SLOVENSKI STANDARD
SIST EN 1644-1:2000

01-januar-2000

Preskusne metode za netkane komprese za uporabo v medicini - 1. del: Netkane tkanine, ki se uporabljajo za izdelavo kompres

Test methods for nonwoven compresses for medical use - Part 1: Nonwovens used in the manufacture of compresses

Prüfverfahren für mechanische Vliesstoffkompressen - Teil 1: Vliesstoffe zur Herstellung von Kompressen

Méthodes d'essai pour compresses en non tissé a usage médical - Partie 1: Non tissés utilisés pour la fabrication des compresses

Ta slovenski standard je istoveten z: **EN 1644-1:1997**

ICS:

11.120.20	Sanitetni materiali, obveze in komprese	Wound dressings and compresses

SIST EN 1644-1:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1644-1

February 1997

ICS 11.120.20

Descriptors: medical equipment, bandages, materials, nonwoven fabrics, manufacturing, physical tests, chemical tests, estimation, characteristics, testing conditions, conditioning

English version

Test methods for nonwoven compresses for medical use - Part 1: Nonwovens used in the manufacture of compresses

Méthodes d'essai pour compresses en nontissé à usage médical - Partie 1: Nontissés utilisés pour la fabrication des compresses

Prüfverfahren für medizinische Vliesstoffkompressen - Teil 1: Vliesstoffe zur Herstellung von Kompressen

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Contents **Page**

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of an identical text or by endorsement, at the latest by August 1997, and conflicting national standards shall be withdrawn at the latest by August 1997

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, 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

Nonwovens used for the manufacture of 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 nonwoven should be stable with or without agents which are commonly used in wound management including antiseptics and cleaning 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 nonwoven, biological retesting may be necessary.

NOTE 1: Biocompatibility aspects for materials used in medical devices are covered by the EN 30993 Series of Standards prepared by CEN/TC 206.

NOTE 2: Specific tests for finished compresses are covered in Part 2 of this European standard.

1 Scope

This Part of EN 1644 specifies physical and chemical test methods for the evaluation of nonwovens used as materials for compresses for medical use.

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 29073-3: 1992	Textiles - Test methods for nonwovens - Part 3: Determination of tensile strength and elongation
ISO 565: 1990	Test sieves - Metal wire cloth, perforated metal plate and electroformed sheet - Nominal sizes of openings

ISO 3696 Water for analytical laboratory use - Specification and test methods

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 carry out tests under the conditions given in annex A.

5 Physical properties

5.1 Methods are given for determination of the following properties:

- Liquid absorbency time: according to annex B.
- Liquid absorptive capacity: according to annex C.

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

NOTE: In order to deal with an important property of compresses, which is their ability adequately to cleanse wounds, the inclusion of "abrasiveness" among these physical properties was considered. It was envisaged to adapt a kinetic friction test (used in the paper industry) to this particular situation. 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.

6 Chemical properties

Methods are given for determination of the following properties:

- Water soluble substances: according to annex D.

- Fluorescence: according to annex E.

- Acidity/alkalinity of aqueous extract: according to annex F.

- Non-polar soluble substances: according to annex G.

- Surface-active substances: according to annex H.

NOTE: Results of tests on nonwovens are not necessarily comparable with the results of similar tests performed on gauze: some tests usually performed on gauze have been found irrelevant for nonwovens and are therefore not listed here.

Annex A (normative)

Test method for conditioning

A.1 Principle

The object of this procedure is to specify the conditioning atmosphere and the method of conditioning nonwovens before and during testing.

A.2 Conditioning atmosphere

A.2.1 ***Temperature:*** (20 ± 2) °C.

A.2.2. ***Relative humidity:*** (65 ± 5) % r.h.

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 conditions 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.4 Procedure

A.4.1 ***Preliminary treatment***

The equilibrium moisture content of a nonwoven is achieved by absorption. Hold test specimens at (20 to 35) % relative humidity and not more than 40 °C until the test specimen is in a state to absorb water from the atmosphere specified in A.2 (24 h will usually suffice).

This preconditioning can be omitted where it is demonstrated that to do so will not lead to unacceptable errors.

A.4.2 ***Conditioning***

A.4.2.1 Place the test specimen in the conditioning atmosphere.

A.4.2.2 Suspend or support the test specimen so that the conditioning atmosphere has free access to its whole surface.

A.4.2.3 Weigh the test specimen at intervals of not less than 2 h.

A.4.2.4 Retain the test specimen in the conditioning atmosphere until the two last weightings do not differ by more than 0,25 % of the total mass of the test specimen.

A.4.3 ***Testing***

Unless otherwise specified, carry out all tests under the conditions given in A.2.

Annex B (normative)

Test method for determination of liquid absorbency time

B.1 Principle

This test method evaluates the liquid absorbency time of nonwovens, i.e. the time required for a test specimen of nonwoven to become completely wetted by the test liquid and imbibe test liquid into its interior structure.

The liquid absorbency time test measures the time required for the complete wetting of a test specimen (of mass 5 g) loosely rolled into a cylindrical wire basket (of mass 3 g) and dropped onto the surface of the liquid from a height of 25 mm.

In this method the liquid comes into contact with all surfaces of the test specimen.

B.2 Equipment

B.2.1 ***Cylindrical wire basket***, open at one end, of height (80 ± 1) mm, diameter (50 ± 1) mm, mass (3 ± 0,1) g, and constructed of suitable gauge wire to achieve a mass of 3 g (e.g. 0,5 mm diameter stainless steel wire) and having a mesh size of approximately 20 mm x 20 mm.

B.2.2 ***Container for liquid***

B.2.3 ***Stop-watch***

B.2.4 ***Test liquid, of known surface tension***

[Unless otherwise specified, distilled or deionized water of grade 3 conforming with ISO 3696].

B.3 Procedure

B.3.1 ***Either:***

a) cut five test specimens in the machine direction of width (76 ± 1) mm and of sufficient length such that they each weigh (5 ± 0,1) g. Space these strips equally across the sheet of nonwoven; or

b) if the nonwoven is produced in insufficient width to allow a test specimen of 76 mm width to be taken, cut test specimens of the maximum width possible such that they each weigh (5 ± 0,1) g.