ICS 11.180.20 SLOVENSKÁ TECHNICKÁ NORMA Júl 2024

STN	**Produkty absorbujúce moč a stolicu Základné princípy hodnotenia produktu určeného pre dospelého používateľa na jedno použitie z perspektívy používateľa a poskytovateľa starostlivosti (ISO 16021: 2024)**	**STN EN ISO 16021** 85 6213

Absorbent incontinence products for urine and/or faeces - Basic principles for evaluation of single-use adult products from the perspective of users and caregivers (ISO 16021:2024)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 06/24

Obsahuje: EN ISO 16021:2024, ISO 16021:2024

Oznámením tejto normy sa ruší
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EUROPEAN STANDARD

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ICS 11.180.20 Supersedes EN ISO 16021:2000

English Version

Absorbent incontinence products for urine and/or faeces - Basic principles for evaluation of single-use adult products from the perspective of users and caregivers (ISO 16021:2024)

Produits d'incontinence pour l'absorption d'urine et/ou de matières fécales - Principes de base pour l'évaluation des produits à usage unique pour adultes par les utilisateurs et les soignants (ISO 16021:2024)

Urinaufsaugende Hilfsmittel - Grundprinzipien für die Bewertung von Einmalgebrauchs-Hilfsmitteln für inkontinente Erwachsene aus der Sicht von Anwendern und Pflegekräften (ISO 16021:2024)

This European Standard was approved by CEN on 25 August 2023.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 16021:2024 E

Contents

Page

European foreword

This document (EN ISO 16021:2024) has been prepared by Technical Committee ISO/TC 173 "Assistive products" in collaboration with Technical Committee CEN/TC 293 “Assistive products and accessibility” 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of an identical text or by endorsement, at the latest by October 2024, and conflicting national standards shall be withdrawn at the latest by October 2024.

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

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Endorsement notice

The text of ISO 16021:2024 has been approved by CEN as EN ISO 16021:2024 without any modification.

International Standard

ISO 16021

Absorbent incontinence products for urine and/or faeces — Basic principles for evaluation of single-use adult products from the perspective of users and caregivers

Second edition
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Contents

Page

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 173, *Assistive products*, Subcommittee SC 3, *Aids for ostomy and incontinence,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, *Assistive products and accessibility,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 16021:2000), which has been technically revised.

The main changes are as follows:

— clarified the scope;

— added references to new relevant standards;

— updated reference list;

— terminology has been harmonized with ISO 22748.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document provides basic principles for conducting user evaluations of single-use, body-worn urine-absorbing products for adult incontinent users, their caregivers, or both. It gives guidance for users or caregivers in evaluating products in actual use and can be used for comparing products. EDANA has provided useful guidelines on the evaluation of baby diapers[4] many of which apply equally to absorbent products for adult incontinence. Whether a user evaluation or a clinical investigation is planned, it is important to check if ethics committee approval will be required.

The comparison of user evaluation data obtained from 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 document.

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

International Standard **ISO 16021:2024(en)**

Absorbent incontinence products for urine and/or faeces — Basic principles for evaluation of single-use adult products from the perspective of users and caregivers

1 Scope

This document provides guidelines and requirements for designing and conducting an evaluation of single-use adult incontinence absorbing products. It provides guidelines and requirements on creating data collection tools. In particular, it provides a framework for eliciting and recording the views of users and their carers on the acceptability of products. In addition, a product diary is described which can help to quantify some parameters of product use, such as wear times, the mass of urine absorbed by the product and the severity of any leakage from it.

This document does not cover direct comparison between products based on statistical parameters, neither does it provide guidelines on measuring the clinical efficacy of products; that is available in ISO 14155.

2 Normative references

There are no normative references in this document.