SLOVENSKI STANDARD
SIST EN 14079:2003

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Neaktivni medicinski pripomoļ ki - Zahtevane lastnosti in preskusne metode za vpojno bombaģno gazo in viskozno gazo

Non-active medical devices - Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze

Nichtaktive Medizinprodukte - Leistungsanforderungen und Prüfverfarhen für Verbandmull aus Baumwolle und Verbandmull aus Baumwolle und Viskose

Dispositifs médicaux non actifs - Exigences de performance et méthodes d'essais pour la gaze de coton absorbante et la gaze de coton et viscose absorbante

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN 14079:2003) has been prepared by Technical Committee CEN /TC 205, "Non-active medical devices" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2003, and conflicting national standards shall be withdrawn at the latest by October 2003.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this document.

This standard is based on the European Pharmacopoeia monographs. As charged by CEN/TC 205 it is a mere reformatting of the monographs. It includes requirements and test methods as far as they are in line with the essential requirements as defined in Annex I of the Medical Device Directive 93/42/EEC. This standard does not describe the full state of the art and therefore will be revised immediately after finalization.

Annexes A and B are normative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Absorbent cotton gauze, absorbent cotton ribbon gauze and absorbent cotton and viscose ribbon gauze were described in the European Pharmacopoeia. Due to the introduction of the Medical Device Directive 93/42/EEC, those monographs have been removed from the European Pharmacopoeia.

1 Scope

This standard describes the requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauzes. The standard does not consider gauzes impregnated with a pharmaceutical substance.

2 Normative references

This standard contains no normative references

3 Terms and definitions

For the purposes of this European Standard the following terms and definitions apply:

3.1
absorbent cotton gauze
cotton cloth of plain weave, bleached to a good white and purified, being white and practically odourless, containing not more than slight traces of leaf, pericap seed-coat or other impurities and reasonably free from weaving defects

3.2
absorbent cotton ribbon gauze
woven cloth supplied in continuous ribbons of various widths with fast selvedges, made from cotton threads that are purified, bleached and made absorbent either before or after weaving, being white and practically odourless, containing not more than slight traces of leaf, pericap seed-coat or other impurities and reasonably free from weaving defects

3.3
absorbent cotton and viscose ribbon gauze
woven cloth supplied in continuous ribbons of various widths with fast selvedges, having in the warp cotton threads and in the weft viscose threads or combined cotton and viscose threads, made from threads that are purified, bleached and made absorbent either before or after weaving, being white and practically odourless, containing not more than slight traces of leaf, pericarp seed-coat or other impurities and reasonably free from weaving defects

4 Requirements

4.1 Fibre Identification

4.1.1 Absorbent cotton gauze and absorbent cotton ribbon gauze

When tested according to 5.2.1 the cotton fibres shall conform to the IDENT tests A, B and C.

4.1.2 Absorbent cotton and viscose ribbon gauze

When tested according to 5.2.2 the cotton fibres shall conform to the IDENT tests A and C and the viscose fibres shall conform to IDENT test B.

If it is necessary to differentiate between lustrous or matt viscose, the IDENT test D shall be used.

4.2 Acidity and alkalinity

When tested according to 5.3 neither solution shall be pink.

4.3 Foreign fibres

When tested according to 5.4 the cotton and viscose fibres shall conform to 5.4, only occasionally a few isolated foreign fibres being allowed.

4.4 Fluorescence

When tested according to 5.5 the cotton and viscose gauzes shall conform to 5.5.

4.5 Thread count

When tested according to 5.6 the thread counts per 100 mm shall be as given in Table 1 and Table 2.

Table 1 — Textile and physical requirements for absorbent cotton gauze

Type (number of threads per cm^2)	Threads in warp per 100 mm	Minimum breaking load in Newton per 50 mm warp way	Threads in weft per 100 mm	Minimum breaking load in Newton per 50 mm weft way	Minimum mass in g/m^2
12	73 ± 4	-	45 ± 4	-	13,0
13 light	73 ± 4	-	57 ± 4	-	14,0
13 heavy	70 ± 4	35	60 ± 4	20	17,0
17	100 ± 5	50	70 ± 4	30	23,0
18	100 ± 5	50	80 ± 5	30	24,0
20	120 ± 6	60	80 ± 5	35	27,0
22	120 ± 6	60	100 ± 5	40	30,0
24 a	120 ± 6	60	120 ± 6	50	32,0
24 b	140 ± 6	70	100 ± 6	40	32,0

Table 2 — Textile and physical requirements for absorbent cotton ribbon gauze and absorbent cotton and viscose ribbon gauze

Type (number of threads per cm^2)	Threads in warp per 100 mm	Minimum breaking load in Newton per 50 mm warp way	Threads in weft per 100 mm	Minimum mass in g/m^2
22 a	120 ± 3 [a]	60	100 ± 5	33,5
22 b	120 ± 3 [a]	60	100 ± 5	44,0
24 a	120 ± 3 [a]	60	120 ± 6	36,0
[a] The limits are increased to ± 4 for ribbon gauze 25 mm or 50 mm wide and to ± 8 for ribbon gauze 12,5 mm wide.				

4.6 Mass per square metre

When tested according to 5.7 the mass per square metre in grams shall be as given in Table 1 and Table 2.

4.7 Minimum breaking load

When tested according to 5.8 the minimum breaking load in Newton per 50 mm shall be as given in Table 1 and Table 2.

4.8 Sinking time

When tested according to 5.9 the sinking time shall not exceed 10 s.

4.9 Ether-soluble substances

When tested according to 5.10 the amount of ether-soluble substances shall not be more than 0,50 % .

4.10 Surface active substances

When tested according to 5.11 the froth height above the surface of the liquid after 300 s shall not exceed 2 mm.

4.11 Water-soluble substances

When tested according to 5.12 the amount of water-soluble substances shall not be more than 0,50 % .

4.12 Starch and dextrin

When tested according to 5.13 the solution shall not show any blue, violet, reddish or brownish colour.

4.13 Extractable colouring matter

When tested according to 5.14 the liquid obtained shall not be more intensely coloured than reference solution Y_5, GY_6 or a reference solution prepared as follows: to 3,0 ml of blue primary solution add 7,0 ml of hydrochloric acid (1 % m/V HCl) and dilute 0,5 ml of this solution to 10,0 ml with hydrochloric acid (1 % m/V HCl).

NOTE See annex A for reference solutions.

4.14 Loss on drying

When tested according 5.15 the loss of mass shall not be more than 8,0 %.

4.15 Sulphated ash

When tested according to 5.16 the amount of sulphated ash shall be as given in Table 3.

Table 3 — Sulphated ash for different materials

Material	Sulphated ash
Absorbent cotton gauze	shall not exceed 0,40 %
Absorbent cotton gauze Type 13 light	shall not exceed 0,75 %
Absorbent cotton and matt viscose ribbon gauze	shall not exceed 1,20 %
Absorbent cotton and lustrous viscose ribbon gauze	shall not exceed 0,45 %

5 Test methods

5.1 General

All tests shall be performed with the material in its final form i.e. sterile or non-sterile.

All reagents used shall be of analytical grade.

NOTE The preparation of test solution S is given in annex B.

5.2 Fibre identification

5.2.1 Absorbent cotton gauze and absorbent cotton ribbon gauze

5.2.1.1 Reagents

a) **Zinc chloride solution, iodinated**: Dissolve 20 g ± 0,5 g of zinc chloride and 6,5 g ± 0,1 g of potassium iodide in 10,5 ml ± 0,1 ml of water. Add 0,5 g ± 0,05 g of iodine and shake for 15 min. Filter if necessary. Store protected from light.

b) **Zinc chloride-formic acid solution**: Dissolve 20 g ± 0,5 g of zinc chloride in 80 g ± 1 g of an 85 % m/V solution of anhydrous formic acid.

5.2.1.2 Tests

Untwist a few threads in the warp and in the weft to free a few of the fibres to be examined and carry out IDENT tests A, B and C.

IDENT A: When examined under a microscope, the cotton fibre shall be flat, ribbon-like, 10 µm to 40 µm wide, with thickened ends and an irregularly shaped lumen.

IDENT B: When treated with iodinated zinc chloride solution, the fibres shall become violet.

IDENT C: To 0,1 g ± 0,05 g fibres add 10 ml ± 0,1 ml of zinc chloride-formic acid solution. Heat to 40 °C and allow to stand for 2,5 h, shaking occasionally.

5.2.2 Absorbent cotton and viscose ribbon gauze

5.2.2.1 Reagent

Hydrogen peroxide solution, dilute: Contains not less than 2,5 % m/m and not more than 3,5 % m/m of hydrogen peroxide in water.

5.2.2.2 Tests

Untwist a few threads in the warp and in the weft to free a few of the fibres to be examined and carry out IDENT tests A, B and C. The fibres from the warp shall comply with IDENT test A and C. The fibres from the weft shall comply with IDENT test B and C and where a mixture of fibres is present some of the fibres from the weft shall comply with IDENT test A.

IDENT A: Examined under a microscope, each cotton fibre shall consist of a single cell, up to about 40 mm long and up to 40 µm wide, in the form of a flattened tube with thick and rounded walls and often twisted.

IDENT B: The viscose fibres shall have an average length of 25 mm to 50 mm and when examined under a microscope in the dry state they shall be of uniform width; they shall be crimped and they shall have many longitudinal parallel lines distributed unequally over the width. The end-cuts shall be more or less straight. The surface of each fibre can be uneven, and the cross-section shall be approximately circular or elliptical, with a diameter of 10 µm to 20 µm. The matt fibres shall contain numerous granular particles of about 0,25 µm to 1 µm average diameter.

IDENT C: When treated with iodinated zinc chloride solution (5.2.1.1), the fibres shall become violet.

IDENT D: Dissolve the residue obtained in the test for sulphated ash (see clause 4.15) by warming gently with 5 ml ± 0,1 ml of sulphuric acid . Allow to cool and add 0,2 ± 0,01 ml of dilute hydrogen peroxide solution. The solution obtained from the product containing lustrous viscose shall undergo no change in colour; that from the product containing matt viscose shall show an orange-yellow colour, the intensity of which shall depend on the quantity of titanium dioxide present.

Note The residue from the test for sulphated ash can be yellowish in colour.

5.3 Test method for acidity or alkalinity

5.3.1 Reagents

a) **Phenolphthalein solution**. Dissolve 0,1 g ± 0,01 g of phenolphthalein solution in 80 ml of ethanol (containing 95,1 % to 96,9 % V/V ethanol) and make up to 100 ml with water.

b) **Methyl orange solution**. Dissolve 0,1 g ± 0,01 g of methyl orange in 80 ml ± 0,5 ml of water and make up to 100 ml ± 0,5 ml with ethanol (containing 95,1 % to 96,9 % V/V ethanol).

5.3.2 Test

To 25 ml ± 0,5 ml of solution S add 0,15 ml ± 0,01 ml of phenolphthalein solution and to another 25 ml ± 0,5 ml add 0,05 ml ± 0,001 ml of methyl orange solution.

Check for compliance with 4.2.

5.3.3 Tests for sensitivity.

a) To 0,1 ml ± 0,01 ml of the phenolphthalein solution add 100 ml ± 1 ml of carbon dioxide-free water. The solution shall be colourless. Not more than 0,2 ml of 0,02 N sodium hydroxide is required to change the colour to pink. Colour change: pH 8,2 (colourless) to pH 10,0 (red).

b) A mixture of 0,1 ml ± 0,01 ml of the methyl orange solution and 100 ml ± 1 ml of carbon dioxide-free water shall be yellow. Not more than 0,1 ml of 0,1 N hydrochloric acid is required to change the colour to red. Colour change: pH 3.0 (red) to pH 4.4 (yellow).