SLOVENSKI STANDARD
SIST EN ISO 15883-1:2009/A1:2014

01-oktober-2014

Čistilno-dezinfekcijske naprave - 1. del: Osnovne zahteve, termini, definicije in preskusi (ISO 15883-1:2006/Amd 1: 2014)

Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006/Amd 1: 2014)

Reinigungs-Desinfektionsgeräte - Teil 1: Allgemeine Anforderungen, Begriffe und Prüfverfahren (ISO 15883-1:2006/Amd 1: 2014)

Laveurs désinfecteurs - Partie 1: Exigences générales, termes et définitions et essais (ISO 15883-1:2006/Amd 1: 2014)

Ta slovenski standard je istoveten z: **EN ISO 15883-1:2009/A1:2014**

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment

SIST EN ISO 15883-1:2009/A1:2014 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15883-1:2009/A1

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English Version

Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006/Amd 1:2014)

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This amendment A1 modifies the European Standard EN ISO 15883-1:2009; it was approved by CEN on 21 June 2014.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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.

This amendment 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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 15883-1:2009/A1:2014) 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 Amendment to the European Standard EN ISO 15883:2009 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2015, and conflicting national standards shall be withdrawn at the latest by January 2015.

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(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, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 15883-1:2006/Amd 1:2014 has been approved by CEN as EN ISO 15883-1:2009/A1:2014 without any modification.

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 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 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 European Standard	Essential requirements (ERs)of EU Directive 93/42/EEC	Qualifying remarks/Notes
4,5.2.1, 5.4.1.2, 5.5.1, 5.7, 5.24, 5.25, 6.10, 6.11, 6.12, 9.2	7.2	Including reference to EN 61010–2-040:2005, 5.4.4 b), e), f), 5.4.5 and 5.4101
4.6, 5.1, 5.2, 5.7, 6.9	7.3	Including reference to EN 61010–2-040:2005, 5.4.3 k), m), 11.1 and 11.2
5.1.7, 5.1.8, 5.2, 5.4, 5.4.1.2, 5.4.5.3, 6.5.3, 5.24, 5.25, 8.2 g), and h), 10 c)	7.5	Including reference to EN 61010–2-040:2005, 5.2, 11.3 and 11.4
4.5.3, 4.5.4, 5.3.2, 5.26, 6.11	7.6	Including reference to EN 61010–2-040:2005, 5.3.4 and 11.101
4, 5.2, 5.3.1, 5.3.2, 5.4.3, 5.4.4, 5.5.1, 5.24, 5.26, 6.1, 6.2, 6.11	8.1	
3, 4, 5.1.11, 5.2, 8.1 b), 8.3	9.1	Including reference to EN 61010–2-040:2005, 5.4.3, Clause 14, ISO 14121:1999, EN ISO 14971:2013 and EN 61508–1:2010
4, 5.1, 5.1.5, 5.1.9, 5.2.1, 5.2.2, 5.2.3, 5.4.1.9, 5.4.2, 5.4.3.4, 5.10.2, 5.10.3, 5.27.1, 5.28, 5.29	9.2	Including reference to EN 61010–2-040:2005, Clause 7, ISO 14121:1999 and EN 61508–1:2010
5.2	9.3	
5.7	10.1	
5.2.1, 5.2.2, 8.2 c) and d)	11.1	Including reference to EN 61010–2-040:2005, Clause 12 and

		EN 61326–1:2006
5.2.1, 5.2.2	11.4.1	Including reference to EN 61010–2-040:2005, Clause 12 and EN 61326–1:2006
5.2.1, 5.2.4, 5.4, 5.7.4, 5.7.6, 5.8., 5.11, 5.12.7, 5.12.8, 5.12.9, 5.12.10, 5.13.2 g), 5.14 g), 5.17.2, 5.18, 5.20, 5.21	12.1	Including reference to EN 61010–2-040:2005, 4.4, 7.104, 14.103 and 14.104, and EN ISO 14971:2013 State of the art comprehends many standards; note refers to EN ISO 12100:2003, ISO 13489-2:2003, and EN 954–1:1997
5.2	12.5	Including reference to EN 61326–1:2006
5.2	12.6	Including reference to EN 61010–2-040:2005, 1.4, Clauses 4, 5 and 6, 11.6, Clause 14. Note refers to ISO 14121:1999 and EN 61508–1:2010
5.1, 5.2, 5.4, 5.27.1 b)	12.7.1	Including reference to EN 61010–2-040:2005, 7.2, 7.3 and 7.4.101
5.2	12.7.2	Including reference to EN 61010–2-040:2005, Clause 8
5.2	12.7.3	Including reference to EN 61010–2-040:2005, 12.5.1
5.2	12.7.4	Including reference to EN 61010–2-040:2005, Clause 6
5.2, 5.8	12.7.5	Including reference to EN 61010–2-040:2005, 10.1
5.10, 5.12	12.9	Including reference to IEC 60417:2004, ISO 7000:2012 and IEC 80416–1:2008
5.2, 5.4.1.3, 5.4.2, 5.23, 7, 8, 9.1	13.1	Including reference to EN 61010–2-040:2005, Clause 5
5.10.3	13.2	Including reference to IEC 60417:2004, ISO 7000:2012 and IEC 80416–1:2008
9.1 b) and c)	13.3 k)	
9.1 a)	13.3 l)	
8.1 b)	13.4	
8 k), 8 a), 8 j),	13.6 a)	
5.2.3, 7, 8, 9.1	13.6 a), b), c), d)	Including reference to EN 61010–2-040:2005, 5.1.2
8.1, 6.1.3	13.6 i)	
8.3 j)	13.6 q)	

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 European Standard	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
5.2.3, 5.2.4	1	
5.1.1, 5.2, 5.3.2.1 a)	1.1.3	
9.2	1.1.5	
5.12.3, 6.6.2	1.1.6	
5.2	1.1.7	
5.12.1	1.2.1	
5.2, 5.18, 5.19	1.2.2	
5.2	1.2.3	
5.2, 5.18, 5.19	1.2.4	
5.18, 5.19	1.2.5	
5.2	1.2.6	
5.4.1.5, 5.18.4, 5.22, 6.3.5, 6.3.7	1.3.1	
5.1, 5.2, 8.3 g)	1.3.2	
5.2	1.3.3	
5.2, 5.6	1.3.4	
5.2	1.3.7	
5.2	1.5.1	
5.2, 6.3.1	1.5.2	
5.2	1.5.3	
5.2	1.5.4	
5.2	1.5.5	
5.2	1.5.6	
5.2	1.5.8	
5.2	1.5.13	
5.2, 5.4.1.7	1.5.14	
5.2, 8.3 g)	1.6.1	

5.1.5	1.6.2	
5.2	1.6.3	
5.1.5	1.6.5	
5.2, 5.10, 5.10.3, 5.12.3, 5.22, 8.3 a), 8.3 b)	1.7.1	
5.2	1.7.2	
5.2, 9.1	1.7.3	
5.2, 8.3, 9.1	1.7.4	

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INTERNATIONAL STANDARD

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AMENDMENT 1
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Washer-disinfectors —

Part 1: General requirements, terms and definitions and tests

AMENDMENT 1

Laveurs désinfecteurs —

Partie 1: Exigences générales, termes et définitions et essais

AMENDEMENT 1

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