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Preskusne metode za netkane komprese za uporabo v medicini - 2. del: Gotove komprese

Test methods for nonwoven compresses for medical use - Part 2: Finished compresses

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Test methods for nonwoven compresses for medical use - Part 2: Finished compresses

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This European Standard 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of an identical text or by endorsement, at the latest by July 2000, and conflicting national standards shall be withdrawn at the latest by July 2000.

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, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Annexes A, B, C, D, E, F, G and H are normative.

Introduction

Compresses should not constitute a hazard to health nor release, under the conditions of intended use, substances in quantities that will produce such a hazard, before and after sterilization.

The compress should be stable with or without agents which are commonly used in wound management including antiseptics and cleansing solutions.

Generally, only physical and chemical tests will be necessary for routine quality control once biological test requirements have been fulfilled. If changes are made to the product, biological retesting may be necessary.

NOTE 1 Specific tests for nonwovens used in the manufacture of compresses are covered in EN 1644-1:1997.

NOTE 2 Biocompatibility aspects for materials used in medical devices are covered by the EN 30993 series of standards prepared by CEN/TC 206.

NOTE 3 Bioburden determination methods for medical devices are covered by the work of CEN/TC 204.

1 Scope

This Part of EN 1644 specifies physical and chemical tests for the evaluation of finished nonwoven compresses.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 1644-1:1997	*Test methods for nonwoven compresses for medical use - Part 1: Nonwovens used in the manufacture of compresses*
EN 29073-3	*Textiles - Test methods for nonwovens - Part 3 : Determination of tensile strength and elongation*
EN ISO 3696:1995	*Water for analytical laboratory use - Specification and test methods (ISO 3696:1987)*

3 Definition

For the purposes of this standard the following definition applies:

3.1 compress: Piece or pieces of material(s), 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.

4 Test conditions

Condition the sample and test it according to annex H (which is the same as annex A of EN 1644-1:1997).

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

5 Physical properties

5.1 Methods are given for the determination of the following properties which shall be considered:

- Absorbent capacity : according to annex A;
- Rate of absorption : according to annex B;
- Construction strength : according to annex C;
- Burst strength (dry and wet) for flat plied compresses : according to annex D;
- Conformability for flat compresses : according to annex E;
- Wet linting : according to annex F;
- Dry linting : according to annex G.

NOTE In order to deal with an important property of compresses, which is their ability to cleanse wounds adequately, the inclusion of 'abrasiveness' among these physical properties was considered. Due to the large variety in shapes and forms, and the different ways of application, the coefficient of kinetic friction cannot reliably be determined on the final product; the coefficient determined for the surface material after final treatment, if any, can give an indication. It was envisaged to adapt a kinetic friction test (used in the paper industry) in EN 1644-1:1997.However, in the absence of validation of such a test in this specific context, it was preferred not to delay the publication of the standard while undertaking further research work.

5.2 Measure the tensile strength of compresses according to EN 29073-3.

NOTE The tensile strength of the finished product is adequately covered by testing both the tensile strength of the material (as in EN 29073-3) and constructional strength of the finished product (as in annex C of this European Standard).

6 Chemical properties

Methods are given in EN 1644-1:1997 for the determination of the following properties:

- Water soluble substances;
- Fluorescence;
- Acidity/alkalinity of aqueous extract;
- Non-polar soluble substances;
- Surface-active substances.

These properties of the compress can be determined from the results obtained on the nonwovens and other materials used in the compress, or by application of the methods in EN 1644-1:1997 to compresses, in which case adaptation of the volumes and masses specified therein is necessary.

NOTE If processing the materials changes their chemical properties, tests for chemical properties should be performed on either the processed material or the compress.

Annex A (normative)

Test method for absorbent capacity

A.1 Intended application and principle

This test method covers the evaluation of one aspect of the behaviour of nonwoven compresses in the presence of liquids, i.e. absorbent capacity, or water-retention capacity. The absorbent capacity test measures the water-retention of the compress by difference of mass before immersion of the compress in water and after immersion, draining and compression.

A.2 Equipment

A.2.1 ***Stainless steel tank***

A.2.2 ***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.

A.2.3 ***Metal weight***, of suitable non-corrodible material that exerts a pressure of 2 $kN \cdot m^{-2}$ (20 $gf \cdot cm^{-2}$).

A.3 Procedure

A.3.1 Weigh the whole compress and place it on the stainless steel tray with the surface intended for tissue or wound contact in direct contact with the perforated surface.

A.3.2 Immerse the tray and material in deionized water, of grade 3 conforming to EN ISO 3696: 1995, at (18 to 22) °C for 10 s.

A.3.3 Transfer the tray and material to the stainless steel tank and allow the contents to drain for 10 s.

A.3.4 Place the metal weight on the surface of the compress such that a force of 2$kN \cdot m^{-2}$ is applied evenly over the surface of the sample, leave for 30 s and then remove the weight carefully.

A.3.5 Transfer the compress 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

NOTE For practical reasons, e.g. the shape or size of the compress, more than one compress can be used.

A.3.6 Repeat A.3.1 to A.3.5 twice, each time on a fresh compress.

A.4 Test report

Record the results expressed in grams of absorbed liquid per compress in each of the three determinations and report the mean water-retention capacity.

Any deviations from the test method shall be recorded.

Annex B (normative)

Test method for rate of absorption

B.1 Intended application and principle

This method is used to determine the rate of absorption of the compresses. A compress is lightly dropped on the surface of water contained in a container. The time for the compress to sink or to be completely wetted is a measure of the absorbency rate of the compress.

B.2 Equipment

B.2.1 ***A container,*** at least 15 cm high and with a diameter large enough to allow a compress to be placed flat on the water surface without it touching the sides of the container.

B.2.2 ***Forceps.***

B.2.3 ***Stopwatch.***

B.3 Procedure

B.3.1 Fill the container with deionized water of grade 3 conforming to EN ISO 3696: 1995 at (18 to 22) °C, to a depth of approximately 10 cm.

B.3.2 Using the forceps, drop the compress on the water surface, without splashing or submerging it.

B.3.3 Using the stopwatch, measure the time taken in seconds for the upper surface of the compress to be completely wetted or for the compress to sink completely below the surface of the water.

B.3.4 Repeat B.3.1 to B.3.3 twice.

B.4 Test report

Report the results in seconds and calculate the mean of the three measurements.

Any deviations from the test method shall be recorded.