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Standards

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I.S. EN ISO 15883-3:2009

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

I.S. EN ISO 15883-3:2009

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Údarás um Chaighdeáin Náisiúnta na hÉireann

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 Prüfverfahren für Reinigungs-Desinfektionsgeräten mit
thermischer Desinfektion für Behälter für menschliche
Ausscheidungen (ISO 15883-3:2006)

This European Standard was approved by CEN on 16 May 2009.

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 CEN Management Centre 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, 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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Foreword

The text of ISO 15883-3:2006 has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 15883-3:2009 by Technical Committee CEN/TC 102 “Sterilizers for medical purposes” the secretariat of which is held by DIN.

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 December 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document supersedes EN ISO 15883-3:2006.

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 EC Directive.

For relationship with EC Directive, 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, Bulgaria, 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 the United Kingdom.

Endorsement notice

The text of ISO 15883-3:2006 has been approved by CEN as a EN ISO 15883-3:2009 without any modification.

Annex ZA (informative)

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

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 on medical devices.

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
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard
4.1.1	13.3 a)	This relevant Essential Requirement is partly addressed in this European Standard
-	13.6 q)	This relevant Essential Requirement is not addressed in this European Standard

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

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 – Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
4.1.1	1.1.7, 1.2.2, 1.2.3, 1.2.4, 1.2.5, 1.3.2, 1.3.3, 1.3.4, 1.5.1, 1.5.2, 1.5.3, 1.5.5, 1.5.6, 1.5.8, 1.5.13, 1.5.14, 1.6.2, 1.6.3, 1.6.4, 1.6.5	This relevant EHSR are addressed in this Standard
4.1.1, 4.3	1.1.3	This relevant EHSR is partly addressed in this Standard
4.1.1	1.1.5, 1.1.6, 1.2.1, 1.2.6, 1.3.1, 1.3.7, 1.3.8.1, 1.3.8.2, 1.5.4, 1.6.1, 1.7.1, 1.7.2, ,1.7.3, 1.7.4	This relevant EHSR are partly addressed in this Standard
	1.3.9, 1.4.1, 1.4.2, 1.4.3, 1.5.9, 4	This relevant EHSR are not addressed in this Standard

I.S. EN ISO 15883-3:2009

INTERNATIONAL STANDARD

ISO 15883-3

First edition
2006-04-15

Washer-disinfectors —

Part 3:

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

Laveurs désinfecteurs —

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



Reference number
ISO 15883-3:2006(E)

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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.

Washer-disinfectors —

Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers

1 Scope

This part of ISO 15883 specifies particular requirements for washer-disinfectors (WD) that are intended to be used for emptying, flushing, cleaning and thermal disinfection of containers used to hold human waste for disposal by one operating cycle.

This part of ISO 15883 is to be applied in conjunction with ISO 15883-1.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15883-1:2006, *Washer-disinfectors — Part 1: General requirements, definitions and tests*

ISO/TS 15883-5, *Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15883-1 and the following apply.

3.1

A_0

equivalent time in seconds at 80 °C, delivered by the disinfection process, with reference to a microorganism with a z value of 10 K

[ISO 15883-1:2006, definition 3.1]

NOTE See also ISO 15883-1:2006, Annex B.

3.2

emptying

discharging the contents of a container by gravity

3.3

human waste

excretions and body fluids including faeces, urine, blood, pus, vomit and mucus

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