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

*Aides pour ostomie et incontinence — Dispositifs d'irrigation — Exigences
et méthodes d'essai*



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Foreword

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Aids for ostomy and incontinence — Irrigation sets — Requirements and test methods

1 Scope

This International Standard specifies performance requirements and test methods for irrigation sets, used in colostomy care.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 8670-2, *Ostomy collection bags — Part 2: Requirements and test methods*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply. Certain of these terms are illustrated in Figure 1.

3.1

belt

band of flexible material worn around the waist and secured to the pressure plate of drainage sleeve

3.2

colostomy

surgical opening, or stoma, created between the colon and surface of the body

3.3

connector

device that joins components of the irrigation set

3.4

drainage system

assembly of parts used to drain the colostomy, consisting of drainage sleeve, pressure plate, stoma hole, hook and belt

3.5

drainage sleeve

conduit to pass stomal effluent from the colostomy to a waste disposal container