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

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 16021:2003 sisaldab Euroopa standardi EN ISO 16021:2000 ingliskeelset teksti. Käesolev dokument on jõustatud 19.03.2003 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 16021:2003 consists of the English text of the European standard EN ISO 16021:2000. This document is endorsed on 19.03.2003 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 standard provides guidelines for designing and conducting a user evaluation of single-use adult-incontinence-absorbing aids. It provides guidence 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 described.	**Scope:** This standard provides guidelines for designing and conducting a user evaluation of single-use adult-incontinence-absorbing aids. It provides guidence 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 described.

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Võtmesõnad: definition, definitions, disabled persons, evaluations, handicaped persons, handicapped people, hospitals, hygiene, incontinence, men, nurses, personnel, sanitary ap, sanitary appliances (patient), terminology, urine, user, women

EUROPEAN STANDARD
NORME EUROPÉENNE
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EN ISO 16021

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English version

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

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

This European Standard was approved by CEN on 2000-11-01.

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

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Foreword

International Standard

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

which was prepared by ISO/TC 173 'Technical systems and aids for disabled or handicapped persons' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 293 'Technical aids for disabled persons', the Secretariat of which is held by SIS, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by May 2001 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the 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.

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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.*

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