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

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 1644-2:2000 sisaldab Euroopa standardi EN 1644-2:2000 ingliskeelset teksti. Käesolev dokument on jõustatud 17.07.2000 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 1644-2:2000 consists of the English text of the European standard EN 1644-2:2000. This document is endorsed on 17.07.2000 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This part of EN 1644 specifies physical and chemical tests for the evaluation of finished compresses.	**Scope:** This part of EN 1644 specifies physical and chemical tests for the evaluation of finished compresses.

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Võtmesõnad:

EUROPEAN STANDARD
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English version

Test methods for nonwoven compresses for medical use

Part 2: Finished compresses

Méthodes d'essai pour compresses nontissées à usage médical – Partie 2: Compresses

Prüfungen für medizinische Vliesstoffkompressen – Teil 2: Kompressen

This European Standard was approved by CEN on 1999-11-27.

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.

The European Standards exist 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.

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CEN

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

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

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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.