



SLOVENSKI STANDARD SIST EN ISO 15883-3:2006

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Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2006)

Reinigungs-Desinfektionsgeräte - Teil 3: Anforderungen an und Prüfverfahren für Reinigungs-Desinfektionsgeräten mit thermischer Desinfektion für Behälter für menschliche Ausscheidungen (ISO 15883-3:2006)

Laveurs désinfecteurs - Partie 3: Exigences et essais pour laveurs désinfecteurs destinés à la désinfection thermique de récipients à déjections humaines (ISO 15883-3:2006)

Ta slovenski standard je istoveten z: EN ISO 15883-3:2006

ICS:

11.080.10 Sterilizacijska oprema Sterilizing equipment

SIST EN ISO 15883-3:2006 en

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ICS 11.080.10

English Version

Washer-disinfectors - Part 3: Requirements and tests for
washer-disinfectors employing thermal disinfection for human
waste containers (ISO 15883-3:2006)

Laveurs désinfecteurs - Partie 3: Exigences et essais pour
laveurs désinfecteurs destinés à la désinfection thermique
de récipients à déjections humaines (ISO 15883-3:2006)

Reinigungs-Desinfektionsgeräte - Teil 3: Anforderungen an
und Prüfungen von Reinigungs-Desinfektionsgeräten mit
thermischer Desinfektion für Behälter für menschliche
Ausscheidungen (ISO 15883-3:2006)

This European Standard was approved by CEN on 16 March 2006.

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.

This European Standard exists 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

This document (EN ISO 15883-2:2006) has been prepared by Technical Committee CEN/TC 102 "Sterilizers for medical purposes", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 198 "Sterilization of health care products".

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 October 2006, and conflicting national standards shall be withdrawn at the latest by October 2006.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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ANNEX ZA

(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

| Clauses/subclauses of this International Standard | Essential requirements (ERs) of EU Directive 93/42/EEC | Qualifying remarks/Notes |
|---|--|--|
| 4.1 | 1, 2, 3,4, 5, 6, 7.1, 7.2, 7.3, 7.5, 7.6, 8.1, 9.1, 9.2, 9.3, 12.1, 12.5, 12.6, 12.7.1, 12.7.2, 12.7.3, 12.7.5, 13.1, 13.3, 13.4, 13.6 | The WD shall comply with the requirements of ISO 15883-1:— |
| 4.2 | 7.3, 8.1 | |
| 4.3 | 2, 7.2, 7.5, 8.1, 9.1 | |
| 4.4 | 3, 8.1 | |
| 4.5 | 3, 8.1 | |
| 4.6 | 3, 8.1 | |
| 4.7 | 3, 8.1 | |
| 5.1 | 3, 8.1 | |
| 5.2 | 3, 8.1 | |
| 5.3 | 7.2, 7.5, 8.1 | |
| 6.1 | 1, 2, 3, 6, 7.1, 8.1 | Testing for conformity according to ISO 15883-1:— |
| 6.2 | 7.2, 7.5, 8.1, 9.1 | |

Table ZA.1 (continued)

| Clauses/subclauses of this European Standard | Essential requirements (ERs) of EU Directive 93/42/EEC | Qualifying remarks/Notes |
|--|--|--------------------------|
| 6.3 | 3, 8.1 | |
| 6.4 | 3, 8.1 | |
| 6.5.1, 6.5.2 | 2, 3, 7.2, 7.5, 8.1, 9.1 | |
| 6.6 | 3, 8.1 | |
| 7 | 9.1, 13.1, 13.3, 13.6 | |
| 7 a) | 9.1 | |
| 7 g) | 3, 8.1 | |
| 8 | 1.3, 7.1, 7.2, 7.3, 8.1 | |
| 8 c) | 7.3 | |
| 8 e) | 3, 8.1 | |
| | 7.4, 8.2, 8.3, 8.4, 8.5, 8.6, 8.7, 10.1, 10.2, 10.3, Clause 11, 12.2, 12.3, 12.4, 12.7.4, 12.8, 13.5, 14 | not applicable |

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WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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Washer-disinfectors —

Part 3:

**Requirements and tests for washer-
disinfectors employing thermal
disinfection for human waste containers**

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Laveurs désinfecteurs —

(standards.iteh.ai)

*Partie 3. Exigences et essais pour laveurs désinfecteurs destinés à la
désinfection thermique de récipients à déjections humaines*

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15883-3 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes*, in collaboration with Technical Committee ISO/TC 198, *Sterilization of health care products*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

ISO 15883 consists of the following parts, under the general title *Washer-disinfectors*:

- *Part 1: General requirements, terms and definitions and tests*
- *Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*
- *Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*
- *Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*
- *Part 5: Test soils and methods for demonstrating cleaning efficacy* [Technical Specification]

Introduction

It is recommended that this Introduction be read in conjunction with the introduction to ISO 15883-1.

This part of ISO 15883 is the third of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to bedpan washer-disinfectors. The requirements given in this part apply to washer-disinfectors used for emptying, flushing, cleaning and thermally disinfecting human waste containers intended for re-use such as:

- portable sanitary pans;
- supports for single-use bed pans;
- hospital bowls;
- urine bottles;
- suction bottles; and
- products similar to the above and used for similar purposes.

Fields of application within the scope of the ISO 15883 series of standards include laboratory, veterinary, dental and pharmaceutical applications and other specific applications, such as washer-disinfectors for bedsteads and transport carts and the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

Requirements for washer-disinfectors for other applications are specified in other parts the ISO 15883 series of standards.

Bedpan washer disinfectors are loaded manually. In order to reduce the risk of spillage and the generation of aerosols most machines incorporate means to empty human waste containers automatically e.g. by the action of closing the door.

Where equipment does not provide automatic emptying facilities, extra care is needed by the user to avoid exposure to human waste and contamination of the work environment including the generation of aerosols.

The reliability of a bedpan washer-disinfector may be adversely affected if the machine is connected to a poorly designed or constructed drainage system. The purchaser is therefore recommended to ensure that the drainage system complies with the manufacturer's recommendations in all respects.

Safety requirements for washer-disinfectors are given in IEC 61010-2-045.

In respect of the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfectors:

- a) note that until verifiable European criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfectors remain in force;
- b) this part of ISO 15883 provides no information as to whether the washer-disinfectors may be used without restriction in any of the member states of the EU or EFTA.