



SLOVENSKI STANDARD SIST EN ISO 15883-6:2015

01-oktober-2015

Nadomešča:

SIST EN ISO 15883-6:2011

Čistilno-dezinfekcijske naprave - 6. del: Zahteve in preskusi čistilno-dezinfekcijskih naprav 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)

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)

Laveurs désinfecteurs - Partie 6: Exigences et essais pour les laveurs désinfecteurs utilisant une désinfection thermique 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 15883-6:2015

ICS:

11.080.10 Sterilizacijska oprema Sterilizing equipment

SIST EN ISO 15883-6:2015 en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 15883-6

August 2015

ICS 11.080.10

Supersedes EN ISO 15883-6:2011

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)**

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

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 4 August 2015.

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.

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.

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

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European foreword

This document (EN ISO 15883-6:2015) has been prepared by Technical Committee ISO/TC 198 "Sterilization of healthcare products" in collaboration with 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 February 2016, and conflicting national standards shall be withdrawn at the latest by February 2016.

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 15883-6:2011.

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.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard 'within the meaning of Annex ZA', the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this should be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 15883-1	EN ISO 15883-1:2009+A1:2014	ISO 15883-1:2006+Amd1:2014
ISO/TS 15883-5	CEN/ISO/TS 15883-5:2005	ISO/TS 15883-5:2005

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.

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Endorsement notice

The text of ISO 15883-6:2011 has been approved by CEN as EN ISO 15883-6:2015 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 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 the Essential Requirements of the 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

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
9	7.2	In addition requirements of EN ISO 15883-1 apply.
4.1.1,8	7.2	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1, 4.1.5	7.3	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	7.5	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	7.6	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements

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Clauses/subclauses of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
		are covered
4.1.1	8.1	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.2, 4.1.3, 4.1.5, 4.2, 4.3, 5.1, 5.2, 6.2, 6.3, 8	8.1	
6.1	8.1	Testing for conformity according to EN ISO 15883-1
4.1.1	9.1	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.2, 4.1.3, 7	9.1	
4.1.1	9.2, 9.3	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	12.1	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	12.5	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	12.6	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	12.7.1	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	12.7.2	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	12.7.3	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	12.7.5	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered

Clauses/subclauses of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4.1.1	13.1	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	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	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
7	13.6	

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
4.1.1	1	
4.1.1	1.1.3	See in addition EN ISO 15883-1:2009+A1:2014, 5.1.1, 5.1.2, 5.2 and 5.3.2 a)
4.1.1	1.1.5	See in addition EN ISO 15883-1:2009+A1:2014, 9.2
4.1.1	1.1.6	See in addition EN ISO 15883-1:2009+A1:2014, 5.12.3, 5.27.1 and 6.6.2
4.1.1	1.1.7	See in addition EN ISO 15883-1:2009+A1:2014, 5.2
4.1.1	1.2.1, 1 st and 2 nd dash	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.2, 5.2.4, 5.12.1, 5.20 and 5.22

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Clause(s)/sub-clause(s) of this European Standard	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
4.1.1	1.2.2, 1 st dash	See in addition EN ISO 15883-1:2009+A1:2014, 5.2, 5.12.3, 5.12.8 and 5.12.9
4.1.1	1.2.3	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.2.4	
4.1.1	1.2.5	See in addition EN ISO 15883-1:2009+A1:2014, 5.18 and 5.19
4.1.1	1.2.6	See in addition EN ISO 15883-1:2009+A1:2014, 5.2 and 5.4.1.9
4.1.1	1.3.1	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 Including reference to EN 61010-2-040:2005, 7.3
4.1.1	1.3.2	See in addition EN ISO 15883-1:2009+A1:2014, 5.1, 5.2.1 and 8.3 g)
4.1.1	1.3.3	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 <small>https://standards.iteh.ai/catalog/standards/sist/adcb2342-6256-4dd6-9c27-bafc433d651b/sist-en-iso-15883-6-2015</small>
4.1.1	1.3.4	See in addition EN ISO 15883-1:2009+A1:2014, 5.1.6 and 5.2.1 Including reference to EN 61010-2-040:2005, clause 7
4.1.1	1.3.7	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.3.8	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.5.1	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.5.2	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.5.3	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.5.4	See in addition EN ISO 15883-1:2009+A1:2014,

Clause(s)/sub-clause(s) of this European Standard	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
		5.2.1 and 8.3
4.1.1	1.5.5	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.5.6	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 and 5.8
4.1.1	1.5.8	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.5.13	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 and 8.1 b) Including reference to EN 61010-2-040:2005, clause 11
4.1.1	1.5.14	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 Including reference to EN 61010-2-040:2005, clause 15
4.1.1	1.6.1	See in addition EN ISO 15883-1:2009+A1:2014, 5.1.5 and 5.2.1
4.1.1	1.6.2	See in addition EN ISO 15883-1:2009+A1:2014, 5.1.5 and 5.2.1
4.1.1	1.6.3	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 and 8.2 a) and b)
4.1.1	1.6.4	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 and 5.4.1.6
4.1.1	1.6.5	See in addition EN ISO 15883-1:2009+A1:2014, 4.2.1.1 and 5.1.10
4.1.1	1.7.1	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1, 5.10.2, 5.10.3 and 5.20 h)
4.1.1	1.7.2	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 and 8 f)
4.1.1	1.7.3	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 and 9.1
4.1.1	1.7.4	See in addition EN ISO 15883-1:2009+A1:2014,

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