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Replace GB 19082—2003

Technical Requirements for Single-use Protective Clothing for Medical Use

医用一次性防护服技术要求

(English Translation)

（报批稿）

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FOREWORD

Beijing Institute of Medical Device Testing is in charge of this English translation. In case of any doubt about the contents of English translation, the Chinese original shall be considered authoritative.

4.2, 4.3, 4.6, 4.8 and 4.10 in this Standard are recommendatory and the rest mandatory.

This Standard replaces GB 19082—2003 *Technical Requirements for Single-use Protective Clothing for Medical Use* in whole.

Compared with GB 19082—2003, the main changes are as follows:

—Scope has been revised;

—Normative References have been supplemented and revised;

—Terms and definitions have been editorially revised;

—The requirement and test method for Electrostatic Decay have been added;

—According to GB/T 16886. 10-2005, the technical requirement of “skin irritation” has been revised, and the test method has been clarified;

—For corresponding test method for residual quantity of ethylene oxide, the gas chromatography arbitration method in GB/T 14233.1—2008 has replaced the original method in GB 15980-1995;

—The test method in Normative Annex A has been modified according to ISO 16603:2004, and the original reference method in ASTM F1670: 1998 has been replaced;

—Background information has been supplemented.

Annex A is normative.

This standard is proposed by China Food and Drug Administration.

This standard is prepared by SAC/TC 136 (Standardization Technical Committee of Clinical Laboratory Testing and *In vitro* Diagnostic Test Systems).

The previous edition of GB 19082 is as follows:

——GB 19082—2003

Technical Requirements for Single-use Protective Clothing for Medical Use

1 SCOPE

This Standard specifies the requirements, test methods, marking, instructions for use, packaging and storage of single-use protective clothing for medical use.

This Standard is applicable to single-use protective clothing for medical use (hereinafter referred to as protective clothing) that provides barrier and protection for medical personnels from infectious patients' blood, body fluids, secreta, airborne particulate matter, while they are working.

2 Normative References

The following normative documents contain provisions which, through reference in this text, constitute provisions of this standard. For dated references, subsequent amendments (excluding corrections), or revisions, of any of these publications do not apply to this standard. However parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies.

GB/T 191 *Packaging—Pictorial marking for handling of goods (GB/T 191—2008, ISO 780: 1997, MOD)*

GB/T 3923.1—1997 T*extiles—Tensile properties of fabrics—Part 1: Determination of breaking force and elongation at breaking force—Strip method*

GB/T 4744—1997 *Textile fabrics—Determination of resistance to water penetration—Hydrostatic pressure test (eqv ISO811: 1981)*

GB/T 4745—1997 *Textile fabrics—Determination of resistance to surface wetting—Spray test (eqv ISO 4920: 1981)*

GB/T 5455—1997 *Textiles—Burning behavior—Vertical method*

GB/T 5549—1990 *Surface active agents—Determination of surface tension by drawing up liquid films*

GB/T 12703—1991 *Electrostatic test methods for textile*

GB/T 12704—1991 *Fabrics—Determination of water vapor transmission rate-Dish method*

GB/T 14233. 1—2008 *Test methods for infusion, transfusion, injection equipment for medical use—Part 1: Chemical analysis methods*

GB/T 14233.2 - 2005 *Test Methods for infusion, transfusion, injection equipment for medical use—Part 2: Biological test methods*

GB 15979—2002 *Hygienic standard for disposable sanitary products*

GB/T 16886. 10-2005 *Biological evaluation of medical devices—Part 10: Tests for irritation and delayed-type hypersensitivity (ISO 10993-10: 2002, IDT)*

IST 40.2 (01) *Standard test method for electrostatic decay of nonwoven fabrics*

3 Terms and Definitions

For the purposes of this standard, the following terms and definitions apply.

3.1 Particle

Solid, liquid or solid-liquid mixed granular substance suspended in air, such as microorganisms, dust, smoke, fog, etc.

3.2 Filtering efficiency

Percentage of particles removed by protective clothing under the specified condition.

3.3 Synthetic blood

A synthetic liquid used for experiments having a surface tension and viscosity equivalent to that of blood.

3.4 Protective clothing’s critical zone

The left and right fronts, the left and right sleeves and the back of protective clothing.

3.5 Electrostatic decay

The ability of a material to eliminate charges induced to its surface when grounded.

3.6 Decay time

The time for the induced charge to decay to 10% of its initial level, in seconds.

4 Requirements

4.1 Appearance

4.1.1 Protective clothing shall be dry, clean and free from mildew spots, without adhesions, cracks, holes and other defects on the surface.

4.1.2 The connection parts of protective clothing can be processed by sewing, bonding or heat sealing. The needle hole caused by sewing shall be sealed. The needle spacing shall be 8 to14 stitches per 3 cm. The stitch shall be uniform and straight without skipping. The parts processed by bonding or heat sealing shall be flat, sealed and free of bubbles.

4.1.3 For protective clothing equipped with zippers, the zippers shall not be exposed and the sliders shall be self-locking.

4.2 Structure

4.2.1 Protective clothing consists of hooded jacket and trousers, and can be of one-piece structure and two-piece structure, see Figure 1 and Figure. 2, respectively.

4.2.2 Protective clothing should have a suitable structure and is easy to wear and take off, with the clothing seam being closed.

4.2.3 The cuffs and leg openings should adopt elastic binding-offs, while the facial part of the hood and the waist shall adopt elastic binding-offs, drawstring binding-offs or buckles.

4.3 Size and dimension

The sizes of protective clothing can include 160, 165, 170, 175, 180 and 185. See Table 1 and Table 2 for the size and dimension.

4.4 Liquid barrier performance

4.4.1 Resistance to water penetration

The hydrostatic resistance of protective clothing’s critical zone shall be at least 1.67 kPa (17cm H2O).

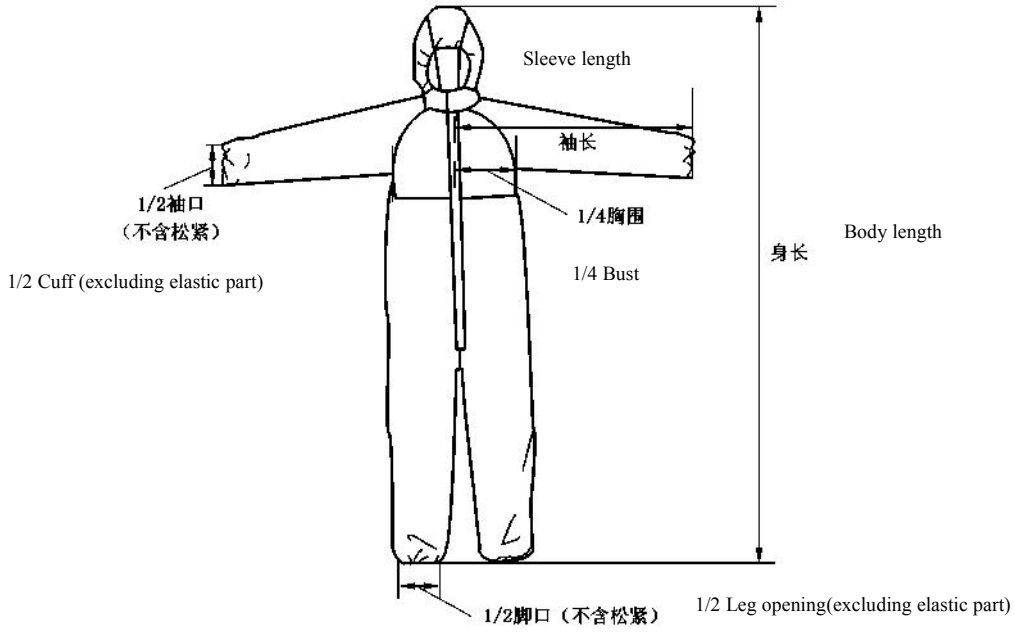

Figure 1 Protective clothing with one-piece structure

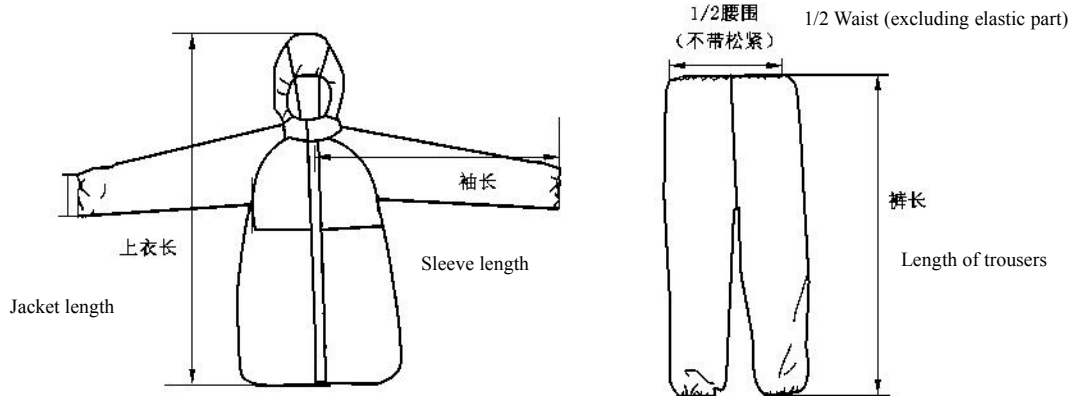

Figure 2 Protective clothing with two-piece type structure

Table 1 Size and dimension of the one-piece type in cm

Size	Body length	Bust	Sleeve length	Cuff	Leg opening
160	165	120	84	18	24
165	169	125	86	18	24
170	173	130	90	18	24
175	178	135	93	18	24
180	181	140	96	18	24
185	188	145	99	18	24
Deviation	±2	±2	±2	±2	±2

Table 2 Size and dimension of the two-piece type in cm

Size	Jacket length	Bust	Length of trousers	Waist
160	76	120	105	100～105
165	78	125	108	105～110
170	80	130	111	110～115
175	82	135	114	115～120
180	84	140	117	120～125
185	86	145	120	125～130
Deviation	±2	±2	±2	±2

4.4.2 Water vapor transmission rate

The water vapor transmission rate of protective clothing materials shall be at least 2500 g/（m^2 • d）。

4.4.3 Resistance to synthetic blood penetration

The resistance to synthetic blood penetration of protective clothing shall be no less than Level 2 in Table 3.

Table 3 Classification of resistance to synthetic blood penetration

Level	Pressure value kPa
6	20
5	14
4	7
3	3. 5
2	1. 75
1	0[a]
[a]This means that the material is only exposed to the pressure of the synthetic blood in the test cell	

4.4.4 Resistance to surface wetting

The spray rating of protective clothing's outside face shall not be less than Level 3.

4.5 Breaking force

The breaking force of the materials of protective clothing's critical zone shall not be less than 45 N.

4.6 Elongation at break

The materials of protective clothing's critical zone should have an elongation at break no less than 15%.

4.7 Filtering efficiency

The non-oily particles filtering efficiency of materials from protective clothing's critical zone , seams and joins shall not be less than 70%.

4.8 Resistance to flame

Protective clothing with resistance to flame should meet the following requirements:

a） Damaged length ≤ 200 mm;

b） Afterflame time ≤15 s;

c） Afterglow time ≤10 s.

4.9 Antistatic property

The charge carried by protective clothing shall not be more than 0. 6 μC per piece

4.10 Electrostatic decay

The electrostatic decay time of protective clothing materials should not exceed 0.5 s.

4.11 Skin irritation

The score of primary irritation shall not exceed 1.

4.12 Microbial cleanliness

4.12.1 Microbial cleanliness of protective clothing shall be in accordance with the requirements given in GB 15979—2002, see Table 4.

4.12.2 Protective clothing marked with the words or illustrations of "sterilization" or "sterility" shall be

sterile.

Table 4 Microbial cleanliness of protective clothing

Total bacterial colonies CFU/g	Coliform bacteria	*Pseudomonas aeruginosa*	*Staphylococcus aureus*	*Hemolytic streptococcus*	Total fungal colonies CFU/g
≤200	Not detected	Not detected	Not detected	Not detected	≤100

4.13 Residual quantity of ethylene oxide

For protective clothing sterilized by ethylene oxide, the residual quantity of ethylene oxide shall not exceed 10 μg/g.

5 Test Method

5.1 Appearance

5.1.1 Visual check. It shall meet the requirements given in 4.1.1.

5.1.2 Visual check. Measured with a common measuring tool, the needle spacing shall meet the requirements given in 4.1.2.

5.1.3 Three pieces of protective clothing are provided for inspection Pull and close the zipper of each protective clothing for 5 timesand all shall meet the requirements given in 4.1.3.

5.2 Structure

Visual check. It should meet the requirements given in 4.2.

5.3 Size and dimension

Three pieces of protective clothing should be measured with common measuring tools for each size, and all should meet the requirements given in 4.3.

5.4 Liquid barrier performance

5.4.1 Resistance to water penetration

The specimens shall be taken from protective clothing's critical zone, and then tested with hydrostatic pressure test method as specified in GB/T 4744—1997. It shall meet the requirements given in 4.4.1.

5.4.2 Water vapor transmission rate

The specimens of protective clothing materials shall be tested in accordance with procedure A moisture

absorption method as specified in GB/T 12704—1991. It shall meet the requirements given in 4.4.2.

5.4.3 Resistance to synthetic blood penetration

The specimens of protective clothing materials shall be tested according to Annex A. It shall meet the requirements given in 4.4.3.

5.4.4 Resistance to surface wetting

The outside face of the specimens shall be tested in accordance with GB/T 4745—1997. It shall meet the requirements given in 4.4.4.

5.5 Breaking force

The specimens of Protective clothing materials from critical zone shall be tested in accordance with strip method as specified in GB/T 3923.1—1997. It shall meet the requirements given in 4.5.

5.6 Elongation at break

The specimens of Protective clothing materials from critical zone shall be tested in accordance with strip method as specified in GB/T 3923.1—1997. It should meet the requirements given in 4.6.

5.7 Filtering efficiency

At least three pieces of protective clothing shall be tested, and all shall meet the requirements given in 4.7.

The test shall be carried out in the environment with relative humidity of 30% ± 10% and temperature of 25℃ ± 5℃, using the sodium chloride aerosol or similar solid aerosol [count median particle diameter (CMD)[1)]: 0.075 μm ± 0.020 μm; geometric standard deviation of particle distribution: ≤ 1.86; concentration: ≤200 mg/m^3]. The air flow rate is set at 15 L/min ± 2 L/min, and the cross-sectional area through which the airflow passes is 100 cm^2.

5.8 Resistance to flame

The specimens of protective clothing materials shall be tested in accordance with the vertical method as specified in GB/T 5455—1997 .It should meet the requirements given in 4.8.

5.9 Antistatic property

The specimens of protective clothing materials shall be tested in accordance with GB/T 12703—1991, 7.2. It shall meet the requirements given in 4.9.

5.10 Electrostatic decay

5.10.1 Test environment

Before test, the specimens shall be conditioned at (23 ± 1)℃ and (50 ± 3)% relative humidity for 24 hours. The test shall also be carried out under this condition.

5.10.2 Sampling

One specimen with the size of 89 mm × (152 ± 6) mm is taken from each part of the protective clothing's critical zone. Latex or cotton-textile gloves shall be worn properly in case of contamination to the sample surface.

5.10.3 Test

The specimens shall be tested in accordance with IST40.2 (01), with an electrostatic decay meter which can generate a voltage of at least (±) 5,000 V. The charge decay time is measured, after a voltage of 5,000 V is applied to the materials. All five specimens tested should meet the requirements given in 4.10.

5.11 Skin irritation

5.11.1 Extraction medium

0.9% sodium chloride solution.

5.11.2 Preparation of extract liquid

Two specimens with the size of 2.5cm×2.5 cm are cut from protective clothing under aseptic environment. The extraction medium added at a ratio of 1mL/cm^2 is placed at 37℃ for 72 hours. The negative control is prepared with the same medium without test specimen.

5.11.3 Test

The specimens shall be tested in accordance with GB/T 16886.10—2005, 6.3. It shall meet the requirements given in 4.11.

5.12 Microbial cleanliness

5.12.1 The samples shall be tested in accordance with GB 15979—2002, Annex B. It shall meet the requirements given in 4.12.1.

5.12.2 The samples shall be tested in accordance with GB/T 14233.2—2005, Clause 3. It shall meet the requirements given in 4.12.2.

5.13 Residual quantity of ethylene oxide

5.13.1 Gas chromatograph conditions

Following conditions shall be adopted:

a) Hydrogen flame detector: sensitivity better than 2×10^{-11}g/s [benzene, carbon disulfide (CS_2)].

b) Chromatographic column: the chromatographic column with certain water tolerance shall be able to separate impurities from ethylene oxide completely in the specimen. See the recommended conditions in Table 5

Table 5 Recommended Conditions for Chromatographic Columns

Column length	Inner diameter	Chromatographic support	Column temperature
1m～2 m	2 mm ～3 mm	GDX-407, 80~100 mesh	About 130℃
		Porapak q-s, 80~100 mesh	About 120℃

c) Temperature of each part of the instrument:

—Vaporizing chamber: 200℃;

—Detector chamber: 250℃.

d) Gas flow rate:

——N_2: 15 mL/min～30 mL/min；

——H_2: 30 mL/min；

——Air: 300 mL/min;

5.13.2 Test procedure

Two specimens are tested in parallel with the exhaustive extraction method using water as extraction medium as specified in GB/T 14233.1—2008, 9.4. The results are obtained with the relative content method as specified in GB/T 14233.1—2008, 9.5.2, and the arithmetic average is calculated. If one result is qualified and the other not, the average shall not be calculated and the test shall be repeated.

6 Marking and Instructions for Use

6.1 Marking

6.1.1 The minimal packaging of protective clothing shall have clear and recognizable information as follows. If the packaging is transparent, the information shall be visible through the packaging:

a) Product name;

b) Name and address of the manufacturer or supplier;

c) Product size and dimension;

d) Executive standard number;

e) Product registration number;

f) If it is a sterilized product, the sterilization method shall be indicated;

g) "Single use" or equivalent words;

h) Date of production;

i) Storage conditions and expiry date;

j) "Read instructions before use" or equivalent words.

6.1.2 The marking in packaging of protective clothing shall at least include:

a) Product name;

b) Name and address of the manufacturer or supplier;

c) Product size and dimension;

d) Executive standard number;

e) Product registration number;

f) Numbers in one packaging;

g) "Single use" or equivalent words;

h) If it is a sterilized product, the sterilization method shall be indicated;

i) Date of production;

j) Storage conditions and expiry date;

k) "Away from sun light", "**Protected from moisture** " and other words and signs.

6.2 Instructions for use

6.2.1 There shall be instructions for use in Chinese at least.

6.2.2 Instructions for use shall be clear and intelligible, and corresponding diagrams can be used.

6.2.3 Instructions for use shall at least include the following contents:

a) Product name;

b) Manufacturer's name, address and contact information;

c) Product usage and use restrictions;

d) Executive standard number;

e) Product registration number;

f) Description of resistance to flame;

g) Inspection before use;

h) List of size and dimension;

i) Method and recommended time for use;

j) Storage conditions and expiry date;

k) Meaning of the symbols and/or diagrams used;

l) Precautions.

7 Packaging and storage

7.1 Packaging

7.1.1 The marks of storage and transportation on the outer packaging shall meet the requirements given in GB/T191.

7.1.2 The packaging used shall be able to prevent protective clothing from mechanical damage and pollution before use.

7.1.3 A copy of instructions for use and product inspection certificate shall be provided in the minimal packaging of protective clothing.

7.2 Storage

Follow the Instructions for use.

Appendix A

(Normative)

Test method for resistance to penetration by synthetic blood

A.1 Scope

This test is to determine the resistance of protective clothing to penetration by synthetic blood under different test pressures.

A.2 Method

The test is conducted by subjecting the protective clothing material to synthetic blood for a continuously applied pressure sequence and observing the visible penetration of the liquid.

A.3 Instruments

The instruments required for the test are as follows:

a) The penetration test cell as shown in Figure A.1 and test instruments as shown in Figure A.2; stainless steel is preferred.

b) Square metal retaining screen, which shall meet the following requirements:

- open porosity> 50%;
- Bending ≤ 5mm at 14kPa;

c) Air source, capable of providing air at 14 kPa ± 1 kPa;

d) Stopwatch, with accuracy of 1 s;

e) Analytical balance, with a precision of 0.01g;

f) Swivel clamp, capable of generating torque of 13.5N•m;

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[1] 2- methyl -4- isothiazolin -3- one hydrochloride (MIT) (0. 5g/L) can be added to **synthetic blood** to prolong the storage period of the solution.

[2] Sigma 9004-32-4, Fluka 9377, Sigma 915-67-3 and Fluka 9377 are examples of suitable products available commercially.This information is provided for the convenience of users of this standard and does not constitute an endorsement of these products.

g) Surface tensiometer.

A.4 Synthetic blood

A.4.1 Ingredients

1L synthetic blood is prepared in accordance with YY/T 0700—2008, Appendix A [1]:

Sodium carboxymethylcellulose [e.g., CMC-Sigma9004-32-4[2], Medium viscosity]	2g
Polyoxyethylene (20) sorbitanmonolaurate {e.g., Tween 20 [Fluka9377[2]]}	0.04g
Sodium chloride (analytical pure)	2.4g
Amaranth dye [e.g., Sigma 915-67-3[2]]	1.0g.
Potassium dihydrogen phosphate (KH_2PO_4)	1.2g
Disodium hydrogen phosphate (Na_2HPO_4)	4.3g
Distilled water or deionized water	up to 1L

A.4.2 Preparation method

Dissolve sodium carboxymethyl cellulose in 0. 5 L water and mix 60 min on a magnetic stirrer.

Weigh the Tween 20 in a small beaker, add water and mix.

Add the Tween 20 solution to the sodium carboxymethylcellulose solution, rinse the beaker several times with distilled water and add it to the former solution.

Dissolve the sodium chloride in the solution. Dissolve the KH_2PO_4 and Na_2HPO_4 in the solution.

Add MIT (if used) and the amaranth dye.

Dilute the solution with water up to nearly 1,000 ml.

Adjust the pH of the synthetic blood to 7.3 ± 0.1 using phosphate buffered solution, and finally set the volume to 1000 mL.

Measure the surface tension of the synthetic blood in accordance with GB/T 5549—1990, and the result shall be 0.042 N/m ± 0.002 N/m.

A.5 Preparation of test samples

Three test specimens with the size of 75 mm × 75 mm are cut randomly from each protective clothing sample.

Seal the edges when testing composite or multi-layer materials, leaving the center area greater than 57 mm diameter for testing.

A.6 Test procedure

A.6.1 Assemble the test cell as shown in Figure A.1:

a) With the test cell placed horizontally on the lab bench, insert the specimen in the penetration cell with the normal outside surface of the material toward the cell reservoir;

b) Place one gasket, the retaining screen and another gasket on the test cell in sequence. Put on the flange cover and transparent cover, and tighten the penetration test cell.

c) Mount the penetration test cell in the test apparatus in a vertical position (drain valve down);

d) Slowly torque the bolts in the penetration test cell to 13.5 N•m each;

e) Close the drain valve.

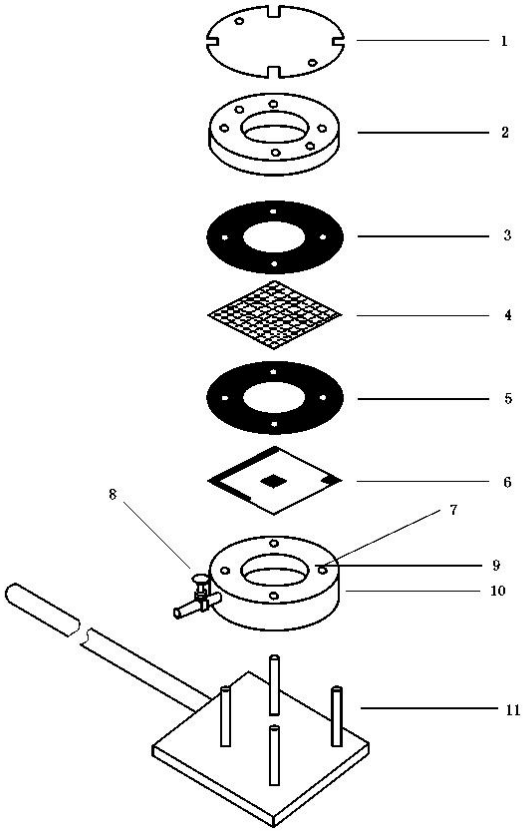
A.6.2 Fill the penetration test cell reservoir through the top port with approximately 50 mL～55 mL of synthetic blood with a funnel or syringe. Observe for 5 min. If liquid penetrates through the test specimen, terminate the test.

A. 6.3 If no synthetic blood penetration is observed, connect the air line to the test instrument shown in Fig. A. 2 and input air with a certain pressure into the penetration test cell via the upper inlet. Gradually increase the pressure to 1.75 kPa. Maintain this pressure for 5 min and observe whether there is liquid penetration on the visible surface of the sample. If liquid penetrates through the test specimen, terminate the test. The resistance of the sample to synthetic blood penetration is Level 1.

A.6.4 If no synthetic blood penetration is observed, slowly increase the pressure to 3.5 kPa and maintain the pressure for 5 min. Check whether there is liquid penetration on the visible surface of the sample. If liquid penetrates through the test specimen, terminate the test. The resistance of the sample to synthetic blood penetration is Level 2.

A.6.5 If no synthetic blood penetration is observed, slowly increase the pressure to 7 kPa and maintain the pressure for 5 min. Check whether there is liquid penetration on the visible surface of the sample. If liquid penetrates through the test specimen, terminate the test. The resistance of the sample to synthetic

blood penetration is Level 3.



1—transparent cover
2—flange cover
3—gasket
4—retaining screen
5—gasket
6—test sample
7—top port
8—drain valve
9—PTFE gasket material
10—cell body
11—cell support

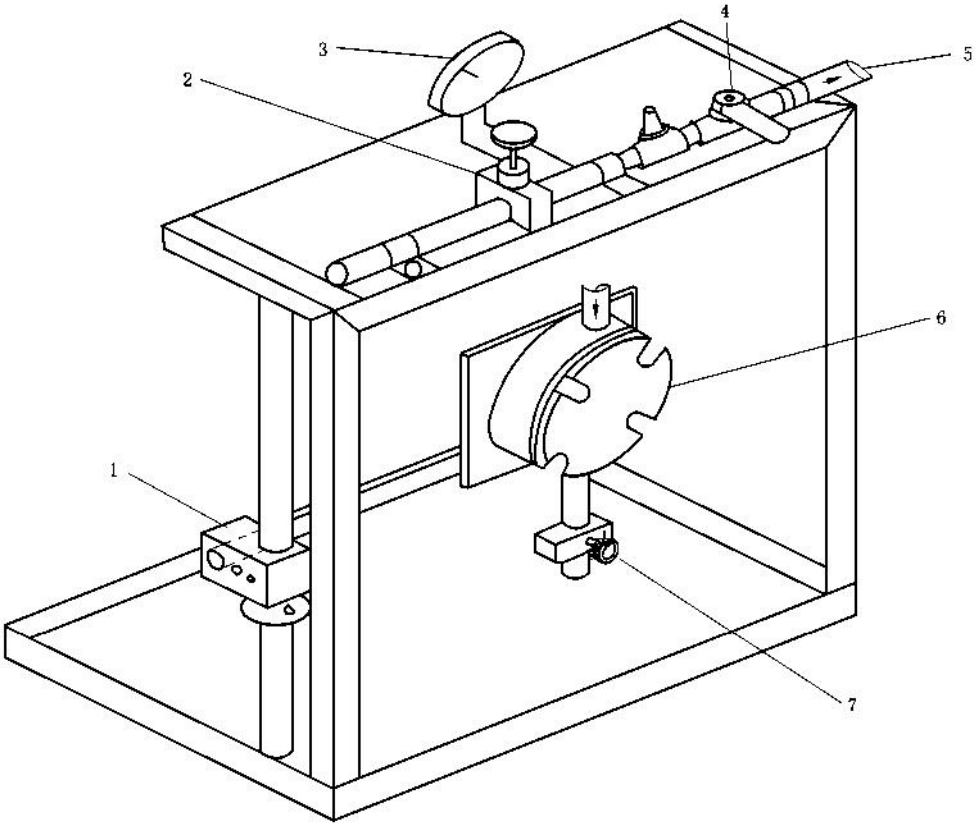
Figure A.1 Structure of test cell

A.6.6 If no synthetic blood penetration is observed, slowly increase the pressure to 14 kPa and maintain the pressure for 5 min. Check whether there is liquid penetration on the visible surface of the sample. If liquid penetrates through the test specimen, terminate the test. The resistance of the sample to synthetic blood penetration is Level 4.

A.6.7 If no synthetic blood penetration is observed, slowly increase the pressure to 20 kPa and maintain the pressure for 5 min. Check whether there is liquid penetration on the visible surface of the sample. If liquid penetrates through the test specimen, terminate the test. The resistance of the sample to synthetic blood penetration is Level 5. If no synthetic blood penetration is observed, the resistance of the sample to synthetic blood penetration is Level 6.

A.6.8 After the test, turn off the pressure and open the cell valve of the penetration test cell to vent position.

A.6.9 Open the drain valve to empty the synthetic blood. Flush the test cell with an appropriate wash liquid to remove the residual blood. Remove the specimen and gasket from the test cell. Clean any external parts of the test cell which may have been touched by synthetic blood.



1—swivel clamp
2—air pressure regulator
3—pressure gauge
4—cell vent valve
5—to test cell
6—test cell
7—drain valve

Figure A.2 Schematic diagram of test apparatus

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[7] YY/T 0700—2008 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 16603: 2004, IDT)

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