SLOVENSKI PREDSTANDARD

oSIST prEN 14079-1:2006

november 2006

Neaktivni medicinski pripomočki - Lastnosti kompres (obvez) in izdelkov za zavijanje (tamponiranje) ran za uporabo v medicini - 1. del: Preskusne metode in zahteve za vpojno bombažno gazo in vpojne bombažne in viskozne gaze, ki se uporabljajo v proizvodnji kompres (obvez) in izdelkov za zavijanje (tamponiranje) ran

Non-active medical devices - Properties for compresses and wound packing products for medical use - Part 1: Test methods and requirements for absorbent cotton gauze and absorbent cotton and viscose gauzes used in the manufacturing of compresses and wound packing products

ICS 11.120.20

Referenčna številka
oSIST prEN 14079-1:2006(en)

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 14079-1

September 2006

ICS

Will supersede EN 14079:2003

English Version

Non-active medical devices - Properties for compresses and wound packing products for medical use - Part 1: Test methods and requirements for absorbent cotton gauze and absorbent cotton and viscose gauzes used in the manufacturing of compresses and wound packing products

Dispositifs médicaux inactifs - Propriétés pour des compresses et produits d'emballage enroulés pour l'usage médical - Partie 1: Examiner les méthodes et les conditions pour la gaze de coton absorbant et les gazes de coton visqueuses absorbantes utilisées à la fabrication des compresses et des produits d'emballage de blessure

Nichtaktive Medizinprodukte - Eigenschaften von Kompressen und Tamponadematerial für den medizinischen Einsatz - Teil 1: Prüfverfahren für und Anforderungen an Verbandmull aus Baumwolle und Verbandmull aus Baumwolle und Viskose, die zur Herstellung von Kompressen und Tamponadematerial verwendet werden

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

This document (prEN 14079-1:2006) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 14079:2003.

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, B, C or D, which is an integral part of this document.

Annexes A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P and Q are normative.

Introduction

Absorbent cotton gauzes and absorbent cotton and viscose gauzes used in the manufacturing of compresses and wound packing products shall not introduce unacceptable risks to health nor release under the conditions of intended use, substances in quantities that will produce such a hazard, before and after sterilization.

The absorbent cotton gauzes and absorbent cotton and viscose gauzes shall be stable with or without agents which are commonly used in wound management, including antiseptics and cleaning solutions.

NOTE Specific tests for finished compresses and wound packing products are covered in part two of EN 14079 which will be developed in parallel.

1 Scope

This European Standard describes the physical and chemical test methods with requirements for the evaluation of absorbent cotton gauzes and absorbent cotton and viscose gauzes used as materials for compresses and wound packing products for medical use. X-ray detectable components are included.

2 Normative references

The following referenced documents are indispensable for the application 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 565:1990, *Test sieves — Metal wire cloth, perforated metal plate and electroformed sheet — Nominal sizes of openings.*

EN ISO 13934-1, *Textiles — Tensile properties of fabrics — Part 1: Determination of maximum force and elongation at maximum force using the strip method*

3 Terms and definitions

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

3.1
absorbent cotton gauze
gauze consisting of cotton cloth, which is made absorbent and white by a bleaching process.

NOTE It is practically odorless, contains not more than slight traces of leaf, pericarp seed coat or other impurities and is reasonable free from processing defects

3.2
absorbent cotton ribbon gauze
ribbon gauze consisting of cotton cloth supplied in continuous ribbons of various widths with fast edges

NOTE It is made absorbent and white by a bleaching process, either before or after processing. It is practically odorless, contains not more than slight traces of leaf, pericarp seed coat or other impurities and is reasonable free from processing defects

3.3
absorbent cotton and viscose ribbon gauze
ribbon gauze consisting of cloth supplied in continuous ribbons of various widths with fast edges and is produced from a combination of cotton and viscose threads.

NOTE It is made absorbent and white by a bleaching process either before or after processing. It is practically odorless, contains not more than slight traces of leaf, pericarp seed coat or other impurities and is reasonably free from processing defects

3.4
absorbent cotton and viscose gauze
gauze consisting of cotton and viscose cloth, which is made absorbent and white by a bleaching process.

3.5
colored absorbent gauze
absorbent gauze that has been dyed to a specific color

3.6
gauze compress
piece or pieces of gauzes in any shape, form or size that is used for one or more of the following purposes;

— for cleansing skin or wounds;

— for absorbing body exudates during surgical procedures:

— for use with agents commonly used in wound management:

— to support organs, tissue, etc. during surgical procedures.

3.7
cross direction
direction perpendicular to the processing direction

3.8
machine direction
direction parallel to the processing direction

3.9
warp
yarns arranged lengthways on a loom, forming the threads through which the weft yarns are woven

3.10
weft
yarn woven across the width of the fabric through the lengthways warp yarn

3.11
wound packing product
medical device used to fill a wound to facilitate healing

3.12
x-ray detectable absorbent cotton gauze
absorbent cotton gauze with a clearly visible x-ray detectable component, fixed to the absorbent cotton gauze in such a way that it shall not become detached

3.13
x-ray detectable absorbent cotton or x-ray detectable cotton and viscose ribbon gauze
ribbon gauze with a clearly visible x-ray detectable component, fixed to it in such a way that it shall not become detached

3.14
x-ray detectable component
component that gives a clear x-ray opacity. It is free from loose fibers and particles and does not impair the softness and flexibility of the absorbent gauze or ribbon gauze

4 Test methods

When required in the test method, samples shall be conditioned according to Annex A.

All reagents used in the test methods shall be of analytical grade.

5 Physical properties

Test methods are given for the determination of the following physical properties:

— fluorescence, according to Annex B;

— thread count in woven gauze, according to Annex C;

— mass per square metre, according to Annex D;

— breaking load, according to Annex E;

— liquid absorbency time, according to Annex F;

— liquid absorptive capacity, according to Annex G;

— opacity of x-ray component, according to Annex H;

— fibre identification, according to Annex I.

6 Chemical properties

Test methods are given for the determination of the following chemical properties:

— acidity or alkalinity of aqueous extracts, according to Annex J;

— substances soluble in non-polar solvents, according to Annex K;

— water soluble substances, according to Annex L;

— starch and dextrin, according to Annex M;

— sulphated ash, according to Annex N;

— color fastness of dyed gauze under moist conditions, according to Annex O;

— surface active substances, according to Annex P;

7 Requirements

Annex Q details the acceptance values for Annex B to Annex P.

NOTE These requirements have been historically accepted for gauzes used in the manufacturing of medical devices.

Annex A
(normative)

Conditioning of test material

A.1 Principle

The object of this procedure is to specify, if applicable, the conditioning atmosphere and the method of conditioning gauzes before and during testing.

A.2 Conditioning atmosphere

A.2.1 Temperature: 20 °C + 2 °C.

A.2.2 Relative humidity: 65 % + 10 %.

A.3 Equipment

A.3.1 Test chamber and measuring instrumentation, provided with automatic equipment for bringing the air to conditions of relative humidity and temperature given in A.2 and so circulating it that the condition at all relevant points are uniformly maintained.

NOTE It is recommended that a recording hygrometer, periodically checked by a standard method (e.g. with wet and dry bulb thermometers) be kept in the test chamber to allow the air conditions to be checked.

A.3.2 Suitable balance, capable of measurement in grams to two decimal places

A.4 Procedure

A.4.1 Conditioning

A.4.1.1 Place the test specimen in the conditioning atmosphere.

A.4.1.2 Suspend or support the test specimen so that the conditioning atmosphere has free access to its whole surface.

A.4.1.3 After at least 1 h weigh the test specimen to 2 decimal places and repeat this after 1 h more, the two weighing shall not differ by more than 0,25 % of the total mass of the last specimen. If it differs repeat the weight after 1 h more.

Annex B
(normative)

Test method for the determination of fluorescence

B.1 Principle

This test method evaluates the fluorescence of gauze by observing for fluorescence under ultra violet light.

B.2 Equipment

Ultra violet lamp, having a maximum output at a wavelength of 365 nm.

B.3 Procedure

Examine at least a two-ply layer of the gauze under the ultra violet lamp.

B.4 Test report

The report shall include at least the following information:

a) type and batch number of gauze;

b) record whether or not the gauze fluoresces;

c) identification of person carrying out the test.

NOTE For routine in-house testing the signature of the person carrying out the test can be omitted

Annex C
(normative)

Test method for the determination of thread count in woven gauze

C.1 Principle

This test method determines the number of warp and weft threads per 100 mm in cotton gauze.

C.2 Equipment

C.2.1 Magnifying glass, if necessary.

C.2.2 Ruler, divided in mm.

C.3 Procedure

C.3.1 For absorbent cotton gauze count the number of threads in the warp and in the weft in a square piece with 100 mm sides, well away from the edges. Repeat both counts twice in 2 different places so that the 3 counts in both directions are well distributed over the sample to be tested.

C.3.2 For absorbent cotton and absorbent cotton and viscose ribbon gauze count the number of threads in the warp and the weft over a length of 100 mm: If the width of the ribbon gauze is less than 100 mm, count the number of threads over the whole of the width. Calculate the number of threads per 100 mm on the basis of the declared width. If the width of the ribbon gauze is greater than 100 mm, do not include the selvedge in the count. Repeat both counts twice in 2 different places so that the 3 counts in both directions are well distributed over the sample to be tested. If the width of the ribbon gauze is less than 100 mm, the warp count shall only be performed once.

C.4 Calculation of results

Calculate the average of the three individual counts for both the warp and weft directions.

C.5 Test Report

The report shall include at least the following information:

a) type and batch number of gauze;

b) if applicable, width of ribbon gauze;

c) individual and average warp threads per 100 mm;

d) individual and average weft threads per 100 mm;

e) if applicable, classification of the sample according to Table Q.1 or Table Q.2;

f) identification of person carrying out the test.

NOTE For routine in-house testing the signature of the person carrying out the test can be omitted

Annex D
(normative)

Test method for the determination of mass per square metre

D.1 Principle

This test method determines the mass per square metre of gauzes.

D.2 Equipment

D.2.1 Suitable balance, capable of measurement in grams to two decimal places

D.2.2 Ruler divided in mm.

D.3 Procedure

D.3.1 Condition the samples in accordance with Annex A.

D.3.2 Weigh a piece of absorbent cotton gauze 1 m ± 0,01 m in length using the full width or, for smaller samples, pieces not less than 2500 mm² to give a total surface of at least 50 000 mm².

D.3.3 For absorbent cotton or absorbent cotton and viscose ribbon gauze, weigh the total mass and then determine the weight per square metre by multiplying the nominal width of the ribbon by the length, measured on the unrolled and flattened gauze.

D.4 Test Report

The report shall include at least the following information:

a) type and batch number of gauze;

b) the calculated weight in grams per square metre of the gauze;

c) if applicable, classification of the sample according to Table Q.1 or Table Q.2;

d) any deviation from the test method;

e) identification of person carrying out the test.

NOTE For routine in-house testing the signature of the person carrying out the test can be omitted