International Standard

ISO 15621

Absorbent incontinence products for urine, faeces, or both — General guidelines on evaluation

Produits d'incontinence absorbants pour l'urine, les matières fécales ou les deux — Lignes directrices générales pour l'évaluation

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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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This document was prepared by Technical Committee ISO/TC 173, *Assistive products*, Subcommittee SC 3, *Aids for ostomy and incontinence,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, *Assistive products and accessibility,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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 Bibliography.

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 incontinence or faecal incontinence, or both, 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. pads, all-in-ones, pull-ons) and their characteristics (e.g. design to secure leakage security and maintaining skin health);

— cost;

— environmental impact.

Currently, there is a limited amount of published data on these factors. This document 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 and interpretation of test results.

There are a number of stakeholders who can 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 and for them. Practical, in-use suitability is best determined by testing products with the individual end user.

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

— ISO 6658,

— ISO 9999,

— ISO 11948-1,

— ISO 16021, and

— ISO 22748.