Pesur-desinfitseerija. Osa 4: Termotundlike endoskoopide keemiliseks desinfitseerimiseks kasutatavate pesuritele-desinfektoritele esitatavad nõuded ja katsed

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 15883-4:2009 sisaldab Euroopa standardi EN ISO 15883-4:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15883-4:2009 consists of the English text of the European standard EN ISO 15883-4:2009.
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.
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Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2008)

Laveurs désinfecteurs - Partie 4: Exigences et essais pour les laveurs désinfecteurs destinés à la désinfection chimique des endoscopes thermolabiles (ISO 15883-4:2008)

Reinigungs-Desinfektionsgeräte - Teil 4: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit chemischer Desinfektion für thermolabile Endoskope (ISO 15883-4:2008)

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

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Foreword

The text of ISO 15883-4:2008 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 15883-4:2009 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of an identical text or by endorsement, at the latest by December 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.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 15883-4:2008.

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 15883-4:2008 has been approved by CEN as a EN ISO 15883-4:2009 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 this International Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4.1.1	1, 2, 3, 4, 5, 6, 7.1, 7.2, 7.3, 7.5, 7.6, 8.1, 9.1, 9.2, 9.3, 12.1, 12.5, 12.6, 12.7.1, 12.7.3, 12.7.5, 13.1, 13.3, 13.4, 13.6	The WD shall comply with the requirements of ISO 15883-1:2006
4.1.2	1, 3, 4, 6, 7.1, 7.2, 7.5, 8.1, 9.1	
4.1.3	1, 3, 4, 6, 7.1,7.2, 7.5, 8.1, 9.1	
4.1.4	13.3 i), 13.3 k)	
4.1.5	7.3, 8.1	
4.1.6	7.3, 8.1	
4.1.7	3, 7.3, 8.1, 9.1	
4.1.8	13.4, 13.6 h), 13.3 k), 13.3 m)	
4.2	3, 7.3, 7.5, 7.6, 8.1	
4.3	3, 8.1	
4.4	3, 8.1	
4.5	3, 8.1	
4.6	3, 8.1	
4.7	3, 8.1	
4.8	3, 9.1, 9.2	
4.9	13.1, 13.6 d)	
5.1	3, 9.1, 12.7.5	

Table ZA.1 *(continued)*

Clauses/subclauses of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
5.2	3, 8.1, 13.1	
5.3	7.2, 7.5, 8.1	
5.4	3, 8.1	
5.5	3, 8.1	
5.6	2, 3	
6.2	1, 2, 3, 6, 7.1, 8.1	Testing for conformity
6.3	3, 9.1	Testing for conformity
6.4	3, 7.3, 8.1, 9.1	Testing for conformity
6.5	3, 7.5, 8.1, 9.1	Testing for conformity
6.6	3, 7.5, 8.1	Testing for conformity
6.7	3, 8.1	Testing for conformity
6.8	3, 8.1	Testing for conformity
6.9	3, 8.1	Testing for conformity
6.10	3, 8.1	Testing for conformity
6.11	3, 8.1	Testing for conformity
6.12	3, 8.1	
7	13	The requirements of ISO 15883-1:2006 apply.
8	13.1, 13.3, 13.4, 13.6	In addition, the requirements of ISO 15883-1:2006 apply.
9	5, 13	The requirements of ISO 15883-1:2006 apply.
10	1, 3	In addition, the requirements of ISO 15883-1:2006 apply.
-	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**
4.1.1	1.1.7, 1.2.2, 1.2.3, 1.2.4, 1.2.5, 1.3.2, 1.3.3, 1.3.4, 1.5.1, 1.5.2, 1.5.3, 1.5.5, 1.5.6, 1.5.8, 1.5.13, 1.5.14, 1.6.2, 1.6.3, 1.6.4, 1.6.5	This relevant EHSR are addressed in this Standard
4.1.1	1.1.3, 1.1.5, 1.1.6, 1.2.1, 1.2.6, 1.3.1, 1.3.7, 1.3.8.1, 1.3.8.2, 1.5.4, 1.6.1, 1.7.1, 1.7.2, ,1.7.3, 1.7.4	This relevant EHSR are partly addressed in this Standard
	1.3.9, 1.4.1, 1.4.2, 1.4.3, 1.5.9, 4	This relevant EHSR are not addressed in this Standard

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Introduction

It is recommended that this introduction be read in conjunction with the introduction to ISO 15883-1.

The washer-disinfectors specified in this part of ISO 15883 are intended to process devices which can be immersed in water or aqueous solutions. For some devices this will require that, prior to processing, relevant parts of the device are protected from immersion in accordance with the device manufacturer's operating instructions.

Fields of application within the scope of the 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.

Requirements for washer-disinfectors for other applications are specified in other parts of ISO 15883.

Safety requirements for washer-disinfectors are given in IEC 61010-2-040.

With respect to the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfectors:

a) note that, until verifiable European criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfectors remain in force;

b) this part of ISO 15883 provides no information as to whether the washer-disinfectors may be used without restriction in any of the member states of the EU or EFTA.

Washer-disinfectors —

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

1 Scope

This part of ISO 15883 specifies the particular requirements, including performance, for washer-disinfectors (WDs) that are intended to be used for cleaning and chemical disinfection of thermolabile endoscopes.

This part of ISO 15883 also specifies the performance requirements for the cleaning and disinfection of the washer-disinfector and its components and accessories which may be required to achieve the necessary performance.

The methods, instrumentation and instructions required for type testing, works testing, validation (installation, operational and performance qualification on first installation), routine control and monitoring and re-validation, periodically and after essential repairs, are also specified.

NOTE 1 In addition, Annex A gives guidance on an appropriate division of responsibility for the range of activities covered by this part of ISO 15883.

NOTE 2 WDs complying with this part of ISO 15883 can also be used for cleaning and chemical disinfection of other thermolabile re-usable medical devices for which the device manufacturer has recommended this method of disinfection.

WDs complying with the requirements of this part of ISO 15883 are not intended for cleaning and disinfection of medical devices, including endoscopic accessories, which are heat stable and can be disinfected or sterilized by thermal methods (see ISO 15883-1:2006, 4.1.5).

The specified performance requirements of this part of ISO 15883 may not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

NOTE 3 If it is considered that prion protein might 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 from the load or washer-disinfector.

This part of ISO 15883 can be used by prospective purchasers and manufacturers as the basis of agreement on the specification of WD manufacturers of endoscopes, cleaning products, disinfecting products, and also by users.

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 11731-2, *Water quality — Detection and enumeration of Legionella — Part 2: Direct membrane filtration method for waters with low bacterial counts*

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

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

IEC 61010-2-040, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15883-1 and the following apply.

3.1
air break
physical separation in water supply pipes to prevent back syphonage into the water supply from a device connected to it

NOTE See EN 1717.

3.2
inoculated carrier
supporting material on or in which a defined number of viable test organisms has been deposited

[ISO 11138-1:2006, definition 3.10]

3.3
leak test
test intended to establish that the surface covering the device and/or lining a device channel is intact to the extent necessary to maintain a slightly positive pressure

3.4
liquid transport systems
those components of the washer-disinfector used to store, pump or transport water and/or solutions within the washer-disinfector, excluding pipework before the air break

3.5
microbial inactivation factor
measured change in microbial population, expressed as $\log_{10}$, caused by the lethal effect of the disinfectant

3.6
microbial reduction factor
measured change in microbial population expressed as $\log_{10}$ caused by the combination of the microbial inactivation factor and the physical removal of microorganisms

3.7
obstruction
partial or complete blockage