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Urine collection bags - Part 2: Requirements and test methods (ISO 8669-2:1996)

Urinauffangbeutel - Teil 2: Anforderungen und Prüfverfahren (ISO 8669-2:1996)

Poches de recueil d'urine - Partie 2: Prescriptions et méthodes d'essai (ISO 8669-2:1996)

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Ta slovenski standard je istoveten z: EN ISO 8669-2:1996

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ICS:

11.180.20 X!^ \^Á|æ|æ|Á|ã •\^ Aids for ostomy and
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EUROPEAN STANDARD

EN ISO 8669-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 1996

ICS 11.180

Descriptors: see ISO document

English version

Urine collection bags - Part 2: Requirements and test methods (ISO 8669-2:1996)

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CEN

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

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

EN ISO 8669-2 : 1996**Foreword**

The text of the International Standard ISO 8669-2:1996 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of an identical text or by endorsement, at the latest by June 1997, and conflicting national standards shall be withdrawn at the latest by June 1997.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 8669-2:1996 was approved by CEN as a European Standard without any modification.

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INTERNATIONAL STANDARD

ISO
8669-2

Second edition
1996-12-15

Urine collection bags — Part 2: Requirements and test methods

Poches de recueil d'urine —

Partie 2: Prescriptions et méthodes d'essai

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Reference number
ISO 8669-2:1996(E)

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Printed in Switzerland

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.

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International Standard ISO 8669-2 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 editions of ISO 8669-2:1988, ISO 8669-3:1990 and ISO 8669-4:1990, which have been technically revised.

ISO 8669 consists of the following parts, under the general title *Urine collection bags*:

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

Annex A forms an integral part of this part of ISO 8669.

Introduction

Users of this part of ISO 8669 are advised to consider the desirability of third-party certification of product conformity with this part of ISO 8669, 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.

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Urine collection bags —

Part 2: Requirements and test methods

1 Scope

This part of ISO 8669 specifies performance requirements and test methods for open-ended and closed-ended urine collection bags of the following types:

- a) urine collection bags intended to be worn on the body (body-worn bags);
- b) urine collection bags intended to be used with a hanger or a floor stand (non-body-worn bags).

It does not apply to urostomy bags, urimeters and urine bags intended specifically for paediatric use.

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2 Normative reference

[SIST EN ISO 8669-2:2000](https://standards.iteh.ai/catalog/standards/sist/f19fd9dc-ac64-4a39-9f76-4a457091e210)

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The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 8669. 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 8669 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 8669-1:1988, *Urine collection bags — Part 1: Vocabulary*.

3 Definitions

For the purposes of this part of ISO 8669, the definitions given in ISO 8669-1 and the following definitions apply.

3.1 closed-ended urine collection bag: Flexible container for collecting urine, without an opening for drainage of the contents.

3.2 open-ended urine collection bag: Flexible container for collecting urine, with an opening for drainage of the contents.

3.3 rated volume: Capacity of the bag, expressed in millilitres, as stated by the manufacturer.

3.4 test volume: That volume on which is based the volume of liquid added, or the force applied, to a urine collection bag when performing tests to verify the strength and leakage resistance of the bag assembly (see 6.1).

4 Requirements

4.1 Rated volume

When measured by the method given in 6.1, the bag shall have a rated volume not larger than the test volume.

4.2 Freedom from leakage without load

When tested by the method given in 6.2, the bag shall not leak.

4.3 Freedom from leakage under load

When tested by the method given in 6.3, the bag shall not leak.

4.4 Freedom from leakage under impact

When tested by the method given in 6.4, the bag shall not leak.

4.5 Nonreturn valve

If a nonreturn valve is fitted, when tested by the method given in 6.5, the reflux flowrate shall not exceed 10 ml/min.

4.6 Strength of the attachment system

When the attachment system of bags provided with cutouts is tested by the method given in 6.6, none of the attachment points shall fail to support the bag.

When the attachment system of bags provided with a button and buttonhole system is tested by the method given in 6.7, none of the buttons and buttonholes shall fail to support the bag.

When bags provided with integral suspensory systems are tested by the method given in 6.8, no part of the integral suspensory system shall fail to support the bag.

4.7 Strength of attachment of the inlet tubing

When tested by the method given in 6.9, the inlet tubing shall not become detached from the bag.

4.8 Pressure/time required to initiate flow into the bag and filling rate

When tested by the method given in 6.10, the water shall start flowing into the bag within 1 min and the average filling rate shall be not less than 10 ml/s.

4.9 Dimensions

If dimensions are given, they shall be measured in accordance with annex A.

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

6.1.2 Reagent

6.1.2.1 Tap water

6.1.3 Apparatus

6.1.3.1 Graduated cylinders, of capacities to suit the bags being tested and having a measurement accuracy of $\pm 2\%$.

6.1.3.2 Filling system, of arrangement and dimensions shown in figure 1.

To maintain a constant hydrostatic head, the rate of flow into the reservoir of the filling system shall be higher than the rate of the filling of the bag.

6.1.3.3 Stopwatch, or similar timing device.

6.1.4 Procedure

6.1.4.1 Cut the inlet tubing so that the reservoir tap is positioned as close as possible to the bag.

NOTE — For bags having extensible tubing, these should be drawn out to their maximum length before cutting.

6.1.4.2 Remove as much air as possible from the bag. Close the drainage tap afterwards.

NOTE — Most bags have a drainage tap through which air can be squeezed out.

6.1.4.3 Measure the distance between bottom and top of the bag (l_4 in figure A.1) and mark a horizontal line at $0,75 l_4$, measuring from the bottom of the bag.

6.1.4.4 Suspend a non-body-worn bag using the manufacturer's recommended suspension system. Suspend a body-worn bag freely in a vertical position, so that the volume of the bag is not restricted.

6.1.4.5 Using the filling system (6.1.3.2), ensure that the reservoir tap is closed, turn on the water supply (6.1.2.1) and adjust the hydrostatic head to $500 \text{ mm} \pm 5 \text{ mm}$. Connect the reservoir tap to the inlet tubing of the bag.

6.1.4.6 Open the reservoir tap and allow water to enter the bag, ensuring that no air is entrained.

6.1.4.7 When the water level inside the bag has risen to the $0,75 l_4$ line, start the stopwatch (6.1.3.3).

6.1.4.8 After 1 min but before 1 min 10 s, close the reservoir tap.

6.1.4.9 Visually inspect the bag to determine whether or not leakage has occurred. If leakage has occurred, deem the test invalid and repeat it, using a fresh bag if necessary.

6.1.4.10 Clamp the inlet tubing as close to the filling top surface of the bag as possible. Remove the bag from the filling system and empty the water from the bag into a graduated cylinder (6.1.3.1). Measure the volume, in millilitres, and record it as the test volume to an accuracy of $\pm 2\%$.