

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा

**यूरिन और/या मल असंयमिता अवशोषित सहायक उत्पाद —
उपयोगकर्ताओं और देखभाल करने वालों के दृष्टिकोण से एकल-प्रयोग
वयस्क उत्पाद के मूल्यांकन के लिए मूलरूप विशिष्ट तत्त्व**
(IS/ISO 16021 का पहला पुनरीक्षण)

Draft Indian Standard

**Absorbent Incontinence Products for Urine and/or Faeces —
Basic Principles for Evaluation of Single Use Adult Products from
the Perspective of Users and Caregivers**
(First Revision of IS/ISO 16021)

[ICS 11.180]

Assistive Products including Rehabilitation Last date for comments: 27 September 2025
Appliances, Orthotic and Prosthetic Items
Sectional Committee, MHD 09

NATIONAL FOREWORD

(Adoption clause will be added later)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'
- Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

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 help to quantify some parameters of product can 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.

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 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.

The technical content of the document has not been enclosed as it is identical with the corresponding ISO standard. For details, please refer to ISO 16021:2024 or kindly contact:

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