SLOVENSKI STANDARD
SIST EN ISO 16021:2001

01-november-2001

Pripomočki za absorpcijo urina - Temeljna načela za ovrednotenje absorpcijskih pripomočkov za enkratno uporabo za odrasle, ki ne morejo zadrževati blata ali vode, z vidika uporabnikov in negovalcev

Urine-absorbing aids - Basic principles for evaluation of single-use adult-incontinence-absorbing aids from the perspective of users and caregivers (ISO 16021:2000)

Urinaufsaugende Hilfsmittel - Grundprinzipien für die Bewertung von Einmalgebrauchs-Hilfsmitteln für inkontinente Erwachsene aus der Sicht von Anwendern und Pflegekräften (ISO/FDIS 16021:2000)

Aides pour absorption d'urine - Principes de base pour l'évaluation des aides pour incontinents adultes par les utilisateurs et le personnel soignant (ISO/FDIS 16021:2000)

Ta slovenski standard je istoveten z: EN ISO 16021:2000

ICS:

11.180.20	Vrečke za blato in urinske vrečke	Aids for ostomy and incontinence

SIST EN ISO 16021:2001 en

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16021

November 2000

ICS 11.180

English version

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This European Standard was approved by CEN on 1 November 2000.

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

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Foreword

The text of the International Standard ISO 16021:2000 has been prepared by Technical Committee ISO/TC 173 "Technical systems and aids for disabled or handicapped persons" in collaboration with Technical Committee CEN/TC 293 "Technical aids for disabled persons", the secretariat of which is held by SIS.

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of an identical text or by endorsement, at the latest by May 2001, and conflicting national standards shall be withdrawn at the latest by May 2001.

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.

Endorsement notice

The text of the International Standard ISO 16021:2000 was approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 16021

First edition
2000-11-01

Urine-absorbing aids — Basic principles for evaluation of single-use adult-incontinence-absorbing aids from the perspective of users and caregivers

Aides pour absorption d'urine — Principes de base pour l'évaluation des aides pour incontinents adultes par les utilisateurs et le personnel soignant

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 16021 was prepared by Technical Committee ISO/TC 173, *Technical systems and aids for disabled or handicapped persons*, Subcommittee SC 3, *Aids for ostomy and incontinence*.

Introduction

This International Standard provides basic principles for conducting user evaluation of single-use, body-worn urine-absorbing aids by adult incontinent users, their caregivers, or both. It gives guidance in the understanding of product performance in actual use and hence can be used when making purchasing or reimbursement decisions, or both, from among a variety of products whose performance characteristics vary.

The focus of this International Standard is on the basic principles, which should be considered for evaluation of a single product in actual use. Where several products are to be evaluated, the procedure suggested should be applied to each, although the exact evaluation protocol used might vary, based on the unique characteristics of each product, the population of users being used for the evaluation, or both.

The comparison of user evaluation data obtained in evaluating several products is statistically complex and highly dependent upon the information desired from the evaluation, the differences between or among products, and the size of the user population used in the evaluation, to mention only three important factors. Direct comparison between products based on statistical parameters is not covered by this International Standard.

It is essential that those wishing to make statistically robust comparisons between different products consult a medical statistician for advice on, for example, the number of evaluation subjects they should recruit and randomizing the order of evaluating different products.

This International Standard draws on a French national standard [Q34-019: *Méthode d'essai au porter pour les articles d'hygiène infantile, féminine et de l'incontinence (articles à usage unique)*] and the protocols for incontinence product evaluation developed by the Continence Products Evaluation Network at University College London, England.

This International Standard is based upon an extensive body of data and experimentation on the ways in which evaluation of incontinence products by users may be done to gain useful information on product performance for a variety of purposes. Selected references are given in the Bibliography as an aid to the user of this International Standard in applying it to particular situations of interest.

ISO 16021 should be read in conjunction with the following related International Standards for Urine-absorbing aids:

— ISO 9949-1, *Urine absorbing aids — Vocabulary — Part 1: Conditions of urinary incontinence.*

— ISO 9949-2, *Urine absorbing aids — Vocabulary — Part 2: Products.*

— ISO 9949-3, *Urine absorbing aids — Vocabulary — Part 3: Identification of product types.*

— ISO 11948-1, *Urine-absorbing aids — Part 1: Whole-product testing.*

— ISO 11948-2, *Urine-absorbing aids — Part 2: Determination of short-time liquid release (leakage) under conditions of light incontinence and low pressure.*

— ISO 15621, *Urine-absorbing aids — General guidance on evaluation.*

Urine-absorbing aids — Basic principles for evaluation of single-use adult-incontinence-absorbing aids from the perspective of users and caregivers

1 Scope

This International Standard provides guidelines for designing and conducting a user evaluation of single-use adult-incontinence-absorbing aids. It provides guidance on creating data collection tools. In particular, it provides a framework for eliciting and recording the views of users and their carers on product performance. In addition, an optional approach for establishing the leakage performance and wear times of products and the mass of urine in them is described.

This International Standard does not cover direct comparison between products based on statistical parameters.

2 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply (in alphabetical order).

2.1
caregiver
person who assists user(s) with applying and changing incontinence products

NOTE Caregivers may be paid staff or family/friends.

2.2
ethics committee
body whose role is to protect the interests of evaluation subjects — particularly in institutions — by inspecting proposed evaluation protocols

NOTE Ethics committee permission is normally required before an evaluation can begin.

2.3
evaluation centre coordinator
person in charge of the evaluation in a given centre

2.4
principal investigator
person in overall charge of an evaluation

2.5
product
body-worn absorbent product intended to aid incontinent persons

NOTE Further information regarding products and product types is given in ISO 9949-2 and ISO 9949-3.

2.6
product line
group of similar products provided by a manufacturer/supplier which have similar construction but which differ from one another in such details as size or absorbency level