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

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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 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.

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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.

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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.

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 absorbent incontinence *products* (3.5)

Note 1 to entry: Caregivers can 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

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