INTERNATIONAL STANDARD

ISO 12505-2

First edition
2016-10-15

Skin barrier for ostomy aids — Test methods —

Part 2: Wet integrity and adhesive strength

Barrière cutanée pour appareillages stomiques — Méthodes d'essai —

Partie 2: Résistance des adhésifs et intégrité une fois mouillés

Reference number
ISO 12505-2:2016(E)

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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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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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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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Skin barrier for ostomy aids — Test methods —

Part 2:
Wet integrity and adhesive strength

CAUTION — These test methods may not provide design information as there may be no direct relationship between laboratory test results and functional requirements. Data shall not be interpreted as applying to clinical use of the skin barrier because of variations in the skin and in the user's pouching techniques.

1 Scope

This part of ISO 12505 specifies test methods dealing with face plates of skin barriers for ostomy aids.

This part of ISO 12505 does not cover medical properties (cytotoxicity, sensitization, irritation/intracutaneous reactivity, buffering effect, microbiological effects, etc.).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 24214, *Skin barrier for ostomy aids — Vocabulary*

ISO 12505-1, *Skin barrier for ostomy aids — Test methods — Part 1: Size, surface pH and water-absorbency*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 24214, ISO 12505-1 and the following apply.

3.1
wet integrity
ability of a skin barrier to maintain its physical form when exposed to fluid

3.2
adhesive strength
force required to peel a skin substitute from the surface of a skin barrier specimen

3.3
specimen
single typical part or example taken from the trial sample sheet as a test piece

4 Evaluation of skin barriers

4.1 General

This part contains the following tests/measurements:

Wet integrity test and adhesive strength (resistance upon removal) test.

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