PESU-DESINFEKTSIOONISEADMED. OSA 6: MITTEINVASIIVSETE, MITTEKRIITILISTE MEDITSIINISEADMETE JA TERVISHOIUSEADMETE TERMILISEKS DESINFEKTSIOONIKS ETTE NÄHTUD PESU-DESINFEKTSIOONISEADMETE NÕUDED JA KATSED (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)

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 15883-6:2015 sisaldab Euroopa standardi EN ISO 15883-6:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15883-6:2015 consists of the English text of the European standard EN ISO 15883-6:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 19.08.2015.	Date of Availability of the European standard is 19.08.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Ref. No. EN ISO 15883-6:2015 E

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.

Endorsement notice

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

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, 1st and 2nd 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

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, 1st 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
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,

Clause(s)/sub-clause(s) of this European Standard	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
		Clause 7 and Clause 8

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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Introduction

It is intended that this Introduction be read in conjunction with the Introduction to ISO 15883-1.

This part of ISO 15883 is the sixth of a series specifying the performance of washer-disinfectors and specifies the particular requirements for performance applicable to general-purpose washer-disinfectors. Its requirements apply to washer-disinfectors used for the cleaning and disinfection of non-invasive and non-critical reusable medical devices (i.e. not penetrating skin or contacting mucosal surfaces) and for other items for use without further treatment in healthcare settings. Such reusable items need to be cleaned and disinfected, but their processing in a washer-disinfector for surgical instruments (see ISO 15883-2), for human waste containers (see ISO 15883-3) or for endoscopes (see ISO 15883-4) is inappropriate and/or impractical.

Some examples are

— non-invasive medical devices,

— washbowls,

— cleaning equipment (buckets),

— footwear,

— container systems used to transport medical devices, including trolleys and transport carts, and

— bedsteads, wheelchairs, aids for the disabled.

Fields of application within the scope of ISO 15883 include laboratory, veterinary and dental use, and other specific applications such as washer-disinfectors for the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

Requirements for washer-disinfectors for other applications are specified in other parts of ISO 15883.

The efficacy of disinfection can be impaired if soil removal is incomplete before the start of the disinfection process. It is desirable that manufacturers of washer-disinfectors be very clear about the items that can be processed in the washer-disinfector, and that reference be made to the instructions for reprocessing provided by the manufacturer of the items to be processed.

In respect of the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfectors, it is noteworthy that

a) until verifiable international criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfectors remain in force, and

b) the ISO 15883 series of standards provides no information as to whether the washer-disinfectors may be used without restriction in any of the ISO member states.

Washer-disinfectors —

Part 6:
Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment

WARNING — Devices identified within the scope of ISO 15883-2, ISO 15883-3 and ISO 15883-4 shall not be processed in washer-disinfectors specified in this part of ISO 15883. Examples of medical devices that are not to be processed in these devices include powered devices, lumened devices and other invasive devices.

1 Scope

This part of ISO 15883 specifies particular requirements for washer-disinfectors (WDs) intended for use when the level of assurance of disinfection that is necessary can be achieved by cleaning and thermal disinfection (A_0 not less than 60) and does not require an independent automated record of critical processes to be kept. It is intended to be used in conjunction with ISO 15883-1, which gives general requirements for WDs.

The range of products on which WDs of this particular type can be used is restricted to devices and equipment which are non-invasive and non-critical (i.e. not penetrating skin or contacting mucosal surfaces).

NOTE Thermal disinfection can be achieved by rinsing the load with hot water, exposure to steam or combination of the two.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15883-1:2006, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

ISO/TS 15883-5, *Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy*

