# SLOVENSKI STANDARD
# oSIST prEN ISO 16021:2023

**01-julij-2023**

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**Izdelki za absorpcijo urina - Temeljna načela za ovrednotenje izdelkov za enkratno uporabo za odrasle, ki ne morejo zadrževati blata ali urina, z vidika uporabnikov in negovalcev (ISO/DIS 16021:2023)**

Urine-absorbing products - Basic principles for evaluation of single-use adult-incontinence products from the perspective of users and caregivers (ISO/DIS 16021:2023)



Urinaufsaugende Hilfsmittel - Grundprinzipien für die Bewertung von Einmalgebrauchs-Hilfsmitteln für inkontinente Erwachsene aus der Sicht von Anwendern und Pflegekräften (ISO/DIS 16021:2023)



Produits pour l'absorption d'urine - Principes de base pour l'évaluation des produits d'incontinence adulte à usage unique par les utilisateurs et les soignants (ISO/DIS 16021:2023)

**Ta slovenski standard je istoveten z:** **prEN ISO 16021**

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| 11.180.20 | Pripomočki pri stomi in inkontinenci | Aids for incontinence and ostomy |

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DRAFT INTERNATIONAL STANDARD

# ISO/DIS 16021

ISO/TC **173**/SC **3** Secretariat: **SIS**

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

ICS: 11.180.20



This document is circulated as received from the committee secretariat.

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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.

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.*



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

The main changes are as follows:

— Clarified that the recommendation in the standard is related to guidance for users and caregivers evaluating products and not for producers evaluating performance which require a clinical investigation

— Adding connection to new relevant standards

— Updated reference list

— Terminology has been harmonised with ISO 16021 to be consistent with ISO 22748 (new since ISO 16021 was first written). For example, we replaced "pad" with "absorbent product" since - in ISO 16021 - "pad" refers to a specific type of absorbent product.

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 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.

The focus of this document is on the basic principles which should be considered in evaluating products to determine their acceptability in actual use.). EDANA has provided useful guidelines on the evaluation of baby diapers (Guidelines for the Testing of Baby Diapers, EDANA, Brussels, 2016) many of which apply equally to absorbent products for adult incontinence. Whether a user evaluation or a clinical investigation is planned, it is vital to check if ethics committee approval will be required.

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 document.

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

This document 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 the acceptability of products 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 22748:2021 Absorbent incontinence products for urine and/or faeces — Product type names and illustrations

— ISO 15621, Absorbent incontinence aids for urine and/or faeces — General guidelines on evaluation

— ISO 14155 Clinical investigation of medical devices for human subjects - Good clinical practice

— EDANA Guidelines for the Testing of Baby Diapers Version 2.0 – April 2016

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

## 1 Scope

This document provides guidelines for designing and conducting an evaluation of single-use adult incontinence absorbing products. 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 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 guidance on measuring the clinical efficacy of products: that is available in ISO 14155 Clinical investigation of medical devices for human subjects – Good clinical practice.

## 2 Normative references

There are no normative references in this document.



## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.



ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

**3.1**
**caregiver**
person who assists user(s) with applying and changing incontinence products

Note 1 to entry: Caregivers may be paid staff or family/friends.

**3.2**
**ethics committee**
body whose role is to protect the interests of evaluation subjects — particularly in institutions — by inspecting proposed evaluation protocols

Note 1 to entry: Ethics committee permission is normally required before an evaluation can begin.

**3.3**
**evaluation centre coordinator**
person in charge of the evaluation in a given centre

**3.4**
**principal investigator**
person in overall charge of an evaluation

**3.5**
**product**
body-worn absorbent product intended to aid incontinent persons

Note 1 to entry: Further information regarding products and product types is given in ISO 22748.

**3.6**
**product variant**
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

**3.7**
**user**
person who wears the product(s) subject to evaluation

# 4 Creating the evaluation protocol

## 4.1 Questionnaires

This evaluation employs a series of questionnaires designed to collect users'/caregivers' observations and opinions on aspects of the acceptability of a product, or several products, over an agreed period of time. Further questionnaires are used to ascertain the age and health of the user, the severity of their incontinence and other relevant background information.

The information entered on the questionnaires is processed for each user and each product tested at the end of the evaluation period and is used to produce a report on the acceptability of each product in terms of the level of satisfaction of the users.



This document does not provide a standard protocol, since objectives for running evaluations, user populations, evaluation sites, products, and specific data of interest vary widely. Instead, it lists the primary issues, which should be considered in creating a protocol, along with guidelines on how to address them.



A record of the decisions made on these issues should be included in the evaluation report (see 8).

NOTE Some lists of issues to be considered in writing questionnaires and other documentation are provided, but users of this document are cautioned against using any of them exactly as found here without first verifying their usefulness for the intended study.

## 4.2 Selection of products

The *products* (3.5) or *product variants* (3.6) to be evaluated should be selected. Consideration should be given to obtaining samples from multiple production batches in order to randomize the selection and reduce the impact of atypical results emanating from, say, a faulty batch.

## 4.3 Selection of users

A group of users appropriate to the product to be evaluated should be selected in accordance with the manufacturers' intended use, as described in their technical documentation.

The severity of users' incontinence should be matched to the absorbency of the product(s) as declared by the manufacturer.

NOTE 1 In order to make a good match between users and products it might be useful to establish the absorption requirements of potential evaluators by weighing their used products over a period of several days. It will usually be possible to estimate the product absorption capacity an evaluator needs by weighing 10 or more of each user's used products.