

**Pesur-desinfitseerija. Osa 3: Nõuded ja testid  
inimjätmete konteinerite termilise desinfektsiooni  
pesur-desinfitseerijatele**

Washer-disinfectors - Part 3: Requirements and tests for  
washer-disinfectors employing thermal disinfection for  
human waste containers

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 15883-3:2009 sisaldab Euroopa standardi EN ISO 15883-3:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 30.11.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 03.06.2009.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 15883-3:2009 consists of the English text of the European standard EN ISO 15883-3:2009.

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.

Date of Availability of the European standard text 03.06.2009.

The standard is available from Estonian standardisation organisation.

ICS 11.080.10

### Standardite reprodutseerimis- ja levitamiseõigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonilisse süsteemi või edastamine ükskõik millises vormis või millisel teel on keelatud ilma Eesti Standardikeskuse poolt antud kirjaliku loata.

Kui Teil on küsimusi standardite autorikaitse kohta, palun võtke ühendust Eesti Standardikeskusega:  
Aru 10 Tallinn 10317 Eesti; [www.evs.ee](http://www.evs.ee); Telefon: 605 5050; E-post: [info@evs.ee](mailto:info@evs.ee)

### Right to reproduce and distribute Estonian Standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without permission in writing from Estonian Centre for Standardisation.

If you have any questions about standards copyright, please contact Estonian Centre for Standardisation:  
Aru str 10 Tallinn 10317 Estonia; [www.evs.ee](http://www.evs.ee); Phone: +372 605 5050; E-mail: [info@evs.ee](mailto:info@evs.ee)

English Version

**Washer-disinfectors - Part 3: Requirements and tests for  
washer-disinfectors employing thermal disinfection for human  
waste containers (ISO 15883-3:2006)**

Laveurs désinfecteurs - Partie 3: Exigences et essais pour  
laveurs désinfecteurs destinés à la désinfection thermique  
de récipients à déjections humaines (ISO 15883-3:2006)

Reinigungs-Desinfektionsgeräte - Teil 3: Anforderungen an  
und Prüfverfahren für Reinigungs-Desinfektionsgeräten mit  
thermischer Desinfektion für Behälter für menschliche  
Ausscheidungen (ISO 15883-3:2006)

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**

## Foreword

The text of ISO 15883-3:2006 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 15883-3:2009 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 15883-3:2006.

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 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 15883-3:2006 has been approved by CEN as a EN ISO 15883-3:2009 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, 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, 13.6	The WD shall comply with the requirements of ISO 15883-1:—
4.2	7.3, 8.1	
4.3	2, 7.2, 7.5, 8.1, 9.1	
4.4	3, 8.1	
4.5	3, 8.1	
4.6	3, 8.1	
4.7	3, 8.1	
5.1	3, 8.1	
5.2	3, 8.1	
5.3	7.2, 7.5, 8.1	
6.1	1, 2, 3, 6, 7.1, 8.1	Testing for conformity according to ISO 15883-1:—
6.2	7.2, 7.5, 8.1, 9.1	

Table ZA.1 (continued)

Clauses/subclauses of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
6.3	3, 8.1	
6.4	3, 8.1	
6.5.1, 6.5.2	2, 3, 7.2, 7.5, 8.1, 9.1	
6.6	3, 8.1	
7	9.1, 13.1, 13.3, 13.6	
7 a)	9.1	
7 g)	3, 8.1	
8	1.3, 7.1, 7.2, 7.3, 8.1	
8 c)	7.3	
8 e)	3, 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
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard
4.1.1	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, 4.3	1.1.3	This relevant EHSR is partly addressed in this Standard
4.1.1	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

# Contents

Page

Foreword.....	iv
Introduction.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Performance requirements.....	2
4.1 General.....	2
4.2 Chemical dosing systems.....	2
4.3 Emptying.....	3
4.4 Cleaning.....	3
4.4.1 Flushing.....	3
4.4.2 Washing.....	3
4.4.3 Test requirements.....	3
4.5 Disinfecting.....	3
4.6 Rinsing.....	4
4.7 Drying.....	4
5 Mechanical and control requirements.....	4
5.1 Instrumentation and control.....	4
5.2 Process.....	4
5.3 Venting, draining and purging.....	4
5.4 Water quality.....	5
6 Testing for conformity.....	5
6.1 General.....	5
6.2 Test for drain seal integrity.....	5
6.3 Test for flushing of non-absorbent materials.....	5
6.4 Test for flushing of absorbent material (toilet tissue).....	5
6.5 Test for loading/emptying of containers.....	5
6.5.1 Automatic emptying.....	5
6.5.2 Manual emptying.....	6
6.6 Tests for soil removal from chamber walls, load carrier and load.....	6
7 Information to be supplied by the manufacturer.....	6
8 Information to be requested from the purchaser by the supplier of the WD.....	7
Annex A (informative) Summary of test programmes.....	8
Annex B (normative) Specification for toilet tissue for use in tests on washer-disinfectors for human-waste containers.....	9
Annex C (informative) Measurement of water absorbency of toilet tissue by the basket method.....	10
Bibliography.....	11

## Introduction

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

This part of ISO 15883 is the third of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to bedpan washer-disinfectors. The requirements given in this part apply to washer-disinfectors used for emptying, flushing, cleaning and thermally disinfecting human waste containers intended for re-use such as:

- portable sanitary pans;
- supports for single-use bed pans;
- hospital bowls;
- urine bottles;
- suction bottles; and
- products similar to the above and used for similar purposes.

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 the ISO 15883 series of standards.

Bedpan washer disinfectors are loaded manually. In order to reduce the risk of spillage and the generation of aerosols most machines incorporate means to empty human waste containers automatically e.g. by the action of closing the door.

Where equipment does not provide automatic emptying facilities, extra care is needed by the user to avoid exposure to human waste and contamination of the work environment including the generation of aerosols.

The reliability of a bedpan washer-disinfector may be adversely affected if the machine is connected to a poorly designed or constructed drainage system. The purchaser is therefore recommended to ensure that the drainage system complies with the manufacturer's recommendations in all respects.

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) 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 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers

### 1 Scope

This part of ISO 15883 specifies particular requirements for washer-disinfectors (WD) that are intended to be used for emptying, flushing, cleaning and thermal disinfection of containers used to hold human waste for disposal by one operating cycle.

This part of ISO 15883 is to be applied in conjunction with ISO 15883-1.

### 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, definitions and tests*

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

### 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

##### emptying

discharging the contents of a container by gravity

#### 3.3

##### human waste

excretions and body fluids including faeces, urine, blood, pus, vomit and mucus