

This is a preview of "ISO 15883-1:2006". [Click here to purchase the full version from the ANSI store.](#)

First edition  
2006-04-15

---

---

## Washer-disinfectors —

### Part 1: General requirements, terms and definitions and tests

*Laveurs désinfecteurs —*

*Partie 1: Exigences générales, termes et définitions et essais*



Reference number  
ISO 15883-1:2006(E)

© ISO 2006

This is a preview of "ISO 15883-1:2006". [Click here to purchase the full version from the ANSI store.](#)

**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.

© ISO 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

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](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

This is a preview of "ISO 15883-1:2006". [Click here to purchase the full version from the ANSI store.](#)

## Contents

Page

|   |    |
|---|----|
| Foreword.....   | v  |
| Introduction .....  | vi |
| 1 Scope .....   | 1  |
| 2 Normative references .....                                | 1  |
| 3 Terms and definitions.....                                | 2  |
| 4 Performance requirements .....                            | 8  |
| 4.1 General.....  | 8  |
| 4.2 Cleaning.....   | 10 |
| 4.3 Disinfection .....                                      | 10 |
| 4.4 Rinsing .....   | 11 |
| 4.5 Drying.....   | 11 |
| 4.6 Process chemicals.....                                  | 12 |
| 5 Mechanical and process requirements .....                 | 12 |
| 5.1 Materials, design and manufacture/construction.....     | 12 |
| 5.2 Safety .....  | 14 |
| 5.3 Calorifiers and tanks .....                             | 14 |
| 5.4 Loading and unloading doors and their controls.....     | 15 |
| 5.5 Pipework and fittings.....                              | 17 |
| 5.6 Spray systems.....                                      | 17 |
| 5.7 Dosing systems .....                                    | 18 |
| 5.8 Load temperature protection.....                        | 18 |
| 5.9 Process temperature control limits .....                | 19 |
| 5.10 Switches, gauges and indicating devices.....           | 20 |
| 5.11 Process verification.....                              | 20 |
| 5.12 Instrumentation and controls .....                     | 21 |
| 5.13 Temperature indicating systems.....                    | 22 |
| 5.14 Pressure indicating systems .....                      | 23 |
| 5.15 Timing equipment.....                                  | 23 |
| 5.16 Operating cycle indicating equipment.....              | 23 |
| 5.17 Recording instruments (if fitted) .....                | 23 |
| 5.18 Control systems .....                                  | 25 |
| 5.19 Override of automatic control .....                    | 26 |
| 5.20 Microprocessor control systems .....                   | 27 |
| 5.21 Access to software .....                               | 27 |
| 5.22 Fault indication systems.....                          | 27 |
| 5.23 Water supply .....                                     | 28 |
| 5.24 Venting and drainage systems.....                      | 28 |
| 5.25 Drainage.....  | 29 |
| 5.26 Air filters installed within the WD.....               | 29 |
| 5.27 Load handling and supports for use within the WD ..... | 29 |
| 5.28 Trolleys .....   | 30 |
| 5.29 Environment .....                                      | 31 |
| 6 Testing for conformity.....                               | 31 |
| 6.1 General.....  | 31 |
| 6.2 Test equipment .....                                    | 34 |
| 6.3 Tests on doors, interlocks and fault indications.....   | 35 |
| 6.4 Tests on water quality and water volume .....           | 37 |
| 6.5 Tests on pipework .....                                 | 39 |
| 6.6 Tests on instrumentation fitted to the WD .....         | 41 |

This is a preview of "ISO 15883-1:2006". [Click here to purchase the full version from the ANSI store.](#)

|   |  |    |
|---|--|----|
| 6.7   | Tests on load carriers .....   | 42 |
| 6.8   | Thermometric tests .....   | 43 |
| 6.9   | Chemical dosing tests .....  | 46 |
| 6.10  | Tests of cleaning efficacy .....   | 47 |
| 6.11  | Tests of air quality .....   | 48 |
| 6.12  | Load dryness test .....  | 49 |
| 6.13  | Automatic control test .....   | 49 |
| 7   | Documentation .....  | 50 |
| 8   | Information to be supplied by the manufacturer .....                           | 50 |
| 8.1   | General .....  | 50 |
| 8.2   | Before delivery of the WD and for installation .....                           | 51 |
| 8.3   | At delivery of the WD .....  | 51 |
| 9   | Marking, labelling and packaging .....   | 53 |
| 9.1   | Marking and labelling .....  | 53 |
| 9.2   | Packaging .....  | 53 |
| 10  | Information to be requested from the purchaser by the supplier of the WD ..... | 53 |
| Annex A (informative) Test programme .....  |  | 55 |
| Annex B (informative) $A_0$ concept — Comparative lethality of moist heat processes .....                       |  | 59 |
| Annex C (normative) Test methods for the detection and assessment of residual proteinaceous contamination ..... |  | 63 |
| Annex D (normative) Microbiological recovery medium for estimation of bacterial contamination of water .....    |  | 68 |
| Bibliography .....  |  | 69 |

This is a preview of "ISO 15883-1:2006". [Click here to purchase the full version from the ANSI store.](#)

## 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 15883-1 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

This part of ISO 15883 is the first of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to all washer-disinfectors. The requirements given in this part of ISO 15883 are applicable to all washer-disinfectors specified in subsequent parts of the ISO 15883 series, except insofar as they may be modified or added to by a subsequent part, in which case the requirements of that particular part will apply.

Fields of application within the scope of 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.

Washer-disinfectors should be used only for processing the type of loads specified by the manufacturer of the washer-disinfector.

In selecting the appropriate washer-disinfector, reference should be made both to this part of ISO 15883 and to the relevant subsequent parts of ISO 15883 series. It is the user's responsibility to ensure that the choice of type of washer-disinfector, operating cycle or quality of services or process chemicals is appropriate for any particular load.

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

This part of ISO 15883 has been prepared on the basis that each individual washer-disinfector will be subject to validation tests (commissioning and performance qualification on first installation) and that in use continued compliance will be established by periodic tests carried out by, or on behalf of, the user.

Verification of cleaning efficacy is a key aspect of establishing satisfactory performance of a washer-disinfector. The current state of knowledge has not permitted development of a single test method. As an interim measure reference has been made to test methods which are currently being applied in a number of different countries. The specification for these test methods including their test soils can be found in ISO/TS 15883-5. It remains the intention of the Technical Committee of TC 198 to develop a single test method.

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

- 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-disinfector remain in force;
- b) the ISO 15883 series of standards provides no information as to whether the washer-disinfector may be used without restrictions in any of the member states of the EU or EFTA.