Irish Standard
I.S. EN ISO 15883-4:2009

Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2008)

I.S. EN ISO 15883-4:2009

Incorporating amendments/corrigenda issued since publication:

This document replaces:	*This document is based on:*	*Published:*
I.S. EN ISO 15883-4:2008	EN ISO 15883-4:2009 EN ISO 15883-4:2008	3 June, 2009 12 January, 2009

This document was published under the authority of the NSAI and comes into effect on:
19 August, 2009

ICS number:
11.080.10

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W **NSAI.ie**

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Price Code:
Q

Údarás um Chaighdeáin Náisiúnta na hÉireann

I.S. EN ISO 15883-4:2009

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15883-4

June 2009

ICS 11.080.10

Supersedes EN ISO 15883-4:2008

English Version

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.

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 15883-4:2009: E

Contents

Page

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

I.S. EN ISO 15883-4:2009

INTERNATIONAL STANDARD

ISO 15883-4

First edition
2008-05-01

Washer-disinfectors —

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

Laveurs désinfecteurs —

Partie 4: Exigences et essais pour les laveurs désinfecteurs destinés à la désinfection chimique des endoscopes thermolabiles

Reference number
ISO 15883-4:2008(E)

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.

COPYRIGHT PROTECTED DOCUMENT

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

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 15883-4 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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*

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.