International Standard

ISO 15883-1

Washer-disinfectors —

Part 1: General requirements, terms and definitions and tests

Laveurs désinfecteurs —

Partie 1: Exigences générales, termes et définitions et essais

Second edition
2024-10

Reference number
ISO 15883-1:2024(en)

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Published in Switzerland

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 15883-1:2006), which has been technically revised. It also incorporates ISO 15883-1:2006/Amd 1:2014.

The main changes are as follows:

— alignment of terms and definitions with ISO 11139:2018 + Amd 1:2024;

— addition of requirements for load carrier(s);

— clarification of water quality requirements;

— elaboration of load dryness tests for external and internal surfaces of load items (see 6.12);

— relocation of former Annex C, *Test methods for the detection and assessment of residual proteinaceous contamination,* to ISO 15883-5:2021;

— redesignation of former Annex D, *Microbiological recovery medium for estimation of bacterial contamination of water,* as Annex C;

— increase in the minimum temperature limit for thermal disinfection and calculation of A_0 values from 65 °C to 70 °C (see Reference [48]);

— revision of the Bibliography.

A list of all parts in the ISO 15883 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

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

Fields of application within the scope of ISO 15883 series can include laboratory, veterinary, dental and pharmaceutical applications and other specific applications, such as WD for bedsteads and transport carts and the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

WD are used only for processing the type of loads specified by the manufacturer of the WD.

In selecting the appropriate WD, references are made both to this document and to the relevant parts of ISO 15883 series. It is the user's responsibility to ensure that the choice of type of WD, operating cycle or quality of services or process chemicals is appropriate for any particular load.

This document has been prepared on the basis that each individual WD is subject to validation tests (e.g. installation qualification, operational qualification, and performance qualification on first installation) and that in use continued conformance is established by periodic tests.

NOTE Local or national regulations can apply in respect of the potential adverse effects on the quality of water intended for human consumption or environmental impacts caused by the WD and its intended use.

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Washer-disinfectors —

Part 1:
General requirements, terms and definitions and tests

1 Scope

This document specifies general performance requirements for washer-disinfectors (WD) and washer-disinfector accessories that are intended to be used for cleaning and disinfection of reusable medical devices. It specifies performance requirements for cleaning and disinfection as well as for the accessories that can be required to achieve the necessary performance. The methods and instrumentation required for validation, routine control and monitoring and requalification, periodically and after essential repairs, are also specified.

NOTE 1 The requirements can be applied to WD intended for use with other articles used in the context of medical, dental, pharmaceutical and veterinary practice.

The requirements for WD intended to process specific loads are specified in ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7. For WD intended to process loads of two or more different types, the requirements of the applicable parts of ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7 apply.

This document does not specify requirements intended for machines for use for laundry or general catering purposes.

This document does not include requirements for machines which are intended to sterilize the load, or which are designated as “sterilizers” and addressed in other standards.

The specified performance requirements of this document do not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

NOTE 2 Chemicals in some cleaning agents and disinfectants can react with prion protein in a manner that can inhibit its removal or inactivation. If the presence of prion protein is considered a possibility, then this can influence the choice of cleaning agent and disinfectant.

NOTE 3 This document can be used by prospective purchasers and manufacturers as the basis of agreement on the specification of a WD. The test methods for demonstration of conformity with the requirements of this document can also be employed by users to demonstrate continued conformity of the installed WD throughout its service life. Guidance on a routine test programme is given in Annex A.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

ISO 14644-3, *Cleanrooms and associated controlled environments — Part 3: Test methods*

ISO 14971, *Medical devices — Application of risk management to medical devices*

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ISO 15883-2[1)], *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 15883-3, *Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

ISO 15883-4, *Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*

ISO 15883-5:2021, *Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy*

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

ISO 15883-7[2)], *Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment*

IEC 60417-DB, *Graphical symbols for use on equipment*

IEC 60584-1:2013, *Thermocouples — Part 1: EMF specifications and tolerances*

IEC 60751:2008, *Industrial platinum resistance thermometer and platinum temperature sensors*

IEC 61010-2-040:2020, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*

IEC 61326-1:2020, *Electrical equipment for measurement, control and laboratory use. EMC requirements — Part 1: General requirements*

IEC 80416-1, *Basic principles for graphical symbols for use on equipment — Part 1: Creation of graphical symbols for registration*

European Pharmacopoeia, *Assays – 2.5.30 Oxidising substances*; *Biological tests* - 2.6.14 *Bacterial endotoxins*

United States Pharmacopeia, *Chemical tests <541> Titrimetry, Oxidation-Reduction (Redox) titrations*; *Biological tests <85> Bacterial endotoxins test*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
A_0
measure of microbiological lethality delivered by a moist heat *disinfection* (3.14) process expressed in terms of the equivalent time in seconds at 80 °C with reference to a *microorganism* (3.33) with a *z* value of 10 K

Note 1 to entry: See Annex B.

[SOURCE: ISO 11139:2018, 3.1, modified — Note 1 to entry has been added.]

1) 2006 version title (current version). The second edition title will be: *Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices.*

2) 2016 version title (current version). The second edition title will be: *Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile non-critical medical devices and healthcare equipment.*

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