Meditsiiniliseks kasutamiseks ettenähtud laustekstiilmähiste katsemeetodid. Osa 1: Laustekstiilsed materjalid, mida kasutatakse mähiste tootmisel

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

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 1644-1:1999 sisaldab Euroopa standardi EN 1644-1:1997 ingliskeelset teksti. Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 1644-1:1999 consists of the English text of the European standard EN 1644-1:1997. This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Standardi käesolev osa esitab selliste laustekstiilmaterjalide füüsikalise ja keemilise hindamise testimismeetodid, mida kasutatakse meditsiiniliseks otstarbeks ettenähtud mähiste materjalidena.	**Scope:**

ICS 11.120.20

Võtmesõnad: füüsikalised testid, hindamine, keemilised testid, konditsioneerimine, laustekstiilmaterjalid, materjalid, meditsiiniaparatuur, parameetrid, sidemed, testimistingimused, tootmine

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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

Prüfungen für medizinische Vliesstoff-kompressen – Teil 1: Vliesstoffe zur Herstellung von Kompressen

This European Standard was approved by CEN on 1997-01-05.

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.

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

CEN

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 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