



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 41170.2-2021

**Skin barrier for ostomy aids - Test methods - Part 2: Wet
integrity and adhesive strength
(English Translation)**

Issued on: January 1, 1970

Implemented on: January 1, 1970

**Issued by: State Administration for Market Regulation, China National
Standardization Administration**

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Reference

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules of Standardization Documents" drafted:

This document is part 2 of GB/T 41170 "Test methods for skin protection products for ostomy aids": GB/T 41170 has been issued the following parts are distributed:

--- Part 2: Moisture integrity and bond strength:

This document is identical to ISO 12505-2:2016 "Test methods for skin protection products for ostomy aids - Part 2: Endurance to moisture Integrity and Adhesive Strength":

Please note that some content of this document may be patented: The issuing agency of this document assumes no responsibility for identifying patents:

Introduction

Skin protectors seal and hold the pouch over the skin, protect the skin around the stoma from stoma discharge, and Keeps skin physiology intact by absorbing or permeating sweat:

Skin characteristics vary from person to person, and product performance also depends on the type of stoma, purpose of use, environmental factors, care techniques, and the user's daily life:

These complicate the testing situation, and many testing methods have been developed based on laboratory and clinical testing: However, despite Efforts and improvements have been made, users of the product still have problems, and trial and error may still be the primary method of finding the right product:

Our main concern is the rationality of users (buyers, professionals, ostomy patients, etc:)

about the product and the testing methods used ability to assess:

Skin protection products are an important part of ostomy products: It protects the skin around the cornea and secures the pouch in place current location: The stoma auxiliary skin protection product is elastic, corrosion-resistant, skin-friendly, and has adhesiveness, which makes the ostomy bag easy to use:

It stays in place during the process and can be removed after use: Skin protectors for ostomy aids come in a variety of shapes with different convexities and elasticity: Understanding how ostomy-assisted skin protection is designed and works will help provide the best ostomy patient or consumer product:

The nature of skin protection products varies, so they need to be properly evaluated: Skin protection products can pass clinical trials or Laboratory test methods are evaluated: Clinical trials are not included in this document, this work is in other standards: used in other international standards the laboratory test method was not developed for ostomy auxiliary skin protection products, but for industrial tapes: The test used in this document the test method covers the evaluation of moisture integrity and bond strength: This method is specifically designed for stoma-assisted skin protection products:

GB/T 41170 is intended to consist of two parts:

--- Part 1: Dimensions, surface pH and water absorption;

--- Part 2: Moisture integrity and bond strength:

Test methods for skin protection products for ostomy aids Part 2: Moisture Integrity and Bond Strength Note: Since there is not necessarily a direct relationship between laboratory test results and functional requirements, this test method does not provide design information interest: Due to differences in user skin and ostomy bag technology, test data should not be interpreted as suitable for clinical use of skin protection products:

1 Scope

This document describes the test methods for moisture integrity and adhesive strength of stoma-assisted skin protection products:

This document does not contain the medical properties (cytotoxicity, sensitization, irritation/intradermal reactions, buffering, micro biological effects, etc.):

2 Normative references

The contents of the following documents constitute essential provisions of this document through normative references in the text: Among them, dated citations documents, only the version corresponding to that date applies to this document; for undated references, the latest edition (including all amendments) applies to this document:

ISO 12505-1 Test methods for skin protection products for ostomy aids - Part 1:
Dimensions, surface pH and water absorption (Skinbarrierforostomyaids-Testmethods-Part
1:Size,surfacepHandwater-absorbency) ISO 24214 Terminology for skin protection articles
for ostomy aids (Skinbarrierforostomyaids-Vocabulary)

3 Terms and Definitions

Terms and definitions defined in ISO 12505-1, ISO 24214 and the following apply to this document:

Moisture Integrity Wetintegrity the ability of a skin protection article to maintain its physical form when exposed to liquids:

Adhesivestrength

The force required to peel the skin substitute from the surface of the skin protectant sample:

Specimen

Select a representative part or sample from the test sample as the test piece:

4 Evaluation of skin protection products

4.1

General

This document contains the following tests: Moisture Integrity and Adhesive Strength (Peel Resistance) Tests:

The methods of this document are not intended to specify or recommend specific designs, styles and sizes of products, nor are they recommended for medical use, such as treatment, nursing Wait: This test method should be used according to market needs to meet the performance of skin protection products: