



NSAI
Standards

Irish Standard
I.S. EN ISO 15621:2017

Absorbent incontinence aids for urine and/or faeces - General guidelines on evaluation (ISO 15621:2017)

I.S. EN ISO 15621:2017

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

I.S. EN ISO 15621:2017 is the adopted Irish version of the European Document EN ISO 15621:2017, Absorbent incontinence aids for urine and/or faeces - General guidelines on evaluation (ISO 15621:2017)

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 15621

July 2017

ICS 11.180.20

English Version

**Absorbent incontinence aids for urine and/or faeces -
General guidelines on evaluation (ISO 15621:2017)**

Aides à l'incontinence pour l'absorption d'urine et/ou
de matières fécales - Directives générales d'évaluation
(ISO 15621:2017)

Hilfen zur Urinabsorption - Allgemeine Richtlinien für
die Evaluierung (ISO 15621:2017)

This European Standard was approved by CEN on 28 May 2017.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EN ISO 15621:2017 (E)

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European foreword

This document (EN ISO 15621:2017) has been prepared by Technical Committee ISO/TC 173 “Assistive products for persons with disability” in collaboration with Technical Committee CEN/TC 293 “Assistive products for persons with disability” 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of an identical text or by endorsement, at the latest by January 2018, and conflicting national standards shall be withdrawn at the latest by January 2018.

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 15621:2017 has been approved by CEN as EN ISO 15621:2017 without any modification.

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INTERNATIONAL STANDARD

**ISO
15621**

Third edition
2017-06

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

*Aides à l'incontinence pour l'absorption d'urine et/ou de matières
fécales — Directives générales d'évaluation*



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

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 173, *Assistive products for persons with disability*, Subcommittee SC 3, *Aids for ostomy and incontinence*.

This third edition cancels and replaces the second edition (ISO 15621:2011), which has been technically revised.

Introduction

Incontinence is a set of diseases that affects between 4 % and 8 % of the population or the lives of approximately 400 million people worldwide. Absorbent aids can help people affected by urinary and/or faecal incontinence to live an independent and dignified life. There are many absorbent incontinence aids 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 aids, for example:

- the particular needs of the end user (e.g. the nature and severity of their incontinence);
- the needs of an assisting carer (e.g. ergonomics in the design of the product);
- the design of the aids (e.g. inserts, all-in-ones, pull-ons), their characteristics (e.g. absorption capacity and ease of putting on) and cost;
- environmental factors.

Currently, there is a limited amount of published data on these factors. ISO 15621 gives guidance for evaluating absorbent incontinence aids so that informed choices can be made. It describes the needs of the incontinent population, 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, nursing home managers, prescribers, caregivers, manufacturers, suppliers, sick funds, insurance companies and end users. 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 gender, age, the nature and severity of incontinence, mobility, dexterity, 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 aids and performing user trials include

- ISO 6658,
- ISO 9999,
- ISO 11948-1, and
- ISO 16021.

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

1 Scope

This document gives guidelines for evaluating absorbent incontinence aids for urine and/or faeces. 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 terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1 General terms

3.1.1

absorbent incontinence aid

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

3.1.2

absorption capacity

amount of liquid that can be absorbed by an *absorbent incontinence aid* (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 aid* (3.1.1) under specified conditions

3.1.4

end user

person who uses an *absorbent incontinence aid* (3.1.1)

3.1.5

carer

person or organization who helps someone to perform their tasks of daily living, such as managing their incontinence

3.1.6

retention capacity

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

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