ILNAS

Institut luxembourgeois de la normalisation
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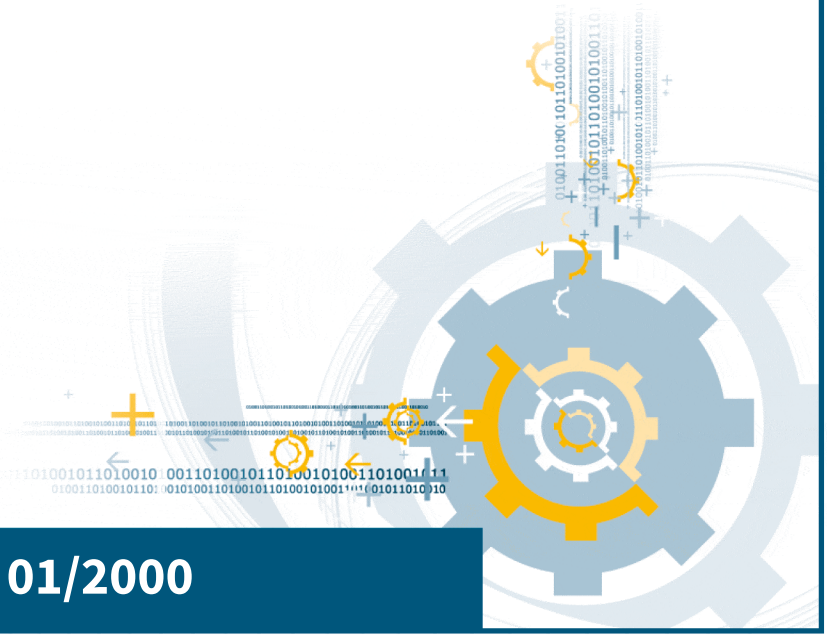
ILNAS-EN 1644-2:2000

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



01/2000

National Foreword

This European Standard EN 1644-2:2000 was adopted as Luxembourgish Standard ILNAS-EN 1644-2:2000.

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EUROPEAN STANDARD EN 1644-2

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English version

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

This European Standard was approved by CEN on 27 November 1999.

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. 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.

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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 1644-2:2000 E

Contents

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of an identical text or by endorsement, at the latest by July 2000, and conflicting national standards shall be withdrawn at the latest by July 2000.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