SLOVENSKI STANDARD
SIST EN ISO 15883-1:2009

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Nadomeġļa:
SIST EN ISO 15883-1:2006

Ļistilno-dezinfekcijske naprave - 1. del: Osnovne zahteve, termini, definicije in preskusi (ISO 15883-1:2006)

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

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

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

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

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment

SIST EN ISO 15883-1:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

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

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

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

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

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

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

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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	

Table ZA.1 *(continued)*

Clauses/subclauses of thisEuropean Standard	Essential requirements (ERs)of EU Directive 93/42/EEC	Qualifying remarks/Notes
5.29	3	
6.1	1, 2, 3, 6, 7.1, 8.1	Testing for conformity
6.2	1, 2, 3, 6, 7.1, 8.1	Testing for conformity
6.3.5	2, 3	
6.3.6	2, 3	
6.3.7	2, 3	
6.4	3	
6.5.3	7.5	
6.5.4	3	
6.5.5	3	
6.5.6	3	
6.6	3	
6.7	3	
6.8	3	
6.9	3, 7.3	
6.10	3, 7.2, 7.5	
6.11	3, 7.2, 7.5	
6.12	3, 7.2, 7.5	
6.13	3, 7.2, 7.5	
7	13	
8	13.1, 13.3, 13.4, 13.6	
9	5, 13.3	
10	1	
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard
7, 8, 9	13.3 a)	This relevant Essential Requirement is partly addressed in this European Standard
-	13.6 q)	This relevant Essential Requirement is not addressed in this European Standard

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 EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
5.1.1, 5.2, 5.3.2.1 a)	1.1.3	This relevant EHSR is partly addressed in this Standard
9.2	1.1.5	This relevant EHSR is partly addressed in this Standard
5.12.3, 6.6.2	1.1.6	This relevant EHSR is partly addressed in this Standard
5.2	1.1.7	This relevant EHSR is addressed in this Standard
5.12.1	1.2.1	This relevant EHSR is partly addressed in this Standard
5.2, 5.18, 5.19	1.2.2	This relevant EHSR is addressed in this Standard
5.2	1.2.3	This relevant EHSR is addressed in this Standard
5.2, 5.18.5.19	1.2.4	This relevant EHSR is addressed in this Standard
5.18, 5.19	1.2.5	This relevant EHSR is addressed in this Standard
5.2	1.2.6	This relevant EHSR is partly addressed in this Standard
5.4.1.5, 5.18.4, 5.22, 6.3.5, 6.3.7	1.3.1	This relevant EHSR is partly addressed in this Standard
5.1, 5.2, 8.3 g)	1.3.2	This relevant EHSR is addressed in this Standard
5.2	1.3.3	This relevant EHSR is addressed in this Standard
5.2, 5.6	1.3.4	This relevant EHSR is addressed in this Standard
5.2	1.3.7	This relevant EHSR is partly addressed in this Standard
5.2	1.3.8.1	This relevant EHSR is partly addressed in this Standard
5.2	1.3.8.2	This relevant EHSR is partly addressed in this Standard
	1.3.9	This relevant EHSR is not addressed in this Standard
	1.4.1	This relevant EHSR is not addressed in this Standard
	1.4.2	This relevant EHSR is not addressed in this Standard

Table ZA.2 *(continued)*

Clause(s)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
	1.4.3	This relevant EHSR is not addressed in this Standard
5.2	1.5.1	This relevant EHSR is addressed in this Standard
5.2, 6.3.1	1.5.2	This relevant EHSR is addressed in this Standard
5.2	1.5.3	This relevant EHSR is addressed in this Standard
5.2	1.5.4	This relevant EHSR is partly addressed in this Standard
5.2	1.5.5	This relevant EHSR is addressed in this Standard
5.2	1.5.6	This relevant EHSR is addressed in this Standard
5.2	1.5.8	This relevant EHSR is addressed in this Standard
	1.5.9	This relevant EHSR is not addressed in this Standard
5.2	1.5.13	This relevant EHSR is addressed in this Standard
5.2, 5.4.1.7	1.5.14	This relevant EHSR is addressed in this Standard
5.2, 8.3 g)	1.6.1	This relevant EHSR is partly addressed in this Standard
5.1.5	1.6.2	This relevant EHSR is addressed in this Standard
5.2	1.6.3	This relevant EHSR is addressed in this Standard
5.1.5	1.6.4	This relevant EHSR is addressed in this Standard
5.1.5	1.6.5	This relevant EHSR is addressed in this Standard
5.2, 5.10, 5.10.3, 5.12.3, 5.22, 8.3 a), 8.3 b)	1.7.1	This relevant EHSR is partly addressed in this Standard
5.2	1.7.2	This relevant EHSR is partly addressed in this Standard
5.2, 9.1	1.7.3	This relevant EHSR is partly addressed in this Standard
5.2, 8.3, 9.1	1.7.4	This relevant EHSR is partly addressed in this Standard
	4	This relevant EHSR is not addressed in this standard

INTERNATIONAL STANDARD

ISO 15883-1

First edition
2006-04-15

Washer-disinfectors —

Part 1: General requirements, terms and definitions and tests

Laveurs désinfecteurs —

Partie 1: Exigences générales, termes et définitions et essais

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15883-1 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes*, in collaboration with Technical Committee ISO/TC 198, *Sterilization of health care products*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

ISO 15883 consists of the following parts, under the general title *Washer-disinfectors*:

— *Part 1: General requirements, terms and definitions and tests*

— *Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*

— *Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

— *Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*

— *Part 5: Test soils and methods for demonstrating cleaning efficacy* [Technical Specification]