The Committee for Conformity Assessment of Accreditation and Certification on Functional and Technical Textiles

Specified Requirements of Disposable Coveralls for Medical Protective Clothing

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## 1.Scope：

This standard is suitable to the disposable coveralls for medical protective clothing which wear by the medical care personnel working in the healing institute. And not suitable to surgical gown.

Notation 1 : The applicant must attach the animal experimentation report of skin irritation test (the PII value < 2) or skin sensitization test (non-sensitization ), and the acute oral toxicity report of product supplement — mouse > 1,000 mg/kg does not have the death and abnormal phenomenon, the original edition is issued by the authentic laboratory, also perhaps the raw material merchant provides the copying report and written guarantee issued by third party laboratory.

## 2.Terminology：

2.1 medical protective clothing：item of clothing that is specifically designed and constructed for the intended purpose of isolating all or part of the body from a potential hazard or for isolating the external environment from contamination by the wearer of the clothing.

2.2 breaking strength： The stretched force applied to a material carried to rupture.

2.3 bursting strength：The distending force which is applied at right angles to plane of the fabric, under specified conditions, which will result in rupture of textile.

2.4 sewn seam strength：The strength which makes the clothes suturing place is stretched to break.

2.5 tearing strength：The force required to propagate a tear or a continued tear started in the fabric of protective clothing.

2.6 water vapor transmission rate：to determine the amount of water vapor to pass through a material after 24hours later under specified temperature and humidity, express as $g/m^2 \cdot 24h$.

2.7 hydrostatic pressure：the resistance of fabric when subjected to a hydrostatic pressure increasing at a constant rate.

2.8 impact penetration：the resistance of material to penetration of a volume of water by impact.

2.9 body fluid：any liquid produced (secreted or excreted) by the body.

2.10 penetration：in a protective clothing, the flow of a chemical on a non-molecular

level through closures, porous material, seams and pinholes or other imperfections in clothing.

2.11 synthetic blood：a mixture of a red dyes/surfactant, thickening agent, and distilled water having a surface tension and viscosity representative of blood and some other body fluids, and the color of blood.

2.12 penetration of synthetic blood：the penetration of a material by synthetic blood.

2.13 viral penetration：the penetration of a material by a virus.

2.14 sub-micron particulate filtration efficiency：the efficiency of the medical protective clothing in capturing aerosolized particles smaller than one micron; expressed as the percentage of a known number of particles that does not pass the protective clothing at a given flow rate.

## 3.Performance specification：

3.1 the classified as summarized in Table 1：

Table 1 the requirements and performances of medical protective clothing

| Class / item | P2 | P3 |
|---|---|---|
| Breaking Strength | Warp ≥50 N | Warp ≥50 N |
| | Filling ≥40 N | Filling ≥40 N |
| Bursting Strength | ≥200 kPa | ≥200 kPa |
| Sewn Seam Strength | ≥40 N | ≥40 N |
| Tearing Strength | Longitudinal〈Filling yarn〉≥20 N | Longitudinal〈Filling yarn〉≥20 N |
| | Transverse〈Warp yarn〉≥20 N | Transverse〈Warp yarn〉≥20 N |
| Water Vapor Transmission Rate | ≥1500 g/$m^2$·24h | ≥1500 g/$m^2$·24h |
| Hydrostatic Pressure | ≥50 cm$H_2O$ | ≥140 cm$H_2O$ |
| Impact Penetration | ≤1.0 g | ≤0.5 g |
| Penetration of Synthetic Blood | — | No Penetration |
| Viral Penetration | — | No Penetration |
| Sub-Micron Particulate Filtration Efficiency | ≥70% | — |

3.2 Appearance：

3.2.1 Protective clothing must be dry, clean, non- mildew spot, spots or holes on the

surface and so on.

3.2.2 The seam type to use as sewing (permit to pastes with the stopping tape) or melt method base on the performances of protective clothing. Sewing gauge required：8 to 10 stitch/2.54 cm, the stitch gauge is uniform, straight and without stitch skipping or missing stitch.

3.2.3 The edges of sleeve cuff, the open end of pants and cap covering for the head should seam with garter.

## 4.Test method（Summary）：

4.1 Appearance：By visual examination

4.2 Breaking Strength：testing accordance with 6.12(2) grab method of CNS 12915〔Method of Test for Fabrics〕.

4.3 Bursting Strength：testing accordance with 6.16 of CNS 12915〔Method of Test for Fabrics〕.

4.4 Sewn Seam Strength：testing accordance with CNS 8150〔Methods of Test for Seam Strength of Clothes〕

4.5 Tearing Strength：testing accordance with 6.15.4 trapezoid method of CNS 12915〔Method of Test for Fabrics〕.

4.6 Water Vapor Transmission Rate：testing accordance with A-1 method of CNS 12222〔Method of Test for Water Vapor Permeability of Clothes〕.

4.7 Hydrostatic Pressure：testing accordance with 5.1of CNS 10460〔Method of Test for Water Resistance of Clothes-Hydrostatic Pressure Test〕, and selecting the lowest value as the testing result.

4.8 Impact Penetration：testing accordance with CNS 14801〔Method of test for water resistance of material used in protective clothing (Impact penetration test)〕

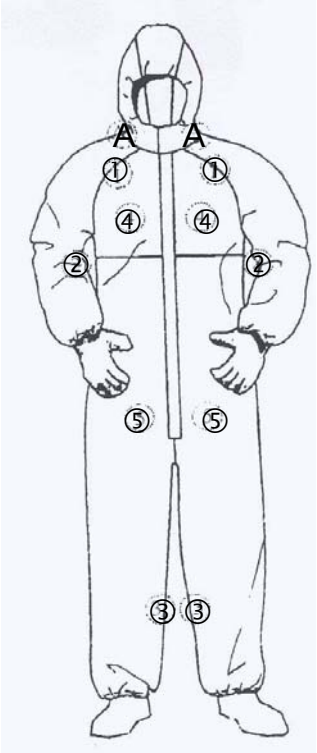
4.9 Penetration of Synthetic Blood：Takes 5 pieces of protective clothing for testing, and each clothes sjhould be sampled based on illustration 1, and tested accordance with CNS 14799〔Method of test for resistance of materials used in protective clothing to penetration by synthetic blood〕.

4.10 Viral Penetration：Takes 5 pieces of protective clothing for testing, and each clothes should be sampled based on illustration 1, and tested accordance with CNS 14800〔Method of test for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a test system〕

4.11 sub-micron particulate filtration efficiency: use the sodium chloride NaCl（gas spray）〔Count mean diameter（CMD）is 0.075±0.02 μm, Geometric standard deviation（GSD）＜1.86〕. NaCl（gas spray） should be used in the specified condition of 25±5 ℃ and 30±10 % R.H. during testing, and be neutralized to reach the Boltzmann equilibrium state. Takes 5 pieces of protective clothing for testing, and each

clothes should be sampled based on illustration 1, and test the filtration efficiency. The gas spray density does not surpass 200 mg/m$^3$, the speed of flow decides as 32±2 L/min, the test result of minimum filtration efficiency must conform to table 1 request.

Illustration 1 regulation of medical protective clothing sampling

| | |
|---|---|
| ① side seam between the body and sleeves<br>② side seam of the sleeves<br>③ side seam of the pants<br>④ front chest<br>⑤ front leg<br>**A.** seam line between the cap and body |  |
| Note 1. if the position ① without any seam line, select the position A to be tested.<br>2. if the position ② and ③ without any seam line, there still be tested.<br>3. if the protective clothing with zipper, the seam line of godet position should be tested.<br>4. if there are seam lines in the back of protective clothing, the position should be tested. | |

## 5. Marking：

5.1 the Chinese indication should affixed on protective clothing so as to be visible, and including following items：

5.1.1 the name and class of product

5.1.2 the name or code number of manufacturer (shall use original text)。

5.2 The smallest packing should indicate the following item：

5.2.1 the name and class of product。

5.2.2 the name and address of manufacturer。

5.2.3 the name and address of importer。

5.2.4 Manufacture date and Expiration date or batch number and validity duration

5.3 Use instruction：the Chinese instruction should including following items :

5.3.1 the condition and limitations of use

5.3.2 suggestions for use and application method

5.3.3 storage condition

5.3.4 Matters needing attention

5.3.5 Expiration date

## 6.Reference standard：

CNS 14798 The performance requirements for disposable medical protective clothing

CNS 8150 Methods of Test for Seam Strength of Clothes。

CNS 10460 Method of Test for Water Resistance of Clothes-Hydrostatic Pressure Test

CNS 12222 Method of Test for Water Vapor Permeability of Clothes

CNS 12915 Method of Test for Fabrics

CNS 14778 Terminology relating to protective clothing

CNS 14799 Method of test for resistance of materials used in protective clothing to penetration by synthetic blood

CNS 14800 Method of test for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a test system

CNS 14801 Method of test for water resistance of material used in protective clothing (Impact penetration test)

JIS L 1912 The methods for nonwoven fabrics of medical use

AAMI PB70/CDV4 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities