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STN	**Absorpčné inkontinenčné pomôcky na moč a/alebo stolicu Všeobecné pokyny na hodnotenie (ISO 15621: 2017)**	**STN EN ISO 15621** 85 2928

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/17

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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.

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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of an identical text or by endorsement, at the latest by January 2018, and conflicting national standards shall be withdrawn at the latest by January 2018.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.

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

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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.

INTERNATIONAL STANDARD **ISO 15621:2017(E)**

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.