



SLOVENSKI STANDARD
SIST EN ISO 15883-4:2008

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

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

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

Ta slovenski standard je istoveten z: EN ISO 15883-4:2008

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11.080.10 Sterilizacijska oprema Sterilizing equipment

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

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This European Standard was approved by CEN on 21 April 2008.

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Management Centre: rue de Stassart, 36 B-1050 Brussels

Contents	Page
Foreword	3
Annex ZA (informative) Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices	4

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Foreword

This document (EN ISO 15883-4:2008) 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of an identical text or by endorsement, at the latest by November 2008, and conflicting national standards shall be withdrawn at the latest by November 2008.

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 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(s).

For relationship with EC Directive(s), see informative Annex ZA, B, C or D, 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.

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Annex ZA (informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

By agreement between ISO and CEN, this CEN annex is included in the DIS and the FDIS but will not appear in the published ISO standard.

This 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 International Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of 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)

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of 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 https://standards.iteh.ai/catalog/standards/sist/46e29961-3407-4088-bd3b-6067432d508/sist-en-iso-15883-4-2008	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.

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

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INTERNATIONAL
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ISO
15883-4

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2008-05-01

Washer-disinfectors —

Part 4:

**Requirements and tests for washer-
disinfectors employing chemical
disinfection for thermolabile endoscopes**

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Laveurs désinfecteurs —

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

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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
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Contents

Page

Foreword.....	v
Introduction	vi
1 Scope	1
2 Normative references	2
3 Terms and definitions.....	2
4 Performance requirements	3
4.1 General.....	3
4.2 Systems for leak testing	4
4.3 Cleaning	6
4.4 Disinfecting	7
4.5 Final (post-disinfection) rinsing	9
4.6 Purging to remove rinse water	9
4.7 Drying.....	9
4.8 Self-disinfection	10
4.9 Water treatment equipment	11
5 Mechanical and process requirements	12
5.1 Materials — Design, manufacture and construction.....	12
5.2 Device channel irrigation system	12
5.3 Venting and drainage systems	13
5.4 Temperature control	14
5.5 Process chemicals	14
5.6 Process verification	14
5.7 Dosing systems	14
6 Testing for conformity	14
6.1 General.....	14
6.2 Test equipment	15
6.3 Water used for final (post-disinfection) rinsing.....	15
6.4 Hardness of water used during type testing.....	15
6.5 Leak test	16
6.6 Channels non-obstruction test.....	18
6.7 Channels non-connection test	19
6.8 Load dryness.....	20
6.9 Thermometric tests.....	20
6.10 Chemical dosing tests.....	21
6.11 Tests of cleaning efficacy	22
6.12 Test of disinfection efficacy	23
7 Documentation and inspection	27
8 Information to be supplied by the manufacturer	27
9 Marking, labelling and packaging	28
10 Information to be requested from the purchaser by the manufacturer	28
Annex A (informative) Summary of activities covered by this Part of ISO 15883.....	29
Annex B (normative) Microbiological testing of the efficacy of chemical disinfection of the load.....	31
Annex C (informative) Summary of test programmes	34
Annex D (normative) Methods for microbiological evaluation of disinfection of liquid transport system.....	35

ISO 15883-4:2008(E)

Annex E (normative) Tests for microbial contamination of post-disinfection rinse water.....	40
Annex F (informative) Typical specifications of trumpet valves and connection ports.....	41
Annex G (informative) Additional notes on microbiological testing of chemical disinfection processes.....	46
Bibliography	48

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[SIST EN ISO 15883-4:2008](https://standards.iteh.ai/catalog/standards/sist/46e29961-3407-4988-bd3b-60fc7432d508/sist-en-iso-15883-4-2008)

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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 15883-4 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*

ISO 15883-4:2008(E)**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:

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- 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.

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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.