

Disposable Surgical Cap – Specification

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Foreword

This Kenya standard has been prepared by the Technical Committee on Towels, Medical and Hygienic Textile Products under the guidance of the Standards Project Committee, and it is in accordance with the procedures of the Kenya Bureau of Standards.

In preparation of this Kenya Standard reference was made to the following document:

EN 14126: 2003 Protective clothing- Performance requirements and test methods for protective clothing against infective agents

Acknowledgement is hereby made for the assistance derived from this source.

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Introduction

Surgical caps (also known as isolation, dental or medical procedure caps) is head gear intended to be worn during medical procedures to prevent transmission of infections to patients and the personnel, by blocking the transmission of pathogens through particles such as hair among others.

Surgical caps are made of a nonwoven fabric created using a melt blowing process and vary by quality and levels of protection.

The development of this standard was necessitated by the need to protect the health care workers from substandard surgical caps in terms of breaking strength, tearing strength, mass per unit area, fiber composition, absorption capacity and workmanship

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KENYA STANDARD

1.0 SCOPE

This Kenyan Standard specifies minimum requirements of non-woven disposable surgical caps mainly used during surgical procedures and other infection prevention control practices

2.0 Normative References:

The following standards were used as normative references.

KS 816-Methods for determination of absorbency of absorbent textile materials

KS 2659 -Packaging of textile products - Code of practice

KS ISO 1833 Textiles — Quantitative chemical analysis (relevant parts)

KS ISO 9073-1, Textiles — Test methods for nonwovens Part 1: Determination of mass per unit area

KS ISO 9073-4, Textiles — Test methods for nonwovens — Part 4: Determination of tear resistance

KS ISO 9073-15, Textiles - Test methods for nonwovens part 15: Determination of air permeability

KS ISO 9073-18, Textiles — Test methods for nonwovens Part 18: Determination of breaking strength and elongation of nonwoven materials using the grab tensile test

ISO 8784-1, Pulp, paper and board — Microbiological examination — Part 1: Enumeration of bacteria and bacterial spores based on disintegration

3.0 Definitions

For the purpose of this standard, the following definition apply

3.1 Air Permeability

Velocity of an air flow passing perpendicularly through a test specimen under a prescribed air pressure differential over a certain time period

Note: Air permeability is expressed in litres per square centimeter per second ($l/cm^2.s$), or any other equivalent unit

3.2 Absorption capacity

Mass of liquid that is absorbed per unit mass of test piece

3.3 Types/designs

Surgical caps are of two types;

- a) Theatre/surgeon Cap-They have tie-on strings to fasten (figure 1)
- b) Surgical caps/ nurse caps- They are either in bouffant or clip (string form)- figure 1 and 2

4.0 REQUIREMENTS

4.1 Materials

4.1.1 General

All materials, dyes and chemicals used in the manufacture of disposable surgical cap shall not cause any undesirable effects to the skin.

4.1.2 Securing mechanism

The disposable surgical cap shall be fitted with an approximate securing mechanism that fits comfortably around the head of the wearer.

4.2 Workmanship

The disposable surgical caps shall be made with first class workmanship throughout and shall be free from defects that affect their appearance and/or serviceability, and free from marks spots or stains incurred in their manufacture.

4.3 Performance requirements

Disposable surgical caps shall comply with the performance requirements given in Table 1 when tested in accordance with the test methods prescribed therein.

Table 1 — Performance requirements for disposable surgical caps

S/N	Characteristic	Requirement	Test method	
i.	Absorption capacity, seconds	Above 60	KS 816 Method 2	
ii.	Air Permeability, l/cm ² .s, min	0.015	KS ISO 9073-15*	
iii.	Breaking Strength, N, min	Cross direction	6	KS ISO 9073-18
		Machine direction		
iv.	Mass per unit area, g/m ² ,min	9	KS ISO 9073-1	
v.	Fiber composition	100% Polyolefin	KS ISO 1833	
vi.	Tearing strength, N, min	Cross direction	6	KS ISO 9073-4
		Machine direction		
*use differential pressure of 100 Pa across the specimen (ISO 9327)				

4.4 Microbiological requirement

Disposable surgical caps shall comply with the microbiological requirements given in Table 2 when tested in accordance to the test methods specified therein.

Table 2 — Microbiological requirements for disposable surgical caps

S/N	Characteristics	Limit	Test Method
i.	Total plate count, cfu/g, max.	300	ISO 8784-1
ii.	<i>Pseudomonas aeruginosa</i> , cfu/g	Not detected in 1 g iii. <i>Staphylococcus aureus</i> , cfu/g of the product	
iii.	<i>Staphylococcus aureus</i> , cfu/g		
iv.	<i>Candida albicans</i> , cfu/g		

5.0 PACKAGING

All disposable surgical caps shall be packaged in accordance with KS 2659 :2016

5.1 The Pack shall be free of contaminants.

6.0 LABELLING

The following information in English shall be legibly and indelibly marked on the secondary packaging in which the disposable surgical cap is supplied

- a) manufacturers name and address
- b) date of manufacture and expiry
- c) country of manufacture
- d) Each box and carton shall be clearly labelled with the name and characteristics (type) of the article
- e) production batch number
- f) Number of units
- g) The color of the product
- h) Instructions for use and disposal

ANNEX A



Fig 1-Theatre/surgeon cap



Fig 2-String form or clip



Fig 3- Bouffant