International Standard

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# Washer-disinfectors —

## Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-critical thermolabile medical devices and health care equipment

*Laveurs désinfecteurs —*

*Partie 7: Exigences et essais pour les laveurs désinfecteurs destinés à la désinfection chimique des dispositifs médicaux thermosensibles non critiques et des équipements de soins de santé*

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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 document 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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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 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 15883-7:2016), which has been technically revised.

The main changes are as follows:

— deletion of 'non-invasive' from the document title and within clauses;

— incorporation of requirements of and reference to ISO 15883-1:2024 and ISO 15883-5:2021;

— revision of cross-references to relevant clauses in ISO 15883-1:2024 and ISO 15883-5:2021;

— alignment with terms and definitions in ISO 11139:2018 and ISO 11139:2018/Amd1:2024;

— update of Introduction and addition of reference to ISO/TS 5111 on water quality;

— clarification on requirement for reused process chemicals (see 4.2.4 and 6.6.2);

— Annex A changed from normative to informative;

— updated Annex C method description to align with ISO 15883-1:2024 and ISO 15883-4:2018;

— revision of normative references and bibliographic references.

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 seventh part of the ISO 15883 series of standards specifying the performance of washer-disinfectors (WD) and the general requirements for performance applicable to instrument WD. The requirements given in this document apply to WD used for cleaning and chemical disinfection of non-critical thermolabile medical devices and health care equipment without further treatment in health care settings. Such reusable equipment is cleaned and disinfected, but processing in a WD for surgical instruments (see ISO 15883-2), for human waste containers (see ISO 15883-3), for endoscopes (see ISO 15883-4), or for thermal disinfection of non-critical medical devices and health care equipment (see ISO 15883-6), is inappropriate and/or impractical. Examples of the equipment to which this document applies are beds and bedside furniture, trolleys and transport carts, operating tables, footwear, wheelchairs, or aids for people with disabilities.

Requirements for WD for other applications are specified in other parts of ISO 15883.

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

The quality of water to be used in a WD is covered 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.

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# Washer-disinfectors —

# Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-critical thermolabile medical devices and health care equipment

## 1 Scope

This document specifies the requirements for washer-disinfectors (WD) intended to be used for the cleaning and chemical disinfection, in a single operating cycle, of reusable items such as:

a) bed frames;

b) bedside tables;

c) transport carts;

d) containers;

e) surgical tables;

f) sterilization containers;

g) surgical clogs;

h) wheelchairs;

i) aids for persons with disabilities.

This document also specifies the performance requirements for the cleaning and disinfection of the WD and its components and accessories.

Devices identified within the scopes of ISO 15883-2, ISO 15883-3, ISO 15883-4, and ISO 15883-6 do not fall within the scope of this document.

In addition, this document specifies the methods for type testing, works testing, validation (installation, operation, and performance qualification on first installation), routine control, and monitoring, as well as requalifications to be carried out periodically and after essential repairs.

NOTE 1 WD covered by this document can also be used for cleaning and chemical disinfection of other thermolabile and reusable devices as recommended in the instructions for use (IFU) for those devices.

NOTE 2 The performance requirements specified in this document cannot ensure the inactivation or removal of the causative agent(s) (prion proteins) of transmissible spongiform encephalopathies.

## 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 11139:2018, *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*

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ISO 11139:2018/Amd1:2024, *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards — Amendment 1: Amended and additional terms and definitions*

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

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[1)], *Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and health care equipment*

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*

EN 10088-1, *Stainless steels — Part 1: List of stainless steels*

EN 10088-2, *Stainless steels — Part 2: Technical delivery conditions for sheet/plate and strip of corrosion resisting steels for general purposes*

EN 12353:2021, *Chemical disinfectants and antiseptics — Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

EN 13727:2012+A2:2015, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity in the medical area — Test method and requirements (phase 2, step 1)*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11139:2018, ISO 11139:2018/Amd1:2024, ISO 15883-1, ISO 15883-4, ISO 15883-5, ISO 15883-6 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/

**3.1**
**non-critical device**
<washer-disinfector> item processed in a washer-disinfector, whose surface(s) are intended to contact intact skin of a body but do not penetrate it, or device not intended for direct patient contact

EXAMPLE Blood pressure cuffs, wheelchairs, trays, bowls, dishes, glassware, receivers, containers for transit.

Note 1 to entry: National regulations can use alternative wording for the definition of this term when applied to medical devices.

[SOURCE: ISO 11139:2018/Amd1:2024, 3.357]

1) Under revision with a modified title, *Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-critical medical devices and health care equipment*. Stage at the time of publication: ISO/DIS 15883-6:2024.

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