



# SLOVENSKI STANDARD SIST EN ISO 15883-3:2009

01-september-2009

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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)

**iTeh STANDARD PREVIEW**

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

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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 15883-3:2009**

## **ICS:**

11.080.10 Sterilizacijska oprema Sterilizing equipment

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**en**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 15883-3**

June 2009

ICS 11.080.10

Supersedes EN ISO 15883-3:2006

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  
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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.



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

**Management Centre: Avenue Marnix 17, B-1000 Brussels**

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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.

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### 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 <a href="https://standards.iteh.ai/catalog/standards/sist/51cb055b-8764-4b46-971f-4a1d1e5c430a/sist-en-iso-15883-3-2009">https://standards.iteh.ai/catalog/standards/sist/51cb055b-8764-4b46-971f-4a1d1e5c430a/sist-en-iso-15883-3-2009</a>	
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.

## EN ISO 15883-3:2009 (E)

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

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ISO  
15883-3

First edition  
2006-04-15

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**Washer-disinfectors —**

Part 3:

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

iTeh STANDARD PREVIEW

*Laveurs désinfecteurs —*

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

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