



SLOVENSKI STANDARD
kSIST prEN 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)

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: prEN ISO 15883-3

ICS:

11.080.10 Sterilizacijska oprema Sterilizing equipment

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EUROPÄISCHE NORM

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English Version

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

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

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 102.

If this draft becomes a European Standard, 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.

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

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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 prEN ISO 15883-3:2009 by Technical Committee CEN/TC 102 “Sterilizers for medical purposes” the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede 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.

Endorsement notice

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

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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.

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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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Washer-disinfectors —

Part 3:

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

iTeh STANDARD PREVIEW

Laveurs désinfecteurs —

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

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