



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
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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.

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.