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Ostomy collection bags - Part 2: Requirements and test methods (ISO 8670-2: 1996)

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Swedish Standards corresponding to documents referred to in this Standard are listed in "Catalogue of Swedish Standards", issued by SIS. The Catalogue lists, with reference number and year of Swedish approval, International and European Standards approved as Swedish Standards as well as other Swedish Standards.

Stomipåsar - Del 2: Krav och provningsmetoder (ISO 8670-2:1996)

Europastandarden EN ISO 8670-2: 1996 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 8670-2: 1996.

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ICS 11.180.00

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English version

**Ostomy collection bags - Part 2: Requirements
and test methods (ISO 8670-2:1996)**

Poches de recueil pour stomie -
Partie 2: Prescriptions et méthodes d'essai
(ISO 8670-2:1996)

Ostomiesammelbeutel - Teil 2: Anforderungen
und Prüfverfahren (ISO 8670-2:1996)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

The text of the International Standard ISO 8670-2:1996 has been prepared by Technical Committee ISO/TC 173 "Technical systems and aids for disabled or handicapped persons" in collaboration with Technical Committee CEN/TC 293 "Technical aids for disabled persons", the secretariat of which is held by SIS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 1997, and conflicting national standards shall be withdrawn at the latest by June 1997.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 8670-2:1996 was approved by CEN as a European Standard without any modification.

Ostomy collection bags -

Part 2: Requirements and test methods

1 Scope

This part of ISO 8670 specifies performance requirements and test methods for one-piece and multiple-piece ostomy systems having collection bags of the following types:

- a) closed-ended bags;
- b) open-ended bags;
- c) urostomy bags.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 8670. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8670 are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8670-1:1996, *Ostomy collection bags – Part 1: Vocabulary*.

3 Definitions

For the purposes of this part of ISO 8670, the definitions given in ISO 8670-1 and the following definitions apply.

3.1 flatus filter: Device that contains a porous material for deodorizing flatus as it escapes from the bag.

3.2 multiple-piece flange system: Effluent collection system in which a component is positioned around the stoma allowing an effluent collection bag to be attached or removed while the component itself remains in position.

3.3 ostomy bag: Flexible container for collecting body effluent from the stoma.

3.4 stoma: Abnormal opening established on the body surface.

3.5 test volume: That volume on which is based the volume of liquid added, or the force applied, to an ostomy collection bag when performing tests to verify the strength and leakage resistance of the bag assembly.

4 Requirements

4.1 Freedom from leakage

4.1.1 When tested by the method given in 6.2, bags without flanges shall not leak.

4.1.2 When tested by the method given in 6.3, bags (systems) with flanges shall not leak.

4.2 Retention of open-ended bag closure

When tested by the method given in 6.4, the open-ended bag closure shall remain in position when used following the bag manufacturer's instructions.

4.3 Burst strength (static)

When tested by the method given in 6.5, the bag shall not leak.

4.4 Marking of the ostomy collection system

4.4.1 For identification purposes, the bag shall be marked with at least the product code and the name and/or trademark of the manufacturer or supplier.

4.4.2 If the opening for the stoma is intended to be enlarged, the maximum opening shall be either

a) marked on the product

or

b) given in the instructions.

5 General test conditions

5.1 Temperature

The standard temperature for testing (atmosphere and reagent) shall be $23\text{ °C} \pm 2\text{ °C}$.

5.2 Test samples

Testing shall be carried out on product samples as supplied to the end-user.

6 Test methods

6.1 Test volume

6.1.1 Principle

The ostomy collection bag is filled with water and the volume of water within the bag is measured.

6.1.2 Reagent

6.1.2.1 lap water.