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

GB/T 41170.1-2023

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

造口辅助器具的皮肤保护用品 试验方法 第1部分：尺寸、表面pH值和吸水性

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Foreword

This document was issued on 6 August 2023 by the State Administration for Market Regulation; Standardization Administration of the PRC and takes effect on 1 March 2024.

It is a GB/T standard: recommended rather than compulsory, but it is the text a Chinese reviewer applies when assessing a submission.

It is classified under ICS 11.180.20, Chinese classification C45.

This document complies with the regulations of GB/T 1.1-2020 "Standardization Work Guidelines Part 1. Structure and Drafting Rules of Standardization Documents"

Custom drafting.

This document is Part 1 of GB/T 41170 "Test Methods for Skin Protective Products for Ostomy Assistive Devices". GB/T 41170 has been

The following sections have been published.

---Part 1. Size, surface pH and water absorption;

---Part 2. Moisture integrity and bonding strength.

This document is modified to adopt ISO 12505-1:2014 "Test methods for skin protection products of stoma assistive devices - Part 1. Dimensions,

Surface pH and water absorption.

The technical differences between this document and ISO 12505-1:2014 and their reasons

are as follows.

---Delete the normative reference document ISO 24214.2006, ISO 24214.2006 has been abolished;

---The normative reference document ISO 7886-1.1993 is replaced by ISO 7886-1.2017. ISO 7886-1.1993 has been abolished.

Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents.

This document is proposed by the Ministry of Civil Affairs of the People's Republic of China.

This document is under the jurisdiction of the National Standardization Technical Committee for Rehabilitation and Special Equipment for Disabled Persons (SAC/TC148).

This document was drafted by. National Research Center for Rehabilitation Assistive Devices, Xiangya Hospital of Central South University, Kefu Medical Technology Co., Ltd., Xiamen Rui

Deli Calibration and Testing Technology Co., Ltd., Pony Testing Group Co., Ltd.

The main drafters of this document. Liu Junling, Ma Fengling, Liu Longfei, Liu Lixia, Li Mingjie, Ma Lifang, Fang Pengyue, Zhang Zhongwu, Sun Zhaozeng.

Introduction

Skin protection products seal and keep the ostomy bag on the skin, protect the skin around the stoma from stoma discharge, and allow the skin to pass through.

Keep the skin's physiological functions intact by absorbing or penetrating sweat.

Skin characteristics vary from person to person. The performance of skin protection products also depends on the type of stoma, purpose of use, environmental factors, nursing techniques, and users.

vary from daily life to lifestyle. These complicate the testing situation. Based on laboratory and clinical testing, a variety of test methods have been developed

Law. However, despite all the efforts and improvements, users still have problems with their skin, and trial and error is the main way to find the right product.

method.

Our main concern is the understanding of the product and the test methods used by users (purchasers, professionals, ostomy patients, etc.)

sexual assessment capabilities.

Skin protection products are an important part of ostomy products. It protects the skin

around the stoma and holds the pouch in place.

Skin protection products are elastic, corrosion-resistant, skin-friendly, and have adhesive properties. This adhesive property keeps the ostomy bag stationary during use.

Can be removed later. Skin protection products come in many shapes, with different convexities and elasticities. Understand how skin protection products are designed and work

formula will help provide the best product for ostomy patients.

Skin protection products have different properties, so they need to be properly evaluated. Skin protection products can pass clinical trials or

Laboratory test evaluation. This document only includes laboratory test methods, not clinical test methods. Actual values used in other national standards

The laboratory test method was not developed for skin protection products but for industrial tapes.

The test methods in this document include evaluation of size, surface pH and water absorption. This method is specially designed for the skin of stoma assistive devices.

Skin protection product design.

GB/T 41170 aims to specify the test methods for the relevant performance of skin protection products for stoma auxiliary devices and is planned to be released in two parts.

---Part 1. Size, surface pH and water absorption. The purpose is to describe the dimensions and appearance of skin protection products for stoma assistive devices.

Test methods for surface pH and water absorption.

---Part 2. Moisture integrity and bonding strength. The purpose is to describe the moisture-resistant integrity of skin protection products for ostomy assistive devices.

and adhesive strength test methods.

Test methods for skin protection products for stoma assistive devices

Part 1. Size, surface pH and water absorption

1 Scope

GB/T 41170.1-2023 gives the laboratory methods for the skin protection product that holds an ostomy pouch on the body and shields the skin around the stoma. A single evaluation clause carries the work: an overview, the test conditions the samples are held at, the dimensional measurement of the barrier chassis, the determination of surface pH, the water absorption test, and what the inspection report has to contain. The three properties are the ones the wearer feels. A barrier that does not match its stated size leaks or presses on the

stoma; the surface pH decides whether the product sits kindly on skin already irritated by stoma output; and absorbency governs how sweat and moisture under the barrier are taken up, which is what decides whether the seal holds for the wear time claimed. Biological properties such as cytotoxicity, sensitization, irritation and microbial effects are deliberately left out and dealt with elsewhere, and nothing here prescribes a design, a style, a size or a course of care, only how to measure what a product does. Part 1 of the GB/T 41170 series. For manufacturers of ostomy accessories, the testing laboratories that support them, and regulatory and procurement staff comparing one barrier against another.

This document specifies test methods for skin protection chassis dimensions, surface pH and water absorption of ostomy assistive devices.

This document does not include medical properties (cytotoxicity, sensitization, irritation/intradermal reactivity, buffering effect, microbial effects, etc.).

The test methods in this document do not apply to specifying or recommending specific designs, styles or sizes of products, or to recommending treatments, care and other medical matters.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations

For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to

this document.

testing-Specifications)

Note. GB 15810-2019 Single-use sterile syringes (ISO 7886-1.2017, MOD)

ISO 10523.2008 Water quality-Determination of pH (Water quality-Determination of pH)

Note. GB/T 22592-2008 General principles for determination of pH value of water treatment agents (ISO 10523.1994, NEQ)

3 Terms and definitions

The following terms and definitions apply to this document.

3.1

Surface pH surface pH

The value measured using a glass electrode pH meter under humid conditions on the part