BS ISO 12505-2:2016

BSI Standards Publication

Skin barrier for ostomy aids — Test methods

Part 2: Wet integrity and adhesive strength

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National foreword

This British Standard is the UK implementation of ISO 12505-2:2016.

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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Part 2: Wet integrity and adhesive strength

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Partie 2: Résistance des adhésifs et intégrité une fois mouillés

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Foreword

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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 stoma effluent 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, 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, based on laboratory and clinical testing. But despite the efforts and improvements made, there are still problems for the user of the products; trial and error may still be the prime method to find an adequate product.

The problem that we primarily focus upon is the ability 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 are flexible, erosion-resistant, skin-friendly and have adhesion properties that allow the bag to stay in place during use and be removed following use. 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 for adhesive products were not developed for skin barriers but for industrial tapes. The test methods found in this part of ISO 12505 cover the evaluation of wet integrity and adhesion. The methods have been specifically designed for skin barriers for ostomy aids.

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