Pesur-desinfitseerija. Osa 1: Üldnõuded, terminid, definitsioonid ja katsed

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 15883-1:2009 sisaldab Euroopa standardi EN ISO 15883-1:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15883-1:2009 consists of the English text of the European standard EN ISO 15883-1:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.11.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.11.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 03.06.2009.	Date of Availability of the European standard text 03.06.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 01.040.11, 11.080.10

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15883-1

June 2009

ICS 11.080.10

Supersedes EN ISO 15883-1:2006

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 15883-1:2009: E

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

Contents

Page

Introduction

This part of ISO 15883 is the first of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to all washer-disinfectors. The requirements given in this part of ISO 15883 are applicable to all washer-disinfectors specified in subsequent parts of the ISO 15883 series, except insofar as they may be modified or added to by a subsequent part, in which case the requirements of that particular part will apply.

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

Washer-disinfectors should be used only for processing the type of loads specified by the manufacturer of the washer-disinfector.

In selecting the appropriate washer-disinfector, reference should be made both to this part of ISO 15883 and to the relevant subsequent parts of ISO 15883 series. It is the user's responsibility to ensure that the choice of type of washer-disinfector, operating cycle or quality of services or process chemicals is appropriate for any particular load.

Safety requirements for washer-disinfectors are given in IEC 61010-2-045.

This part of ISO 15883 has been prepared on the basis that each individual washer-disinfector will be subject to validation tests (commissioning and performance qualification on first installation) and that in use continued compliance will be established by periodic tests carried out by, or on behalf of, the user.

Verification of cleaning efficacy is a key aspect of establishing satisfactory performance of a washer-disinfector. The current state of knowledge has not permitted development of a single test method. As an interim measure reference has been made to test methods which are currently being applied in a number of different countries. The specification for these test methods including their test soils can be found in ISO/TS 15883-5. It remains the intention of the Technical Committee of TC 198 to develop a single test method.

In respect of the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfector:

a) it should be noted that, until verifiable European criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfector remain in force;

b) the ISO 15883 series of standards provides no information as to whether the washer-disinfector may be used without restrictions in any of the member states of the EU or EFTA.

Washer-disinfectors —

Part 1: General requirements, terms and definitions and tests

1 Scope

This part of ISO 15883 specifies general performance requirements for washer-disinfectors (WD) and their accessories that are intended to be used for cleaning and disinfection of re-usable medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice. It specifies performance requirements for cleaning and disinfection as well as for the accessories which can be required to achieve the necessary performance. The methods and instrumentation required for validation, routine control and monitoring and re-validation, periodically and after essential repairs, are also specified.

The requirements for washer-disinfectors intended to process specific loads are specified in subsequent parts of this standard. For washer-disinfectors intended to process loads of two or more different types the requirements of all relevant parts of this standard apply.

This part of ISO 15883 does not specify requirements intended for machines for use for laundry or general catering purposes.

This part of ISO 15883 does not include requirements for machines which are intended to sterilize the load, or which are designated as “sterilizers”, these are specified in other standards e.g. EN 285.

The specified performance requirements of this standard may not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

NOTE If it is considered that prion protein can be present, particular care is needed in the choice of disinfectants and cleaning agents to ensure that the chemicals used do not react with the prion protein in a manner that may inhibit its removal or inactivation.

This part of ISO 15883 may be used by prospective purchasers and manufacturers as the basis of agreement on the specification of a WD. The test methods for demonstration of compliance with the requirements of this part of ISO 15883 may also be employed by users to demonstrate continued compliance of the installed WD throughout its working life. Guidance on a routine test programme is given in Annex A.

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 228-1, *Pipe threads where pressure-tight joints are not made on the threads — Part 1: Dimensions, tolerances and designation*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

ISO 14644-3:2005, *Cleanrooms and associated controlled environments — Part 3: Test methods*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO/TS 15883-5:2005, *Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy*

IEC 60417-DB, *Graphical symbols for use on equipment*

IEC 60584-1:1995, *Thermocouples — Part 1: Reference tables*

IEC 60751:1983, *Industrial platinum resistance thermometer sensors*

IEC 61010-2-045, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-045: Particular requirements for washer disinfectors used in medical, pharmaceutical, veterinary and laboratory fields*

IEC 80416-1, *Basic principles for graphical symbols for use on equipment — Part 1: Creation of symbol originals*

European Pharmacopeia, European Directorate for the Quality of Medicines, Council of Europe, Strasbourg, France

United States Pharmacopeia, USP Pharmacopeia, Rockville, USA

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
A_0
equivalent time in seconds at 80 °C, delivered by the disinfection process, with reference to a microorganism with a z value of 10 K

NOTE See Annex B.

3.2
automatic controller
device that, in response to pre-determined cycle variables, operates the apparatus sequentially through the required stages of the process or processes

3.3
bedpan washer-disinfector
washer-disinfector intended to be used for the emptying, flushing, cleaning and thermal disinfecting of human waste containers

3.4
bioburden
population of viable microorganisms on a product and/or its container

