SLOVENSKI STANDARD
oSIST prEN ISO 15883-7:2024

01-april-2024

Nadomešča:
SIST EN ISO 15883-7:2016

Čistilno-dezinfekcijske naprave - 7. del: Zahteve in preskusne metode za čistilno-dezinfekcijske naprave s kemično dezinfekcijo za nekritične termolabilne medicinske pripomočke in zdravstveno opremo (ISO/DIS 15883-7:2024)

Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-critical thermolabile medical devices and health care equipment (ISO/DIS 15883-7:2024)

Reinigungs-Desinfektionsgeräte - Teil 7: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit chemischer Desinfektion für nicht kritische thermolabile Medizinprodukte und Zubehör im Gesundheitswesen (ISO/DIS 15883-7:2024)

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 (ISO/DIS 15883-7:2024)

Ta slovenski standard je istoveten z: **prEN ISO 15883-7**

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment

oSIST prEN ISO 15883-7:2024 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 15883-7

ISO/TC **198**

Secretariat: **ANSI**

Voting begins on:
2024-02-02

Voting terminates on:
2024-04-26

Washer-disinfectors —

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

ICS: 11.080.10

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 15883-7:2024(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword ..... **v**
Introduction ..... **vii**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **2**
4 Performance requirements **2**
4.1 General 2
4.2 Cleaning 3
4.3 Disinfection 4
4.4 Final rinsing 5
4.5 Self-disinfection 5
4.6 Drying 6
4.7 Water treatment equipment 7
4.7.1 General 7
4.7.2 Disinfection of water treatment equipment 7
4.7.3 Maintenance of piping 8
5 Mechanical requirements **8**
5.1 Materials — Design, manufacture, and assembly 8
5.2 Process verification 8
6 Testing for conformity **8**
6.1 General 8
6.2 Test load 8
6.2.1 Loading with standard goods 8
6.2.2 Loading with special goods 8
6.3 Final rinse water 9
6.4 Load dryness 9
6.4.1 General 9
6.4.2 Procedure 9
6.4.3 Results 9
6.5 Thermometric tests 9
6.5.1 General 9
6.5.2 Load temperature test 9
6.6 Chemical dosing tests 9
6.6.1 General 9
6.6.2 Reused process chemicals 10
6.7 Tests of cleaning efficacy 10
6.7.1 General 10
6.7.2 Materials 10
6.7.3 Procedure 11
6.7.4 Results 11
6.8 Test of disinfection efficacy 11
6.8.1 General 11
6.8.2 Preliminary tests on chemical disinfectants 11
6.8.3 Self-disinfection tests 12
6.8.4 Chemical disinfection of the load 13
7 Documentation **13**
8 Information to be supplied **14**
9 Marking, labelling, and packaging **14**
10 Information to be requested from the purchaser by the WD supplier **14**
Annex A (informative) **Summary of test programmes** **15**

Annex B (normative) **Methods for microbiological evaluation of disinfection of liquid transport system** **17**

Annex C (normative) **Tests for microbiological contamination of final rinse water** **22**

Annex D (normative) **Preparation and evaluation of indicators for microbiological testing of the efficacy of chemical disinfection of the load** **23**

Annex E (informative) **Examples of test locations for the tests with biological indicators** **27**

Annex ZA (informative) **Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered** **31**

Bibliography **35**

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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 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:—[1)] and ISO 15883-5:2021;

— revision of cross-references to relevant clauses in ISO 15883-1:—[2)] and ISO 15883-5:2021;

— alignment with terms and definitions in ISO 11139:2018/A1:—[3)];

— 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;

1) Under preparation. Stage at the time of publication: ISO/FDIS 15883-1:2023.

2) Under preparation. Stage at the time of publication: ISO/FDIS 15883-1:2023.

3) Under preparation. Stage at the time of publication: ISO 11139:2018/FDAmd1:2023.

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

— updated Normative References and 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.

4) Under preparation. Stage at the time of publication: ISO/FDIS 15883-1:2023

Introduction

This document is the seventh part of the ISO 15883 series specifying the performance of washer-disinfectors (WD). It specifies the particular requirements for performance applicable to WD employing chemical disinfection for non-critical thermolabile medical devices, and health care equipment. Its requirements apply to WD used for cleaning and disinfection of thermolabile equipment for use without further treatment in health care settings. Such reusable equipment needs to be cleaned and disinfected, but processing in a washer-disinfector 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 medical devices, and health care equipment employing thermal disinfection (see ISO 15883-6) is inappropriate and/or impractical. Examples of such equipment 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.

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 the following:

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 which are necessary in order to achieve the required performance.

Devices identified within the scopes of ISO 15883-2, ISO 15883-3, ISO I5883-4, and ISO 15883-6 do not fall within the scope of this document.

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

NOTE 1 WD corresponding to this document can also be used for cleaning and chemical disinfection of other thermolabile and reusable devices as recommended in the IFU for those devices.

NOTE 2 The specified performance requirements of 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+A1[5], *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*

ISO 15883-1:—[6], *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

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

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 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/A1:—, 3.357]

4 Performance requirements

4.1 General

4.1.1 The requirements of ISO 15883-1 apply with the exception of:

— ISO 15883-1:—[7], 4.3.1 (which refers to thermal disinfection);

5) Under preparation. Stage at the time of publication: ISO 11139:2018/FDAmd1:2023.

6) Under preparation. Stage at the time of publication: ISO/FDIS 15883-1:2023.

7) Under preparation. Stage at the time of publication: ISO/FDIS 15883-1:2023.