BS ISO 12505-1:2014

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Skin barrier for ostomy aids — Test methods

Part 1: Size, surface pH and water-absorbency

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National foreword

This British Standard is the UK implementation of ISO 12505-1:2014.

The UK participation in its preparation was entrusted to Technical Committee CH/173/-/3, Aids for ostomy and incontinence.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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ISBN 978 0 580 76251 2

ICS 11.180.20

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 28 February 2014.

Amendments issued since publication

Date	Text affected

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INTERNATIONAL STANDARD

ISO 12505-1

First edition
2014-02-15

Skin barrier for ostomy aids — Test methods —

Part 1: Size, surface pH and water-absorbency

Barrière cutanée pour appareillages stomiques — Méthodes d'essai —

Partie 1: Taille, pH de surface et absorbance d'eau

Reference number
ISO 12505-1:2014(E)

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Published in Switzerland

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Foreword

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 173, *Assistive products for persons with disability*, Subcommittee SC 3, *Aids for ostomy and incontinence*.

ISO 12505 consists of the following parts, under the general title *Skin barrier for ostomy aids — Test methods*:

— *Part 1: Size, surface pH and water-absorbency*

— *Part 2: Wet-integrity and adhesive strength*

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Introduction

Skin barriers are made to seal the ostomy bag to the skin and stay on, protecting the peristomal skin from excrements and secretion, and keeping the skin physiology intact by absorbing or permeating sweat.

The skin characteristics vary from person to person, and the products behave differently from each other depending on type of stoma, purpose of use, atmosphere, and other environmental factors, care techniques, the user's way of daily living etc. These make the testing situation complex and a number of test methods have been developed — laboratory and clinically based. But despite the efforts and improvements made, there are still problems for the user of the products — trial and error can still be the prime method to find an adequate product.

The problem that we primarily focus upon is the possibility for the users — purchasers, professional staffs, persons with stoma etc. — to rationally evaluate the products and the test methods used.

The skin barrier is an important part of an ostomy product. It protects the peristomal skin and holds the ostomy bag in place. Skin barriers shall be flexible, erosion-resistant, skin-friendly, and having adhesion properties that allows the bag to stay in place and be removed. Skin barriers are manufactured in a number of shapes and degrees of convexity and flexibility. Understanding how skin barriers are designed and work will help to provide ostomy patients or consumers with the best products.

The properties of skin barriers differ and there is a need to evaluate them properly. Skin barriers can be evaluated by either clinical trials or by laboratory test methods. Clinical trials are not covered here but in other International Standards. Laboratory test methods found in other International Standards were not developed for skin barriers but for industrial tapes. Methods found elsewhere differ by manufacturer, consumer, and medical professional.

The test methods found in this International Standard covers the evaluation of size, pH, and absorption. The methods have been specifically designed for skin barriers for ostomy products.

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