

**Kogumiskotid õõnesorganite tehis-
välisavade jaoks. Osa 2: Nõuded ja
katsemeetodid**

Ostomy collection bags - Part 2: Requirements and
test methods

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 8670-2:1999 sisaldab Euroopa standardi EN ISO 8670-2:1996 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 8670-2:1999 consists of the English text of the European standard EN ISO 8670-2:1996.</p> <p>This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala: Standardi käesolev osa esitab eksploatatsiooninõuded ja testimismeetodid õõnesorganite tehis-välisavade jaoks mõeldud ühes tükis olevatele või mitmetest tükkidest koosnevatele süsteemidele, millel on järgmist tüüpi kogumiskotid: (a) kinnise otsaga kotid; (b) lahtise otsaga kotid; (c) kuseteede tehisavade jaoks mõeldud kotid.</p>	<p>Scope:</p>
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ICS 11.180

Võtmesõnad: funktsionaalsus, kogumiskotid õõnesorganite tehis-välisavade jaoks, meditsiiniaparatuur, puuetega inimesed, tehnilised andmed, testimine, testimisvahendid

ICS 11.180

Descriptors: Medical equipment, ostomy collection bags, performance, testing.

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)

This European Standard was approved by CEN on 1996-12-14 and is identical to the ISO Standard as referred to.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

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

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

International Standard

ISO 8670-2:1996 Ostomy collection bags – Part 2: Requirements and test methods,

which was prepared by ISO/TC 173 'Technical systems and aids for disabled or handicapped persons' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 293 'Technical aids for disabled persons' as a European Standard.

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

In accordance with the CEN/CENELEC Internal Regulations, 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.

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Introduction

Users of this part of ISO 8670 are advised to consider the desirability of third-party certification of product conformity with this part of ISO 8670, based on testing and continuing surveillance, which may be coupled with assessment of a supplier's quality system against the appropriate standards in the ISO 9000 series.

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.