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Non-active medical devices - Properties for compresses and wound packing products for medical use - Part 2: Test methods for absorbent cotton gauze and absorbent cotton and viscose gauze

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Non-active medical devices - Properties for compresses and wound packing products for medical use - Part 2: Test methods for absorbent cotton gauze and absorbent cotton and viscose gauze

Dispositifs médicaux inactifs - Propriétés pour des compresses et produits d'emballage enroulés pour l'usage médical - Partie 2: Examiner les méthodes pour la gaze de coton absorbant et la gaze de coton visqueuse absorbante

Nichtaktive Medizinprodukte - Eigenschaften von Kompressen und Tamponadematerial für den medizinischen Einsatz - Teil 2: Prüfverfahren für Verbandmull aus Baumwolle und Verbandmull aus Baumwolle und Viskose

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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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Contents

Page

Foreword 3

Introduction 3

1 Scope 3

2 Normative references 3

3 Terms and definitions 4

4 Test conditions 4

5 Properties 5

Annex A (normative) Conditioning test for compress or wound packing product 6
A.1 Principle 6
A.2 Conditioning atmosphere 6
A.3 Equipment 6
A.4 Procedure 6
A.4.1 Conditioning 6

Annex B (normative) **Test method for absorbent capacity** 7
B.1 Principle 7
B.2 Equipment 7
B.3 Procedure 7
B.4 Test report 8

Annex C (normative) **Test method for determination of absorption** 9
C.1 Principle 9
C.2 Equipment 9
C.3 Procedure 9
C.4 Test report 9

Annex D (normative) **Test method for construction strength** 10
D.1 Principle 10
D.2 Equipment 10
D.3 Procedure 10
D.4 Test report 10

Annex E (normative) **Test method for determination of opacity of x-ray component** 11
E.1 Principle 11
E.2 Equipment 11
E.3 Procedure 11
E.4 Test report 11

Annex F (normative) **Dimensions of compress** 12
F.1 Principle 12
F.2 Equipment 12
F.3 Procedure 12
F.4 Calculation of results 12
F.4.1 Test reports 12

Foreword

This document (prEN 14079-2:2006) 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, which is an integral part of this document.

Annexes A, B, C, D, E, F are normative.

Annex ZA is informative.

Introduction

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 compresses and wound packing products shall be stable with or without agents, which are commonly used in wound management including antiseptics and cleansing solutions.

1 Scope

Part 2 of prEN14079 specifies physical and chemical tests for the evaluation of absorbent cotton gauze and absorbent cotton and viscose gauze compresses and wound packing products.

Specific tests and requirements for absorbent cotton gauze and cotton and viscose gauzes used in the manufacture of compresses and wound packing products are covered in prEN 14079-1, which can be used in conjunction with this part of the standard.

NOTE 1 Biocompatibility aspects are not covered in this standard, but are addressed in EN ISO 10993.

NOTE 2 Bioburden determination methods are not covered by this standard, but are addressed in EN XXX.

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.

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

ISO 565, Test sieves — Metal wire clothe, perforated metal and electroformed sheet – Nominal sizes of openings.

EN ISO 3696, Water for analytical laboratory use – Specifications and test methods.

PrEN 14079-1, Non-active medical devices — test methods and requirements for compresses and wound packing product for medical use — Part 1: Absorbent cotton gauzes and absorbent cotton and viscose gauzes used in the manufacturing of compresses and wound packing product

3 Terms and definitions

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

3.1
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.

3.2
wound packing product
medical device used to fill a wound to facilitate healing

3.3
x-ray detectable absorbent gauze compress or wound packing product
absorbent gauze compress or wound packing product with a clearly visible x-ray detectable component, fixed to the absorbent gauze in such a way that it shall not become detached

4 Test conditions

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

If the product is to be used sterile, the samples shall be sterilized according to the manufacturer's instructions prior to testing.

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

5 Properties

Test methods are given for the determination of the following properties, which shall be considered:

— absorbent capacity, according to Annex B;

— rate of absorption, according to Annex C;

— construction strength, according to Annex D;

— x-ray opacity of the gauze compress or wound packing product according to Annex E;

— dimensions of the gauze compress or wound packing product include number of plies if applicable, according to Annex F

— sewing thread and tape, if used, during the manufacturing of the compress and wound packing product shall conform to the fluorescence physical requirements and all the chemical requirements of Part 1 of prEN 14079 (clause 5 and 6).

Annex A

(normative)

Conditioning test for compress or wound packing product

A.1 Principle

The object of this procedure is to specify, if applicable, the conditioning atmosphere and the method of conditioning compress or wound packing product before and during testing.

A.2 Conditioning atmosphere

— Temperature: 20 °C ± 2 °C.

— 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

Place the compress or wound packing product in the conditioning atmosphere.

Suspend or support the compress or wound packing product so that the conditioning atmosphere has free access to its whole surface.

After at least 1 hour weigh the compress or wound packing product to 2 decimal places and repeat this after 1 h more, the 2 weighings shall not differ by more than 0,25 % of the total mass of the last product. If it differs repeat the weight after 1 hour more.

Annex B
(normative)

Test method for absorbent capacity

B.1 Principle

This test method covers the evaluation of one aspect of the behaviour of absorbent cotton gauze and cotton and viscose gauze compresses and wound packing products in the presence of liquids, i.e. absorbent capacity, or water retention capacity. The absorbent capacity test measures the water retention of the products by difference of mass before immersion of the product in water and after immersion, draining and compression.

B.2 Equipment

B.2.1 Stainless steel tank

B.2.2 Stainless steel tray

Stainless steel tray, having a perforated metal base which can be suspended in the stainless steel tank, permitting a wet compress laid upon its surface to drain freely through the perforations. The base is perforated with circular holes, 3 mm in diameter, evenly spaced, so that the centre of each hole is 5 mm from the centres of those adjoining it.

B.2.3 Metal weight

Metal weight, of suitable non-corrodible material that exerts a pressure of 2 $kN \cdot m^{-2}$ (20 $gf \cdot cm^{-2}$).

B.2.4 Forceps

B.2.5 Suitable balance, capable of measurement in grams to two decimal places

B.3 Procedure

B.3.1 Weigh the whole product and place it on the stainless steel tray with the surface intended for tissue or wound contact in direct contact with the perforated surface. Immerse the tray and material in deionised water, of grade 3 conforming to (20 ± 2) ºC for 10 s. Transfer the tray and material to the stainless steel tank and allow the contents to drain for 10 s.

Place the metal weight on the surface of the product such that a force of $2kN \cdot m^{-2}$ is applied evenly over the surface of the sample, leave for 30 s and then remove the weight carefully.

Transfer the product immediately to a tared dish by means of forceps, taking care not to lose any water in the process. Weigh and calculate the water retention capacity of the compress fabric.

B.3.2 Repeat B.3.1 twice, each time on a fresh product.

B.4 Test report

The report shall include at least the following information:

a) type and batch number of product;

b) record with the results expressed in grams of absorbed liquid per gram of the product in each of the three determinations and report the mean water retention capacity;

c) any deviations from the test method shall be recorded;

d) 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