SLOVENSKI STANDARD
SIST EN ISO 15621:2017

01-september-2017

Nadomešča:
SIST ISO 15621:2016

Absorbenti za urin in/ali blato v pripomočkih za inkontinenco - Splošne smernice za ovrednotenje (ISO 15621:2017)

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

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

Aides pour l'absorption d'urine - Directives générales d'évaluation (ISO 15621:2017)

Ta slovenski standard je istoveten z: **EN ISO 15621:2017**

ICS:

11.180.20	Pripomočki pri stomi in inkontinenci	Aids for incontinence and ostomy

SIST EN ISO 15621:2017 **en**

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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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of an identical text or by endorsement, at the latest by January 2018, and conflicting national standards shall be withdrawn at the latest by January 2018.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

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 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.

