

Medical Isolation Shoe Covers

1. Product model / specification and its division description

1.1 Product name: Medical isolation shoe cover, hereinafter referred to as shoe cover

1.2 According to the medical device management classification, it belongs to Class I 14-14-05 Medical personnel protective equipment-foot protective equipment, which is provided for non-sterile and disposable use.

1.3 It is divided into: high state type, low state type, there are pressure strip and non-pressure strip according to the product shape and production process

1.4 It can be divided into: L (35-40 yards), XL (41-45 yards) according to the different size

1.5 Basic structure of shoe cover: made of plastic film, non-woven cloth or non-woven cloth film, foot mouth for elastic mouth treatment, the bare foot can be selected by cloth belt tightening, cloth belt with non-woven cloth or non-woven cloth film.

1. Performance index

2.1 Dimensional requirement

It shall meet the requirements of Table 1.

Model Size	High state type, low state type		
	S(34-37)	M(38-42)	L (42-45)
Boots length×Boots width×Boots height(cm)	36×20×25~50	37×21×25~50	38×22×25~50
Tolerance (cm)	±3cm		

2.2 Appearance Requirements

2.2.1 Shoe cover is smooth, no holes, stains, no splicing phenomenon.

2.2.2 The hot closing or sewing place is uniform and straight, and the sewing shall not be less than 2 stitches per centimeter.

2.2.3 No raw edges, leaky seams, cracking and other phenomena are allowed in the hot closing or sewing place.

2.2.4 The layering type should be able to hold the suture line completely, and there should be no exposure of the suture.

2.3 Structural Requirements

2.3.1 The structure of the shoe cover should be reasonable, easy to wear and take off, and the layering type should have a binding design.

2.3.2 The foot mouth adopts elastic closing, and the combination is tight.

2.4 Impermeability

The hydrostatic pressure of key parts should not be less than 1.67kPa(17cmH₂O).

2.5 Resistance to synthetic blood penetration

Resistance to synthetic blood penetration should not be lower than the requirements of level 2 in Table 2.

Table 2 Anti-synthetic blood penetration classification

Grade	Pressure value/kPa
6	20
5	14
4	7
3	3.5
2	1.75
a indicates that the pressure applied to the material is only that generated by the synthetic blood in the test tank	

2.6 Surface moisture resistance

The external side water grade is ≥ 2 .

2.7 Breaking strength

The breaking strength of the material in the key part should not be less than 40N.

2.8 elongation at break

The elongation at break of the material should not be less than 15%.

2.9 Filtration Efficiency

The filtration efficiency of non-oily particles at the key part materials and joints should not be less than 70%.

2.10 Microbiological indicators

Protective boot covers marked as non-sterile supply on the package shall meet the requirements of the following table, as shown in Table 2.

Table3 Microbial index of shoe cover

Total number of	Coliform	Bacillus	Golden yellow	hemolytic streptococc	Total number of
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bacterial colonies CFU/g	bacteria	pseudomonas aeruginosa	staphylococcus	us	fungal colonies CFU/g
≤200	non-detectable	non-detectable	non-detectable	non-detectable	≤100

3. Test method

3.1 Size Requirements

Test method: Use a general measuring tool or a special measuring tool to measure, the results should meet the requirements of 2.1.

3.2 Appearance Requirements

Test method: visual, hand feel, the results should meet the requirements of Article 2.2.

3.3 Structural Requirements

Test method: visual, hand feel, the results should meet the requirements of Article 2.3.

3.4 Impermeability

Sampling of key parts shall be carried out in accordance with the hydrostatic test stipulated in GB/T 4744-2013, and the results shall meet the requirements of 2.4.

3.5 Resistance to synthetic blood penetration

The material shall be tested in accordance with Appendix A of GB 19082-2009 and the results shall meet the requirements of 2.5.

3.6 Surface moisture resistance

The outer side of the material shall be carried out in accordance with the water immersion test specified in GB/T 4745-2013, and the results shall meet the requirements of 2.6.

3.7 Breaking Strength

The key parts of the material shall be tested according to the strip method specified in GB/T 3923.1-2013, and the results shall meet the requirements of 2.7.

3.8 Elongation at break

The test shall be conducted according to the strip method specified in GB/T 3923.1-2013, and the results shall meet the requirements of 2.8.

3.9 Filtering Efficiency

3 samples were taken and tested according to the method specified in 5.7 of GB 19802-2009, and the results should meet the requirements of 2.9.

3.10 Microbiological indicators

The test shall be conducted in accordance with the method specified in Appendix B of GB 15979-2002, and the results shall meet the requirements of 2.7.