
Medical textiles — Shoe covers — Specification



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Medical textiles — Shoe covers — Specification

1 Scope

This standard specifies the requirements for shoe covers (disposable and reusable) intended to be used for medical purpose during various procedures to protect patient/materials from transfer of microorganisms, particulates, contaminants etc. This standard does not cover the requirement of legging/boot legging used in operation theatre.

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 11737-1 : 2018 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 13938-1 – Textiles — Bursting properties of fabrics — Determination of bursting strength and bursting distension: Part 1 Hydraulic method

ISO 24153 - Random sampling and randomization procedures

3 Terms and definitions

For the purpose of this standard the following definitions apply.

3.1

disposable

product intended to be used only once

3.2

lot

all the shoe covers of the same material and dimensions produced under similar conditions of manufacture and sterilization

3.2

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

3.3

reusable

product intended by the manufacturer to be reprocessed and reused

4 Requirements

4.1 The shoe cover 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.

4.2 Shoe covers shall be provided with elastic strip or any other suitable mechanism of fastening at the opening of the shoe cover so as to cover the foot and shoe properly.

4.3 Shoe covers should be slip resistant and water resistant and may be supplied in non-sterile or in sterilized condition as per the requirement of the buyer.

4.4 Workmanship and finish

The shoe covers shall be clean and free from substances liable to cause tendering during storage. The manufacture and preparation of the shoe covers shall be conducted under proper hygienic conditions.

4.5 Performance Requirements

The shoe covers shall conform to the requirements specified in Table 1.

Table 1 - Requirements for Shoe Covers

Characteristics	Requirement	Method of Test
Cleanliness – Microbial (CFU/100 cm ²)	≤ 300	ISO 11737-1
Tensile strength (Dry and wet) (N)	≥ 20	Nonwoven ISO 9073-3, Woven ISO 13934-1
Bursting strength (Dry and wet) (kPa)	≥ 40	ISO 13938-1

5 Packaging

The shoe covers 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 to between the buyer and the seller. Packaging of the product should be such as to maintain the integrity of the product throughout its shelf life.

6 Marking and labelling

Each pack of the shoe covers shall be legibly and indelibly marked in the official language of member state with the following information:

- Name of the product;
- Dimension/size of the product;
- Manufacturer's name, initials or trademark, if any;
- Month and year of manufacture, batch /lot number; and
- Any other statutory requirement as required by the law in force.

7 Sampling and criteria for conformity

7.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

7.2 The number of shoe covers to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 1, 2 and 4 of Table 2.

7.3 These shoe covers shall be selected at random from the lot. For this purpose, reference may be made to ISO 24153.

7.4 Number of Tests and Criteria for Conformity

7.4.1 All the shoe covers selected as per column 2 of Table 2 shall be examined for workmanship and finish (see 4.4).

7.4.2 Any shoe covers failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 3 of Table 2. Otherwise, the lot shall be rejected.

7.4.3 Out of the sample already found satisfactory according to 7.4.2, a sub-sample as per column 4 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

7.4.4 The lot shall be considered as conforming to the requirements of the specification if the total number of defective products found in the sample (as per 7.4.3) is less than, or equal to the acceptance number as given in column 5 of Table 2.

Table 2 – Sample Size and acceptance criteria

Lot size N	Non-destructive testing		Destructive testing	
	No of shoes to be selected (n)	Acceptance no (a)	No of shoes to be selected (n ₁)	Acceptance no (a ₁)
Up to 50	5	0	3	0
51 to 150	8	1	5	0
151 to 280	13 ¹⁾	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

Bibliography

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