
Ostomy collection bags —
Part 2:
Requirements and test methods

Poches de recueil pour stomie —

Partie 2: Prescriptions et méthodes d'essai



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 8670-2 was prepared by Technical Committee ISO/TC 173, *Technical systems and aids for disabled or handicapped persons*, Subcommittee SC 3, *Aids for ostomy and incontinence*.

This second edition cancels and replaces the first edition (ISO 8670-2:1991) which has been technically revised.

ISO 8670 consists of the following parts, under the general title *Ostomy collections bags*:

- *Part 1: Vocabulary*
- *Part 2: Requirements and test methods*

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.

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.