex A
Tensile strength (dry and wet) (N)	≥ 20	≥ 20	≥ 40	≥ 40	Nonwoven: ISO 9073-3 Woven: ISO 13934-1
Seam strength (dry and wet) (N) (see note 2)	≥ 20	≥ 20	≥ 32	≥ 32	Nonwoven: ISO 9073-18 Woven : ISO 13935-1
Bursting strength (dry and wet) (kPa)	≥ 40	≥ 40	≥ 40	≥ 40	ISO 13938-1
Cleanliness-microbial (CFU/100 cm^2)	< 300	< 300	< 300	< 300	ISO 11737 - 1
Resistance to dry microbial penetration,(log cfu) (At challenge concentration 108 cfu/g talcum and 30 min vibration time)	-	-	< 1	< 1	ISO 22612-2
Biocompatibility evaluation (see note 3)					
Cytotoxicity	None	None	None	None	ISO 10993-5

Irritation and skin sensitization	Non-irritant and non-sensitizer	Non-irritant and non-sensitizer	Non-irritant and non-sensitizer	Non-irritant and non-sensitizer	ISO 10993-10
Note 1: 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. Note 2: 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. Note 3: 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.					

4.13 The regulators/user should decide the levels as given in Table 2 to be selected based on anticipated risk from infectious agents, pathogens, microorganism, distance and duration of contact with infectious agents/pathogens/microorganism, barrier protection and performance requirement as given in Table 1.

Table 2 - Use of Different Levels of Bio Protective Coverall

Performance Level	Anticipated Exposure of Risks
Level 1	Low
Level 2	Medium
Level 3	High
Level 4	Very high

4.14 The manufacturer shall declare the number of cycles for reusability/multiple use of coveralls based on authentic documentation and validation of the coveralls. The performance requirements of reusable/multiple use products shall meet after every cycle of sterilization/disinfection as given in Table 1. The probable procedures (only for guidance) for reprocessing, storage, handing, transportation, washing, disinfection of multiple use/reusable coveralls has been given in Annex A.

4.15 The shelf life of the bio-protective coverall shall be 2 years minimum. The storage of the coveralls shall be done in a temperature between 2 °C to 30 °C.

4.16 The bio-protective coveralls conforming to this standard may be supplied in sterile as well as unsterile condition, as per the agreement between the buyer and the seller.

5 Packaging and sterilization

5.1 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.

5.2 For packaging of the products, requirements as per ISO 11607-1 and 2.

5.3 Validation of sterilization process shall be done as per ISO 11135, ISO 11137-1 and 2, ISO 11138-7, ISO 10993-7 and ISO 17665-1 standards.

6 Marking and labelling

Each pack of the coverall shall be legibly and indelibly marked in the official language of member state 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;

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

j) 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”;

k) Performance level;

l) Shelf life and storage condition; and

m) Any other requirement as required by regulator.

7 Sampling and criteria for conformity

7.1 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.

7.2 Unless otherwise agreed, the number of pieces selected at random for inspection shall be in accordance with Table 3.

Table 3 - Sample Size and Permissible Number of Non-Conforming Coveralls

Lot Size	Sample Size	Permissible Number of Non-Conforming Coveralls	Sub Sample Size	Permissible Number of Non-Conforming Coveralls for Sub Sample
Up to 50	5	0	3	0
51 to 150	8	1	5	0
151 to 280	13	1	8	0
281 to 500	20	2	8	0
501 to 1200	32	3	13	0
1201 to 3200	50	5	13	0
3201 to 10000	80	7	20	1
10001 to 35000	125	10	20	1
35001 to 150000	200	14	32	1
150001 to 500000	315	21	32	1
500001 and above	500	21	50	2

7.3 For selection of samples at random from the lot, procedure given in ISO 24153 may be followed.

7.4 Number of samples and criteria for conformity shall be as in Table 4.

Table 4 - Number of Samples and Criteria for Conformity

Characteristics	Number of Samples	Criteria for Conformity
Manufacture, workmanship and finish **4.10**	According to column 2 of Table 3	Number of non-conforming pieces shall not exceed the corresponding number given in column 3 of Table 3
4.11, 4.14 and all other requirements as specified in Table 1	According to column 4 of Table 3	Number of non-conforming pieces shall not exceed the corresponding number given in column 5 of Table 3

Annex A
(normative)

Method of test for determination of water vapour permeability

A-1 Principle

A test specimen is sealed over the open mouth of a test dish which contains water, and the assembly is placed in a controlled environment of 27 ± 2°C at 65 ± 2 percent relative humidity. Following a period of time to establish an equilibrium of the water vapour pressure gradient across the sample, successive readings of the assembled dish are made and the rate of water vapour permeation through the specimen is calculated.

A-2 Sampling

The samples shall be selected from different places in the submitted sample so as to be representative of the whole. Minimum of 3 specimens from each sample shall be taken.

A-3 Conditioning of the sample

The samples need to be conditioned for minimum of 2 h in relative humidity of 65 ± 2 percent and the temperature of 27 ± 2°C.

A-4 Test Procedure

A-4.1 Take care when handling the assembled dishes and avoid splashing the inside surface of the test specimen.

A-4.2 Condition the test fabric or sample at least for 2 h in the standard atmosphere for testing

A.4.3 Take at least 3 circular specimens of approximately 9 cm diameter.

A-4.4 Using a burette, transfer the volume of water at 27 ± 2°C into each open dish predetermined from the dimensions of the dish to give an air layer which is 10 ± 1 mm deep between the surface of the water and the underside of the supported specimens. This requires approximately 46 ml of water in each dish.

A-4.5 Position the triangular sample support in the dish.

A-4.6 Apply a continuous layer of adhesive to the rim of the dish. Position the test fabric such that the face side of the sample is uppermost in the assembly.

A-4.7 Place the cover ring over the rim of the dish, and press firmly down.

A-4.8 Apply a strip of adhesive tape around the full circumference of the assembly sealing the join between the cover ring and the dish.

A-4.9 Place each assembly onto the turntable. Rotate the turntable with the assemblies for a period of 1 h to establish equilibrium of the water vapour transmission for each assembly.

A-4.10 At the end of the equilibrium period carefully weigh each assembly to the nearest 0.001g and record the results.

A-4.11 Record the time these weighings were taken and then replace the dishes on turntable.

A-4.12 Rotate the turntable for a further period of 24 h.

A-4.13 Re-weigh the assemblies to the nearest of 0.001g.

A-5 Calculation

A-5.1 Calculate the water vapour permeability by the formula as given below: Water vapour permeability, $g/m^2/day = (24 \times M) \div (T \times A)$

where
M = loss in weight of assembly after 24 h, in g;
T = time, h
A = area of the dish, m^2 (0.005 411 3 m^2).

A-5.2 Calculate the average water vapour permeability of 3 specimen readings

Annex B
(informative)

Guidelines for reprocessing, disinfection and sterilization of bio-protective coveralls

a) This guidance document, only for onus of selection of the applicable process/procedure, claims and its validation are solely the responsibility of the manufacturer/industry/supplier suiting to their respective product for reprocessing (storage, handing, transportation, washing, disinfection) of multiple use/reusable coveralls.

b) The manufacturer shall decide the suitable and effective reprocessing and disinfection method depending upon type of raw material, manufacturing process, design, anticipated risk, type of coating etc.

c) The manufacturer shall establish, document, implement and maintain a formal quality management system, which includes risk management and maintain its effectiveness. This quality management system shall include requirements throughout product realization, including development, design, manufacture, testing, packaging, labelling, processing and life-cycle control.

d) Microbiological monitoring (as per ISO 14698-1) and air monitoring of clean room (as per ISO 14644-1) shall be maintained by the manufacture.

e) The 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 shall be provided by the manufacturer.

f) The manufacturer shall follow all the applicable statutory guidelines including the medical device rules, the essential principles of safety and performance of medical devices or other rules published from time to time for coveralls.

g) For reprocessing and disinfection the seller is required to select and recommend a suitable method/technology for their product. one of the following methods or their combinations as suggested by the seller (complete and detailed protocol for reprocessing ,disinfection and quality control has to be prepared by seller/designer) based on the scientific experimentations, specific to their product and agreed by the buyer may be used:

1. Washing with detergent;
2. Sodium hypochlorite and/or soap solution;
3. Ultraviolet (UV) irradiation;
4. Gamma and electron beam irradiation;
5. Ethylene oxide sterilization;
6. Vapourised hydrogen peroxide or hydrogen peroxide gas plasma sterilization; and
7. Steam (autoclaving).

h) The manufacturer shall maintain the data for the adequacy of the disinfection method, testing of performance requirement after each cycle, usage life estimation/maximum cycle, validation of the disinfection process and certification. This technical and validated data shall be provided to the user or regulator as and when required.

Bibliography

IS 17423 : 2021 - Medical Textiles — Bio-Protective Coveralls — Specification (First Revision)