

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

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 15883-1:2006 sisaldab Euroopa standardi EN ISO 15883-1:2006 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 29.05.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 15883-1:2006 consists of the English text of the European standard EN ISO 15883-1:2006.</p> <p>This document is endorsed on 29.05.2006 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
--	---

<p>Käsitlusala: 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.</p>	<p>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.</p>
---	---

ICS 11.080.10

Võtmesõnad:

ICS 11.080.10

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, Definitionen und Prüfungen (ISO 15883-1:2006)

This European Standard was approved by CEN on 16 March 2006.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, 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: rue de Stassart, 36 B-1050 Brussels

Foreword

This document (EN ISO 15883-1:2006) has been prepared by Technical Committee CEN/TC 102 "Sterilizers for medical purposes", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 198 "Sterilization of health care products".

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 October 2006, and conflicting national standards shall be withdrawn at the latest by October 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 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, 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.

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 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 this European 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	

Table ZA.1 (continued)

Clauses/subclauses of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
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	
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 this European 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	

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Washer-disinfectors —

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

Laveurs désinfecteurs —

Partie 1: Exigences générales, termes et définitions et essais



PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	v
Introduction.....	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Performance requirements	8
4.1 General	8
4.2 Cleaning	10
4.3 Disinfection	10
4.4 Rinsing	11
4.5 Drying	11
4.6 Process chemicals	12
5 Mechanical and process requirements	12
5.1 Materials, design and manufacture/construction	12
5.2 Safety	14
5.3 Calorifiers and tanks	14
5.4 Loading and unloading doors and their controls	15
5.5 Pipework and fittings	17
5.6 Spray systems	17
5.7 Dosing systems	18
5.8 Load temperature protection	18
5.9 Process temperature control limits	19
5.10 Switches, gauges and indicating devices	20
5.11 Process verification	20
5.12 Instrumentation and controls	21
5.13 Temperature indicating systems	22
5.14 Pressure indicating systems	23
5.15 Timing equipment	23
5.16 Operating cycle indicating equipment	23
5.17 Recording instruments (if fitted)	23
5.18 Control systems	25
5.19 Override of automatic control	26
5.20 Microprocessor control systems	27
5.21 Access to software	27
5.22 Fault indication systems	27
5.23 Water supply	28
5.24 Venting and drainage systems	28
5.25 Drainage	29
5.26 Air filters installed within the WD	29
5.27 Load handling and supports for use within the WD	29
5.28 Trolleys	30
5.29 Environment	31
6 Testing for conformity	31
6.1 General	31
6.2 Test equipment	34
6.3 Tests on doors, interlocks and fault indications	35
6.4 Tests on water quality and water volume	37
6.5 Tests on pipework	39
6.6 Tests on instrumentation fitted to the WD	41

6.7	Tests on load carriers	42
6.8	Thermometric tests	43
6.9	Chemical dosing tests	46
6.10	Tests of cleaning efficacy	47
6.11	Tests of air quality	48
6.12	Load dryness test	49
6.13	Automatic control test	49
7	Documentation	50
8	Information to be supplied by the manufacturer	50
8.1	General	50
8.2	Before delivery of the WD and for installation	51
8.3	At delivery of the WD	51
9	Marking, labelling and packaging	53
9.1	Marking and labelling	53
9.2	Packaging	53
10	Information to be requested from the purchaser by the supplier of the WD	53
Annex A (informative) Test programme		55
Annex B (informative) A_0 concept — Comparative lethality of moist heat processes		59
Annex C (normative) Test methods for the detection and assessment of residual proteinaceous contamination		63
Annex D (normative) Microbiological recovery medium for estimation of bacterial contamination of water		68
Bibliography		69

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]

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