SLOVENSKI STANDARD
SIST EN ISO 15883-6:2011

01-julij-2011

Čistilno-dezinfekcijske naprave - 6. del: Zahteve in preskusi za čistilno-dezinfekcijske naprave s toplotno dezinfekcijo za neinvazivne, nenujne medicinske pripomočke in zdravstveno opremo (ISO 15883-6:2011)

Washer-disinfectors - Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment (ISO 15883-6:2011)

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Reinigungs-Desinfektionsgeräte - Teil 6: Anforderungen und Prüfverfahren von Reinigungs-Desinfektionsgeräten mit thermischer Desinfektion für nichtinvasive, nicht kritische Medizinprodukte und Zubehör im Gesundheitswesens (ISO 15883-6:2011)

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Laveurs désinfecteurs - Partie 6: Exigences et essais pour les laveurs désinfecteurs utilisant une désinfection thermale pour les dispositifs médicaux non invasifs, non critiques et pour l'équipement de soins de santé (ISO 15883-6:2011)

Ta slovenski standard je istoveten z: **EN ISO 15883-6:2011**

ICS:

11.080.10 Sterilizacijska oprema Sterilizing equipment

SIST EN ISO 15883-6:2011 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15883-6

April 2011

ICS 11.080.10

English Version

Washer-disinfectors - Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment (ISO 15883-6:2011)

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Reinigungs-Desinfektionsgeräte - Teil 6: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit thermischer Desinfektion für nicht invasive, nicht kritische Medizinprodukte und Zubehör im Gesundheitswesen (ISO 15883-6:2011)

This European Standard was approved by CEN on 14 April 2011.

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-CENELEC Management Centre or to any CEN member.

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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-CENELEC Management Centre has the same status as the official versions.

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Foreword

This document (EN ISO 15883-6:2011) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with 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 October 2011, and conflicting national standards shall be withdrawn at the latest by October 2011.

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 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.

For relationship with EU 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, Croatia, 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

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The text of ISO 15883-6:2011 has been approved by CEN as a EN ISO 15883-6:2011 without any modification.

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Annex ZA
(informative)

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

This International 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 Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative 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 International 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	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	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	13.3 a)	This relevant Essential Requirement is partly addressed in EN ISO 15883-1
4.1.2	1, 3, 4, 6, 7.1, 8.1, 9.1	
4.1.3	1, 3, 4, 6, 7.1, 8.1, 9.1	
4.1.5	7.3, 8.1	
4.2	3, 8.1	
4.3	3, 8.1	
5.1	3, 8.1	
5.2	3, 8.1	
6.1	1, 2, 3, 4, 7.1, 8.1	Testing for conformity according to ISO 15883-1
6.2	3, 8.1	
6.3	3, 8.1	
7	9.1, 13.6	
8	1, 3, 7.1, 7.2, 8.1	
—	12.1a)	This relevant Essential Requirement is not addressed
—	13.6 q)	This relevant Essential Requirement is not addressed

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WARNING: Other requirements and other EU Directives may be applicable to the products 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, Table ZA.2 details the relevant essential requirements of Directive 2006/42/EC to the extent to which they are more specific than those of Directive 93/42/EEC, along with the corresponding clauses of this International Standard. Table ZA.2, however, does not imply any citation in the Official Journal of the European Communities under the machinery directive and thus does not provide presumption of conformity with that 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)/subclause(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	These relevant Essential Requirements are addressed
4.1.1	1.1.3, 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	These relevant Essential Requirements are partly addressed
—	1.3.9, 1.4.1, 1.4.2, 1.4.3, 1.5.9, 4	These relevant Essential Requirements are not addressed

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INTERNATIONAL STANDARD

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