



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

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**Aids for ostomy and incontinence - Irrigation sets -
Requirements and test methods**

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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"

Drafting.

This document is equivalent to ISO 16391.2002 "Requirements and test methods for lavage devices for ostomy and incontinence aids".

The Chinese documents that have consistent correspondence with the normatively cited international documents in this document are as follows.

---GB/T 16886.1-2011 Biological Evaluation of Medical Devices Part 1.Evaluation and Testing in the Process of Risk Management
(ISO 10993-1:2009, IDT).

This document has also made the following editorial changes.

---Added references.

1 Scope

This document specifies the requirements and test methods for lavage devices for colostomy care.

2 Normative references

The content of the following documents constitutes an indispensable clause of this document through normative references in the text. Among them, dated quotations

Only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to

This document.

ISO 10993-1 Biological Evaluation of Medical Devices Part 1.Evaluation and Testing in the Risk Management Process (Biological evaluation of medical devices-Part 1.Evaluation and testing)

3 Terms and definitions

The following terms and definitions apply to this document. Some terms are illustrated in Figure 1.

3.1

Belt

It is made of flexible material and is wrapped around the waist of the patient to fix the belt of the pressure plate of the drainage tube.

3.2

Colostomy

A surgical incision or stoma made between the colon and the body surface.

3.3

Connector

A device that connects the components of the lavage device.

3.4

Drainagesystem

An assembly for lavage of various parts of the colostomy, including a drainage tube, a pressure plate, a stoma hole, a band hook and a band.

3.5

Drainagesleeve

The catheter through which the lavage sewage passes from the colostomy to the waste disposal container.

3.6

Flowcontroller

A device for adjusting the flow of irrigation water.

Note. The flow controller is adjustable from the closed position to the fully open position.

3.7

Flow indicator

A device that displays the flow of irrigation water.