

Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 15883-2:2006 sisaldab Euroopa standardi EN ISO 15883-2:2006 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 15883-2:2006 consists of the English text of the European standard EN ISO 15883-2:2006.</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>
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<p>Käsitlusala:</p> <p>This part of ISO 15883 specifies particular requirements for washer-disinfectors (WD) that are intended for use for the cleaning and thermal disinfection, in a single operating cycle, of re-usable medical devices such as surgical instruments, anaesthetic equipment, bowls, dishes and receivers, utensils and glassware.</p>	<p>Scope:</p> <p>This part of ISO 15883 specifies particular requirements for washer-disinfectors (WD) that are intended for use for the cleaning and thermal disinfection, in a single operating cycle, of re-usable medical devices such as surgical instruments, anaesthetic equipment, bowls, dishes and receivers, utensils and glassware.</p>
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Võtmesõnad:

English Version

Washer-disinfectors - Part 2: Requirements and tests for
washer-disinfectors employing thermal disinfection for surgical
instruments, anaesthetic equipment, bowls, dishes, receivers,
utensils, glassware, etc. (ISO 15883-2:2006)

Laveurs désinfecteurs - Partie 2: Exigences et essais pour
laveurs désinfecteurs destinés à la désinfection thermique
des instruments chirurgicaux, du matériel d'anesthésie, des
récipients, des ustensiles et de la verrerie, etc. (ISO 15883-
2:2006)

Reinigungs-Desinfektionsgeräte - Teil 2: Anforderungen an
und Prüfungen von Reinigungs-Desinfektionsgeräten mit
thermischer Desinfektion für chirurgische Instrumente,
Anästhesiegeräte, Gefäße, Utensilien, Glasgeräte usw.
(ISO 15883-2:2006)

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 15883-2:2006) 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 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, 12.7.2, 12.7.3, 12.7.5, 13.1, 13.3, 13.4	The WD shall comply with the requirements of ISO 15883-1:—
4.1.2	1, 3, 4, 6, 7.1, 8.1, 9.1	
4.1.3	1, 3, 4, 6, 7.1, 8.1, 9.1	
4.1.5	3, 7.1	
4.1.6	7.3, 8.1	
4.2	3, 8.1	
4.3	3, 8.1	
4.4	3, 8.1	
5.1	3, 8.1	
5.2	3, 8.1	
5.3	3, 8.1	
6.1	1, 2, 3, 4, 7.1, 8.1	Testing for conformity according to ISO 15883-1:—
6.2	3, 8.1	
6.3	3, 8.1	
7	9.1, 13.6	
8	1, 3, 7.1, 7.2, 8.1	
	7.4, 8.2, 8.3, 8.4, 8.5, 8.6, 8.7, 10.1, 10.2, 10.3, Clause 11, 12.2, 12.3, 12.4, 12.7.4, 12.8, 13.5, 14	not applicable

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

Washer-disinfectors —

Part 2:

Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

Laveurs désinfecteurs —

Partie 2: Exigences et essais pour laveurs désinfecteurs destinés à la désinfection thermique des instruments chirurgicaux, du matériel d'anesthésie, des récipients, des ustensiles et de la verrerie, etc.



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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
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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Performance requirements	2
4.1 General.....	2
4.2 Cleaning.....	3
4.3 Disinfecting.....	3
4.4 Temperature of internal surfaces of processed devices.....	4
5 Mechanical and control requirements	4
5.1 Load connectors.....	4
5.2 Control systems.....	5
5.3 Process verification.....	5
6 Testing for conformity	5
6.1 General.....	5
6.2 Tests for soil removal from chamber walls, load carrier and load.....	5
6.3 Thermometric tests.....	6
7 Information to be supplied by the manufacturer	8
8 Information to be requested from the purchaser by the supplier of the WD	8
Annex A (informative) Summary of test programmes	9
Bibliography	10

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 15883-2 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

It is recommended that this Introduction be read in conjunction with the introduction to ISO 15883-1:2006.

This part of ISO 15883 is the second of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to instrument washer-disinfectors. The requirements given in this part apply to washer-disinfectors used for cleaning and thermal disinfection of medical devices intended for re-use such as:

- surgical instruments;
- powered devices;
- instrument trays;
- instruments for minimally invasive surgery;
- lumen devices and tubing;
- rigid endoscopes;
- anaesthetic and respiratory equipment;
- bowls, dishes and receivers;
- glassware;
- containers for transit.

Fields of application within the scope of the ISO 15883 series of standards 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 the ISO 15883 series of standards.

When processed in the instrument washer-disinfector, the medical devices might be intended for immediate use or might be intended for packing and sterilization. In both cases, the efficacy of the cleaning and disinfection is of major importance. In either case, this is for the well being of the patient. In the latter case, it is also for the safety of the staff who handles the instruments in the process of inspection, testing and packing as well as ensuring that the sterilization process is not unduly challenged by residual soil.

The efficacy of disinfection can be impaired if soil removal is incomplete before the start of the disinfection process. Users should be aware that some medical devices might require pre-treatment e.g. soaking, brushing, ultra sonic pre-cleaning, lumen irrigation or any combination of these techniques. Reference should be made to the medical manufacturer's instructions for reprocessing (see also ISO 17664).

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

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

- 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-disinfectors remain in force;
- b) the ISO 15883 series of standards 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 2:

Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

1 Scope

This part of ISO 15883 specifies particular requirements for washer-disinfectors (WD) that are intended for use for the cleaning and thermal disinfection, in a single operating cycle, of re-usable medical devices such as surgical instruments, anaesthetic equipment, bowls, dishes and receivers, utensils and glassware.

NOTE 1 Thermal disinfection can be achieved by rinsing the load with hot water, exposure to steam or combination of the two.

The requirements specified in this part of ISO 15883 are applicable in conjunction with the general requirements specified in ISO 15883-1.

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 2 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.

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 4017, *Hexagon head screws — Product grades A and B*

ISO 5356-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5361, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

ISO 5362, *Anaesthetic reservoir bags*

ISO 5367, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

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

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of re-sterilizable medical devices*

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

EN 10088-2, *Stainless steels — Part 2: Technical delivery conditions for sheet/plate and strip for general purposes*

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

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

[ISO 15883-1:2006, definition 3.1]

NOTE See also ISO 15883-1:2006, Annex B.

3.2

anaesthetic and respiratory accessories

respiratory tubes, anaesthetic reservoir bags and other anaesthetic products that will not be sufficiently flushed by rotating spray nozzles, but which require positioning over fixed spray/jet nozzles

3.3

lumen device

device that consists of tubes, pipes (either single or coaxial combined) which require connecting to the WD by means of dedicated connectors

3.4

powered device

surgical instrument which gives a rotating and/or oscillating movement to other surgical instruments

NOTE The power applied to the driven instrument can be mechanical (from a motor, either through direct coupling, flexible axle or belt) or by the flow of a pressurized fluid or compressed air.

EXAMPLES Dental hand pieces, orthopaedic saws and drills.

3.5

washing temperature

minimum temperature of the washing temperature band

3.6

washing temperature band

range of temperatures, expressed as the washing temperature and the maximum allowable temperature which may prevail throughout the load during the washing time

3.7

washing time

period for which the cycle variables (e.g. temperature of the load, detergent concentration in the chamber) are maintained at or above the values specified for washing

4 Performance requirements

4.1 General

4.1.1 The requirements of ISO 15883-1:2006 apply with the exception of its