



**International
Standard**

ISO 15883-6

Washer-disinfectors —

Part 6:

**Requirements and tests for washer-
disinfectors employing thermal
disinfection for non-critical medical
devices and health care equipment**

Laveurs-désinfecteurs —

*Partie 6: Exigences et essais pour les laveurs-désinfecteurs
utilisant la désinfection thermique pour les dispositifs médicaux
non critiques et les équipements de soins de santé*

**Second edition
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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).

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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 and associated equipment for processing of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 15883-6:2011), which has been technically revised.

The main changes are as follows:

- change of title to reflect application to non-critical medical devices;
- addition of new terms defining critical and semi-critical medical devices, non-critical devices and worst-case conditions;
- alignment of other terms and definitions with ISO 11139:2018+Amd 1:2024;
- revision of cross-references to relevant clauses in ISO 15883-1 and ISO 15883-5;
- revision of the temperature recorded on the surfaces, as specified in [4.3.4](#);
- addition of reference to ISO 15883-1 and ISO 15883-5 for the cleaning efficacy testing;
- addition of water quality specified in [4.4](#);
- update of 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.

Introduction

This document is the sixth part of the ISO 15883 series of standards specifying the general requirements and performance of washer-disinfectors (WD). The requirements given in this document apply to WD used for cleaning and thermal disinfection of non-critical medical devices (i.e. not penetrating skin or contacting mucosal membranes) and for other devices or equipment for use without further treatment in health care settings. Such reusable equipment is cleaned and disinfected, but it is inappropriate or impractical to process it in a WD intended for surgical instruments (see ISO 15883-2), for human waste containers (see ISO 15883-3), for endoscopes (see ISO 15883-4), or for non-critical thermolabile medical devices and health care equipment (see ISO 15883-7).

Examples of non-critical medical devices and health care equipment include:

- laryngoscope handles;
- washbowls and bowls;
- cleaning equipment (buckets);
- footwear;
- transport carriers, trolleys and transport carts;
- bed frames, wheelchairs, aids for the disabled.

Fields of application within the scope of the ISO 15883 series can 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 stage. Manufacturers of washer-disinfectors should be very clear about the devices or equipment that can be processed in the washer-disinfector, and that reference be made to the instructions for reprocessing provided in the instructions for use of the devices or equipment to be processed.

Safety requirements for washer-disinfectors are given in IEC 61010-2-040.

Guidance for the quality of water for use in a WD is given in ISO/TS 5111.

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.

Washer-disinfectors —

Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-critical medical devices and health care equipment

1 Scope

This document specifies particular requirements for washer-disinfectors (WD) 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 specifies general requirements for WD.

The range of products on which WD of this particular type can be used is restricted to non-invasive and non-critical devices and equipment (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.

This document does not cover powered devices, lumened devices, and other semi-critical and critical medical devices.

Devices identified within the scopes of ISO 15883-2, ISO 15883-3, ISO 15883-4, and ISO 15883-7 do not fall within the scope of this document.

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 15883-1:2024, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

ISO 15883-5, *Washer-disinfectors — Part 5: Performance requirements and test method criteria 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.

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/>