Irish Standard
I.S. EN ISO 15883-1:2009&A1:2014

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

I.S. EN ISO 15883-1:2009&A1:2014

Incorporating amendments/corrigenda/National Annexes issued since publication:

EN ISO 15883-1:2009/A1:2014

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Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15883-1:2009/A1

July 2014

ICS 11.080.10

English Version

Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (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)

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

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.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Ref. No. EN ISO 15883-1:2009/A1:2014 E

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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of an identical text or by endorsement, at the latest by January 2015, and conflicting national standards shall be withdrawn at the latest by January 2015.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.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15883-1

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Supersedes EN ISO 15883-1:2006

English Version

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

This European Standard was approved by CEN on 16 May 2009.

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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 Management Centre has the same status as the official versions.

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Foreword

The text of ISO 15883-1:2006 has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 15883-1:2009 by 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 December 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 15883-1:2006.

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 EC Directive.

For relationship with EC 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, 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.

Endorsement notice

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

Annex ZA
(informative)

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

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 Communities 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 thisEuropean Standard	Essential requirements (ERs)of EU Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 4, 3, 6, 7.1, 8.1, 9.1, 7.2, 9.2	
5.1	2, 7.3	
5.1.3	4	
5.1.7	7.5	
5.1.8	7.5	
5.2	1, 2, 6, 7.1, 7.2, 7.3, 7.5, 8.1, 9.1, 9.2, 9.3, 12.5, 12.6, 12.7.1, 12.7.2, 12.7.3, 12.7.4, 12.7.5, 13.1	The WD shall comply with the requirements of IEC 61010-2-045
5.4	7.5	Refers only to leakage
5.4.1.2	7.2, 7.5	
5.4.1.3	13.1	
5.4.1.5	1, 2	
5.4.1.6	1, 2	
5.4.1.7	1, 2	
5.4.1.8	1, 2	
5.4.2	13.1	
5.4.3	8.1	
5.4.4	8.1	
5.4.5.2	2	
5.4.5.3	2, 7.5	

Table ZA.1 *(continued)*

Clauses/subclauses of thisEuropean Standard	Essential requirements (ERs)of EU Directive 93/42/EEC	Qualifying remarks/Notes
5.5.1	2, 7.2	
5.5.2	2	
5.7	3, 7.2, 7.3	
5.8	2, 12.1, 12.7.5	
5.9	3	
5.10.	13.2	
5.11.1	3	
5.11.2	2, 3	
5.11.3	2, 3	The choice of process verification system shall be based on a documented risk analysis
5.11.4	2, 3	
5.12	3, 12.9	
5.13	3	
5.14	3	
5.15	3	
5.16	3	
5.17	3	
5.18	3	
5.19	3	
5.20	12.1	
5.21	12.1	
5.22	2, 3	
5.23	3, 13.1	
5.24	7.2, 7.5	
5.25	7.2, 7.5	
5.27	3	
5.28	3	