SLOVENSKI STANDARD
oSIST prEN ISO 15621:2025

01-februar-2025

Absorbenti za urin in/ali blato v izdelkih za inkontinenco - Splošne smernice za ovrednotenje (ISO/DIS 15621:2024)

Absorbent incontinence products for urine and/or faeces - General guidelines on evaluation (ISO/DIS 15621:2024)

Saugfähige Inkontinenzhilfen für Urin und /oder Stuhl - Allgemeine Richtlinien für die Evaluierung (ISO/DIS 15621:2024)

Produits d'incontinence pour l'absorption d'urine et/ou de matières fécales - Directives générales d'évaluation (ISO/DIS 15621:2024)

Ta slovenski standard je istoveten z: **prEN ISO 15621**

ICS:

11.180.20	Pripomočki pri stomi in inkontinenci	Aids for incontinence and ostomy

oSIST prEN ISO 15621:2025 **en,fr,de**

DRAFT International Standard

ISO/DIS 15621

Absorbent incontinence products for urine and/or faeces — General guidelines on evaluation

ICS: 11.180.20

ISO/TC **173**/SC **3**

Secretariat: **SIS**

Voting begins on:
2024-12-27

Voting terminates on:
2025-03-21

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 15621:2024(en)

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Published in Switzerland

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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).

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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.*

This fourth edition cancels and replaces the third edition (ISO 15621:2017), which has been technically revised.

The main changes are as follows:

— updated terms and definitions

— terminology has been harmonized with ISO 22748;

— updated reference list.

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

Incontinence is a set of diseases that affects between 4 % and 8 % of the population or the lives of approximately 425 million people worldwide. Absorbent products can help people affected by urinary and/or faecal incontinence to live an independent and dignified life. There are many absorbent incontinence products on the market that can help persons to stay dry and comfortable. They can be purchased at pharmacies or supermarkets by consumers or via public procurement from producers or wholesalers, but selecting the right product can be difficult.

There are many factors to consider when choosing absorbent incontinence products, for example:

— the particular needs of the end user (e.g. the nature and severity of their incontinence);

— the needs of assisting caregivers (e.g. ergonomics in the design of the product);

— the design of the products (e.g. inserts, all-in-ones, pull-ons), their characteristics (e.g. design to secure leakage security and maintaining skin health)

— cost;

— and environmental impact.

Currently, there is a limited amount of published data on these factors. ISO 15621 gives guidance for evaluating absorbent incontinence products so that informed choices can be made. It describes the needs of people with incontinence, lists the most important factors for end users and caregivers and gives an overview of testing methodologies/interpretation of test results.

There are a number of stakeholders who could benefit from using this document, e.g. purchasers within healthcare systems, care providers, nursing home managers, prescribers, caregivers, manufacturers, suppliers, sick funds, insurance companies and end users themselves. These stakeholders often have different priorities and different needs. However, it is important to remember that the most important stakeholder is always the end user. End users have different needs depending on, for example, their anatomy, age, the nature and severity of incontinence, mobility, dexterity, cognitive status, mental health, lifestyle, and personal priorities. These factors should be taken into account when the most appropriate products are being chosen by/for them. Practical, in-use suitability is best determined by testing products with the individual end user.

Other standards that might be useful for evaluating absorbent incontinence products and performing user trials include

— ISO 6658,

— ISO 9999,

— ISO 11948-1, and

— ISO 16021,

— ISO 22748,

Absorbent incontinence products for urine and/or faeces — General guidelines on evaluation

1 Scope

This document gives guidelines for evaluating absorbent incontinence products for urine and/or faeces for adults and children. It provides a context for the procedures described in other International Standards and published testing procedures. General factors relating to incontinence products and their usage are also addressed.

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 General terms

3.1.1
absorbent incontinence product
product containing absorbent material to absorb/contain urine and/or contain faeces when the wearer experiences incontinence

3.1.2
absorption capacity
amount of liquid that can be absorbed by an *absorbent incontinence product* (3.1.1) under specified conditions

3.1.3
acquisition speed
time taken for a specified amount of liquid to be absorbed into an *absorbent incontinence product* (3.1.1) under specified conditions

3.1.4
end user
person who wears an *absorbent incontinence product* (3.1.1)

3.1.5
caregiver
person who assists user(s) with applying and changing incontinence products

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

3.1.6
absorbent product with sensors
absorbent product with sensors that are used to monitor the saturation of a product to indicate when it might need changing and/or assist with care planning

3.1.7
retention capacity
amount of liquid that is retained by an *absorbent incontinence product* (3.1.1) after all unbound liquid has been removed under specified conditions

3.1.8
rewet
amount of liquid that escapes from an *absorbent incontinence product* (3.1.1) when it is exposed to external forces or pressure under specified conditions

3.2 Product types

3.2.1
all-in-one
brief
slip
absorbent incontinence product equipped with a fastener system that allows it to be secured to the body.

Note 1 to entry: An all-in-one usually has elastics surrounding the leg openings and/or self-adhesive tape

[SOURCE: ISO 22748:2021]

3.2.2
belted pad
absorbent incontinence product in which the absorbent core is mounted within a chassis, equipped with a re-adjustable waist belt. The belt is designed to help with putting the pad on, especially in the standing position

[SOURCE: ISO 22748:2021]