



SLOVENSKI STANDARD
oSIST prEN ISO 15883-3:2023
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Čistilno-dezinfekcijske naprave - 3. del: Zahteve in preskusi za čistilno-dezinfekcijske naprave s toplotno dezinfekcijo za zbiralnike človeških izločkov (ISO/DIS 15883-3:2023)

Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO/DIS 15883-3:2023)

Reinigungs-Desinfektionsgeräte - Teil 3: Anforderungen an und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit thermischer Desinfektion für Behälter für menschliche Ausscheidungen (ISO/DIS 15883-3:2023)

Laveurs désinfecteurs - Partie 3: Exigences et essais pour laveurs désinfecteurs destinés à la désinfection thermique de récipients à déjections humaines (ISO/DIS 15883-3:2023)

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Washer-disinfectors —

Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers

*Laveurs désinfecteurs —**Partie 3: Exigences et essais pour laveurs désinfecteurs destinés à la désinfection thermique de récipients à déjections humaines*

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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*.

This second edition cancels and replaces the first edition (ISO 15883-3:2006), which has been technically and editorially revised.

The main changes compared to the previous edition are as follows:

- revision of clauses cross-referencing clauses in ISO/DIS 15883-1:2020 and ISO 15883-5:2021;
- alignment of terms and definitions with ISO 11139:2018;
- addition of [clause 4.1.2](#) listing exemptions from the requirements of ISO/DIS 15883-1:2020;
- alignment of text in clauses on cleaning and disinfecting with revised clauses of ISO 15883-2;
- addition of rinsing from former [4.6](#) to [4.4](#) *Cleaning* and [4.5](#) *Disinfection*
- addition of [4.7](#) *Cooling*;
- deletion of references in *Bibliography* already referenced in ISO/DIS 15883-1:2020 or ISO 15883-5:2021.

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

It is recommended that this Introduction be read in conjunction with the introduction to ISO/DIS 15883-1:2020.

This part of ISO 15883 is the third of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to washer-disinfectors for human waste containers. The requirements given in this document apply to washer-disinfectors used for emptying, flushing, washing, and thermally disinfecting human waste containers intended for reuse such as:

- portable sanitary pans;
- supports for single-use bedpans;
- hospital bowls for containment of human waste;
- urine collection containers;
- suction bottles;
- products similar to the above and used for similar purposes.

Fields of application within the scope of the ISO 15883 series of standards can include laboratory, veterinary, dental and pharmaceutical applications, and other specific applications, such as washer-disinfectors for bedsteads and transport carts and 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 the ISO 15883 series of standards.

In order to reduce the risk of spillage and the generation of aerosols most machines incorporate means to empty human waste containers automatically, e.g. by the action of closing the WD door.

Where equipment does not provide automatic emptying facilities, extra care is needed by the user to avoid exposure to human waste and contamination of the work environment including the generation of aerosols.

The reliability of a human waste container washer-disinfector can be adversely affected if the machine is connected to a poorly designed or constructed drainage system. The purchaser is therefore recommended to ensure that the drainage system complies with the manufacturer's recommendations in all respects.

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

In respect of the potential adverse effects on the quality of water intended for human consumption or environmental impacts caused by the washer-disinfector and its intended use, it is noteworthy that the ISO 15883 series of standards provides no information as to whether the washer-disinfectors may be used without restrictions in any of the ISO member states.

Washer-disinfectors —

Part 3:

Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers

1 Scope

This document specifies requirements for washer-disinfectors (WD) that are intended to be used for emptying, flushing, washing and thermal disinfection of containers used to hold human waste for disposal by one operating cycle.

The requirements of this document apply in addition to the general requirements specified in ISO/DIS 15883-1:2020 and ISO 15883-5:2021.

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*

ISO/DIS 15883-1:2020, *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*

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

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/>

3.1

A_0

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

Note 1 to entry: See also ISO/DIS 15883-1:2020, Annex B.

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

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3.2 cleaning

removal of contaminants to the extent necessary for further processing or for intended use

[SOURCE: ISO 11139:2018, 3.46]

3.3 flushing purging

removing by displacement with a fluid

[SOURCE: ISO 11139:2018, 3.121]

3.4 human waste

body fluids and excretions

EXAMPLE Faeces, urine, blood, pus, vomit, mucus.

[SOURCE: ISO 11139:2018, 3.134]

3.5 human waste container

vessel for holding and transporting human waste

[SOURCE: ISO 11139:2018, 3.135]

3.6 washing

removal of contaminants from surfaces by means of an aqueous fluid

[SOURCE: ISO 11139:2018, 3.321]

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4 Performance requirements

4.1 General

4.1.1 The requirements of ISO/DIS 15883-1:2020 apply with the exception of

- 4.1.13 (which refers to pressure inside the pipework during the washing stage);
- [4.3.2](#) (which refers to chemical disinfection, see Scope of this document);
- 5.7.4 (which refers to verification of the dose of process chemical admitted);
- 5.7.5 (which specifies the accuracy and reproducibility of chemical dosing systems);
- 5.8 (which refers to load temperature protection);
- 5.9 (which refers to control of temperatures on the load and chamber walls, see [4.5.3](#) and [4.5.4](#) of this document);
- 5.21 b) (which refers to microprocessor control systems);
- 6.8.5 (which refers to tests for load temperature protection);
- 6.10.3 (which refers to protein residue tests, see also ISO/DIS 15883-1:2020, Table A.1 (load, 6.10.3), ISO 15883-5:2021, Annex A (RAMS), and [Annex A](#) of this document).

4.1.2 The requirements of ISO 15883-5:2021 apply with the exception of

- [4.1.4](#) (requirement that verification and documentation of the full cleaning stage does not interfere with analyte detection, is not applicable);
- [4.4.3](#) (which refers to assay criteria);
- [5.1.1](#) (which refers to validation of test methods);
- 5.1.3 (which refers to validation of detection methods);
- 5.1.4 (which refers to analyte assay methods);
- 5.3.4 (requirements that action levels specified in [4.4.3](#) for the load, and conformance of cleaning efficacy for the test load with the alert levels in [4.4.3](#), are not applicable);
- 5.4.4 (requirements that action levels specified in [4.4.3](#) for the load, and conformance of cleaning efficacy for the test load with the alert levels in [4.4.3](#), are not applicable).

4.1.3 The WD shall be designed to process one or more human waste containers in an operating cycle.

NOTE This can require the use of a variety of types of load carrier(s).

4.1.4 The temperature attained on the surfaces of the load during the disinfection stage shall not be less than the disinfection temperature.

4.2 Chemical dosing systems

4.2.1 Provision shall be made for the installation of a chemical dosing system, when specified by the purchaser, to allow for the injection of a descalant, detergent and/or rinse aid.

4.2.2 The means to control the volume of process chemical(s) admitted shall be adjustable and shall deliver the set volume to an accuracy of $\pm 10\%$ or better.

4.2.3 The WD shall either be fitted with means to ensure that a fault is indicated when insufficient process chemical(s) has/have been admitted, or it shall be possible for the operator to visually verify that the required amount of process chemical(s) has/have been used.

4.3 Emptying

4.3.1 The manufacturer shall require the purchaser to specify whether the human waste containers are required to be emptied manually or automatically.

Manual emptying of human waste containers should be avoided whenever possible.

4.3.2 When the human waste container(s) are to be emptied automatically the emptying system shall ensure that there is no spillage of the human waste container contents or discharge of aerosols of the contents of human waste containers during automatic emptying.

Check for conformance in accordance with [6.5.1](#).

4.3.3 When the human waste container(s) are to be emptied manually into the WD the door aperture and load support system shall be designed to enable the human waste container to be emptied and then located in the load carrier without spillage or splashing.

Check for conformance in accordance with [6.5.2](#).