PESU-DESINFEKTSIOONISEADMED. OSA 7: MITTEINVASIIVSETE, TERMOLABIILSETE MITTEKRIITILISTE MEDITSIINISEADMETE JA TERVISHOIUSEADMETE KEEMILISEKS DESINFEKTSIOONIKS ETTE NÄHTUD PESU-DESINFEKTSIOONISEADMETELE KOHALDATAVAD NÕUDED JA KATSED

Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment (ISO 15883-7:2016)

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 15883-7:2016 sisaldab Euroopa standardi EN ISO 15883-7:2016 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15883-7:2016 consists of the English text of the European standard EN ISO 15883-7:2016.
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 09.03.2016.	Date of Availability of the European standard is 09.03.2016.
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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Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment (ISO 15883-7:2016)

Laveurs désinfecteurs - Partie 7: Exigences et essais pour les laveurs désinfecteurs utilisant la désinfection chimique pour les dispositifs médicaux et les équipements de soins thermosensibles non invasifs et non critiques (ISO 15883-7:2016)

Reinigungs-Desinfektionsgeräte - Teil 7: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit chemischer Desinfektion für nicht invasive, nicht kritische thermolabile Medizinprodukte und Zubehör im Gesundheitswesen (ISO 15883-7:2016)

This European Standard was approved by CEN on 8 February 2016.

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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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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 15883-7:2016 E

European foreword

This document (EN ISO 15883-7:2016) 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 September 2016, and conflicting national standards shall be withdrawn at the latest by September 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 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 11737-1	EN ISO 11737-1:2006 + EN ISO 11737-1:2006/AC:2009	ISO 11737-1:2006 + ISO 11737-1:2006/Cor 1:2007
ISO 11737-2	EN ISO 11737-2:2009	ISO 11737-2:2009
ISO 15883-1	EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014	ISO 15883-1:2006 + ISO 15883-1:2006/Amd1:2014
ISO 15883-2	EN ISO 15883-2:2009	ISO 15883-2:2006
ISO 15883-3	EN ISO 15883-3:2009	ISO 15883-3:2006
ISO 15883-4	EN ISO 15883-4:2009	ISO 15883-4:2008
ISO 15883-6	EN ISO 15883-6:2015	ISO 15883-6:2011
ISO/TS 15883-5	CEN ISO/TS 15883-5:2005	ISO/TS 15883-5:2005
IEC 61010–2-040	EN 61010-2-040:2005	IEC 61010-2-040:2005

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 15883-7:2016 has been approved by CEN as EN ISO 15883-7:2016 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/023 concerning the development of European standards to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, 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 Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of EU Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
7.2	9	In addition requirements of EN ISO 15883-1 apply. Reference to IEC 61010-2-040:2005, Clause 5 included in respect of packaging only
7.3	4.1.1, 4.1.4	
7.4		WD is not designed to deal with such medical products
7.5	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.24.1

Essential Requirements of EU Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
7.6	4.1.1, 4.7.1	
8.1	4.1.1, 4.3, 4.5, 4.7.2	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 4.3.1
9.1	4.1.1, 4.1.3, 5.1.1, 8 a)	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.1.9, 5.1.10, 5.6 and 5.28
9.2	4.1.1, 4.1.3, 5.1.1, 5.1.2	Including reference to IEC 61010-2-040:2005, 5.4.3 and 7.5
9.3		WDs are unlikely to be manufactured of or to contain flammable or explosive substances
10.1		Not likely to apply, see MEDDEV 2.1
11		Intended hazardous radiation is unlikely to be emitted by a WD
12.1	4.1.1	
12.5	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.2
12.6	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
12.7.1	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
12.7.2	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
12.7.3	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
12.7.5	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1

Essential Requirements of EU Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
12.9	4.1.1	
13.1	4.1.1	
13.2	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.10.3
13.3 a), b), d)	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 9.1
13.3 i)	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.29
13.3 k)	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.3
13.3 l)	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 9.1
13.4	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 8.1 b)
13.6 a)		Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 9.1
13.6 b)	8 f)	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 8.3
13.6 c)	4.1.4, 4.3.4	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 8.2 h)
13.6 d)	8 a), c), h)	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 6.1.3.2, 8.1 and 8.3 g)
13.6 q)	8	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, Clause 8

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)

Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this European Standard	Qualifying remarks/Notes
1	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.3 and 5.2.4
1.1.2	4.1.1, 5.1.1, 5.1.2	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.1
1.1.3	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.1.1, 5.1.2, 5.2 and 5.3.2 a)
1.1.5	4.1.1	See in addition EN ISO 15883-1:2009, 9.2
1.1.6	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.12.3, 5.27.1 and 6.6.2
1.1.7	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2
1.2.1, 1st dash and 2nd dash	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.2, 5.2.4, 5.12.1, 5.20 and 5.22
1.2.2, 1st dash	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2, 5.12.3, 5.12.8 and 5.12.9
1.2.3	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.2.4.1	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1 and 5.19

Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this European Standard	Qualifying remarks/Notes
1.2.5	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.18 and 5.19
1.2.6	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2 and 5.4.1.9
1.3.1	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1 Including reference to EN 61010-2-040:2005, 7.3
1.3.2	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.1, 5.2.1 and 8.3 g)
1.3.3	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.3.4	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.1.6 and 5.2.1 Including reference to EN 61010-2-040:2005, Clause 7
1.3.7	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.3.8	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.3.9	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.5.1	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.5.2	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1