

**Pesu-desinfektsiooniseadmed. Osa 6: Mitteinvasiivsete, mittekriitiliste meditsiiniseadmete ja tervishoiuseadmete termiliseks desinfektsiooniks ette nähtud pesu-desinfektsiooniseadmete nõuded ja katsed (ISO 15883-6:2011)**

Washer-disinfectors - Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment (ISO 15883-6:2011)

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 15883-6:2011 sisaldab Euroopa standardi EN ISO 15883-6:2011 ingliskeelset teksti.

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English Version

Washer-disinfectors - Part 6: Requirements and tests for  
washer-disinfectors employing thermal disinfection for non-  
invasive, non-critical medical devices and healthcare equipment  
(ISO 15883-6:2011)

Laveurs désinfecteurs - Partie 6: Exigences et essais pour  
les laveurs désinfecteurs utilisant une désinfection  
thermique pour les dispositifs médicaux non invasifs, non  
critiques et pour l'équipement de soins de santé (ISO  
15883-6:2011)

Reinigungs-Desinfektionsgeräte - Teil 6: Anforderungen  
und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit  
thermischer Desinfektion für nicht invasive, nicht kritische  
Medizinprodukte und Zubehör im Gesundheitswesen (ISO  
15883-6:2011)

This European Standard was approved by CEN on 14 April 2011.

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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## Foreword

This document (EN ISO 15883-6:2011) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with 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of an identical text or by endorsement, at the latest by October 2011, and conflicting national standards shall be withdrawn at the latest by October 2011.

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 EU Directive.

For relationship with EU 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, Croatia, 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 15883-6:2011 has been approved by CEN as a EN ISO 15883-6:2011 without any modification.

## Annex ZA (informative)

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

This International 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 Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative 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**

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	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	13.3 a)	This relevant Essential Requirement is partly addressed in EN 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	7.3, 8.1	
4.2	3, 8.1	
4.3	3, 8.1	
5.1	3, 8.1	
5.2	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	
—	12.1a)	This relevant Essential Requirement is not addressed
—	13.6 q)	This relevant Essential Requirement is not addressed

**WARNING:** Other requirements and other EU Directives may be applicable to the products 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, Table ZA.2 details the relevant essential requirements of Directive 2006/42/EC to the extent to which they are more specific than those of Directive 93/42/EEC, along with the corresponding clauses of this International Standard. Table ZA.2, however, does not imply any citation in the Official Journal of the European Communities under the machinery directive and thus does not provide presumption of conformity with that 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)/subclause(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	These relevant Essential Requirements are addressed
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	These relevant Essential Requirements are partly addressed
—	1.3.9, 1.4.1, 1.4.2, 1.4.3, 1.5.9, 4	These relevant Essential Requirements are not addressed

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## Introduction

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

This part of ISO 15883 is the sixth of a series specifying the performance of washer-disinfectors and specifies the particular requirements for performance applicable to general-purpose washer-disinfectors. Its requirements apply to washer-disinfectors used for the cleaning and disinfection of non-invasive and non-critical reusable medical devices (i.e. not penetrating skin or contacting mucosal surfaces) and for other items for use without further treatment in healthcare settings. Such reusable items need to be cleaned and disinfected, but their processing in a washer-disinfector for surgical instruments (see ISO 15883-2), for human waste containers (see ISO 15883-3) or for endoscopes (see ISO 15883-4) is inappropriate and/or impractical.

Some examples are

- non-invasive medical devices,
- washbowls,
- cleaning equipment (buckets),
- footwear,
- container systems used to transport medical devices, including trolleys and transport carts, and
- bedsteads, wheelchairs, aids for the disabled.

Fields of application within the scope of ISO 15883 include laboratory, veterinary and dental use, and other specific applications such as washer-disinfectors for 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.

The efficacy of disinfection can be impaired if soil removal is incomplete before the start of the disinfection process. It is desirable that manufacturers of washer-disinfectors be very clear about the items that can be processed in the washer-disinfector, and that reference be made to the instructions for reprocessing provided by the manufacturer of the items to be processed.

In respect of the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfectors, it is noteworthy that

- a) until verifiable international criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfectors remain in force, and
- 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 ISO member states.



## Washer-disinfectors —

Part 6:

### Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment

**WARNING** — Devices identified within the scope of ISO 15883-2, ISO 15883-3 and ISO 15883-4 shall not be processed in washer-disinfectors specified in this part of ISO 15883. Examples of medical devices that are not to be processed in these devices include powered devices, lumened devices and other invasive devices.

#### 1 Scope

This part of ISO 15883 specifies particular requirements for washer-disinfectors (WDs) intended for use when the level of assurance of disinfection that is necessary can be achieved by cleaning and thermal disinfection ( $A_0$  not less than 60) and does not require an independent automated record of critical processes to be kept. It is intended to be used in conjunction with ISO 15883-1, which gives general requirements for WDs.

The range of products on which WDs of this particular type can be used is restricted to devices and equipment which are non-invasive and non-critical (i.e. not penetrating skin or contacting mucosal surfaces).

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

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

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