

Medical Device Product Technical Requirements No:

Isolation Shoe Cover

Specification details:

1. Product model / specification and its division description

- 1. 1 Product name: 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 According to the product shape and production process is divided into: ordinary PE type, ordinary PP type.
- 1. 4 According to the different size size can be divided into: small, medium, large.
- 1. 5 Basic structure of shoe cover: made of plastic film, PP material, foot mouth for elastic mouth treatment.

2. Performance index

2.1 Dimensional requirement

It shall meet the requirements of Table 1.

Size \ Model	Common PE type, common PP type		
	S(34-37)	M(38-42)	L (42-45)
Boot width×boot length(cm)	15×38	16×41	17×44
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.

2.3 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 Surface moisture resistance

The external side water grade is ≥ 2 .

2.5 Breaking Strength

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

2.6 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.

Table 3 Microbial index of shoe cover

Total number of bacterial colonies CFU/g	Coliform bacteria	Bacillus pseudomonas aeruginosa	Golden yellow staphylococcus	hemolytic streptococcus	Total number of 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 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 2.4.

3.5 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 2.5.

3.6 Microbiological indicators

The test shall be conducted in accordance with the method specified in Appendix B of GB 15979-2002, and the results shall comply with the requirements of 2.6.