SLOVENSKI STANDARD
oSIST prEN ISO 15883-2:2023

01-julij-2023

Čistilno-dezinfekcijske naprave - 2. del: Zahteve in preskusi za čistilno-dezinfekcijske naprave s toplotno dezinfekcijo za kritične in polkritične medicinske pripomočke (ISO/DIS 15883-2:2023)

Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices (ISO/DIS 15883-2:2023)

Reinigungs-Desinfektionsgeräte - Teil 2: Anforderungen und Prüfverfahren von Reinigungs-Desinfektionsgeräten mit thermischer Desinfektion für kritische und semikritische Medizinprodukte (ISO/DIS 15883-2:2023)

Laveurs désinfecteurs - Partie 2: Exigences et essais pour laveurs désinfecteurs destinés à la désinfection thermique des dispositifs médicaux critiques et semi-critiques (ISO/DIS 15883-2:2023)

Ta slovenski standard je istoveten z: **prEN ISO 15883-2**

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment

oSIST prEN ISO 15883-2:2023 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 15883-2

ISO/TC **198**

Secretariat: **ANSI**

Voting begins on:
2023-04-24

Voting terminates on:
2023-07-17

Washer-disinfectors —

Part 2:
Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices

ICS: 11.080.10

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 15883-2:2023(E)

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Published in Switzerland

Contents

Page

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 15883-2:2006), which has been technically revised.

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

— change to title to reflect application to critical and semi-critical medical devices;

— addition of new terms defining critical and semi-critical medical devices, and non-critical devices;

— alignment of other terms and definitions with ISO 11139:2018;

— revision of cross-references to relevant clauses in ISO/DIS 15883-1:2020 and ISO 15883-5:2021;

— the upper limit of the washing temperature band reduced to +5 °C;

— addition of a clause on water quality (see 4.5);

— clarification of requirements for lumen and powered devices (see 5.1);

— addition of informative Annex B providing guidance on assigning a medical device to a product family for cleaning and thermal disinfection processes;

— revision of references in 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

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 second of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to instrument washer-disinfectors. The requirements given in this document apply to washer-disinfectors (WD) used for cleaning and thermal disinfection of critical and semi-critical medical devices intended for reuse such as:

— surgical instruments, which are divided into instrument product families based on design features, e.g. instruments without hinges, cavities or lumens, with hinges, with sliding shafts, with lumens, microsurgical instruments, and complex instruments (e.g. robotic);

— powered instruments;

— anaesthetic and respiratory equipment;

— medical devices comprised of glass components;

— any non-critical devices used in conjunction with critical and semi-critical medical devices.

Requirements for washer-disinfectors for other applications, such as for processing non-critical devices and thermolabile endoscopes, are specified in other parts of the ISO 15883 series of standards.

When processed in the washer-disinfector, the medical devices can be intended for immediate use or can be intended for further processing. In both cases, the efficacy of the cleaning and disinfection is of major importance. In either case, this is for the well-being of the patient. In the latter case, it is also for the safety of the staff who handles the instruments in the process of inspection, testing and packing as well as ensuring that the sterilization process is not unduly challenged by residual soil.

The efficacy of disinfection can be impaired if soil removal is incomplete before the start of the disinfection process. Users should be aware that some medical devices can require pre-treatment, e.g. soaking, brushing, ultrasonic pre-cleaning, lumen irrigation or any combination of these techniques. Reference should be made to the medical device instructions for reprocessing (see also ISO 17664 series).

Safety requirements for washer-disinfectors are given in IEC 61010-2-040[4].

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 provides no information as to whether the washer-disinfectors may be used without restrictions in any of the ISO member states.

Washer-disinfectors —

Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices

1 Scope

This document specifies requirements for washer-disinfectors (WD) that are intended for use for the cleaning and thermal disinfection, in a single operating cycle, of reusable medical devices such as surgical instruments, anaesthetic equipment, bowls, dishes and receivers, utensils and glassware.

The requirements specified in this document are applicable in conjunction with the general requirements specified in ISO/DIS 15883-1:2020.

The specified performance requirements of this document might not ensure the inactivation or removal of the causative agent(s) (prion protein) 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 4017, *Hexagon head screws — Product grades A and B*

ISO 5356-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5361, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

ISO 5362, *Anaesthetic reservoir bags*

ISO 5367, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO/DIS 15883-1:2020, *Washer-disinfectors — Part 1: General requirements, definitions and tests*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/DIS 15883-1:2020 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]

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
critical medical device
<washer-disinfector> item, processed in a washer-disinfector, intended to be introduced directly into, or have contact with, the vascular system or normally sterile areas of the body

EXAMPLE Surgical instruments.

Note 1 to entry: Critical items will usually require sterilization before use.

Note 2 to entry: There can be national regulations with alternative wording of the definition for this term.

[SOURCE: ISO 11139:2018/DAmd 1:2023, 3.333]

3.4
lumen device
item that consists of tube(s) or pipe(s)

[SOURCE: ISO 11139:2018, 3.158]

3.5
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 Human waste containers, blood pressure cuffs, wheelchairs, trays, bowls, dishes, glassware, receivers, and containers for transit.

Note 1 to entry: There can be national regulations with alternative wording of the definition for this term when applied to medical devices.

[SOURCE: ISO 11139:2018/DAmd 1:2023, 3.357]

3.6
powered device
<washer-disinfector> surgical instrument which gives a rotating and/or oscillating movement to other surgical instruments

EXAMPLE Dental hand pieces, orthopaedic saws, and drills.

Note 1 to entry: The power applied to the driven instrument can be mechanical (from a motor, either through direct coupling, flexible axle, or belt) or by the flow of a pressurized fluid or compressed air.

[SOURCE: ISO 11139:2018, 3.199]

3.7
product family
group or subgroup of product characterized by similar attributes determined to be equivalent for evaluation and processing purposes

Note 1 to entry: Design characteristics present specific challenges during the washing stage of medical devices in a washer-disinfector.

[SOURCE: ISO 11139:2018, 3.218, modified – Note 1 to entry added]

3.8
rinsing
removing process residues through displacement by, and dilution with, water

[SOURCE: ISO 11139:2018, 3.237]

3.9
semi-critical medical device
<washer-disinfector> item, processed in a washer-disinfector, that, during use, contacts mucous membranes or non-intact skin of a body

EXAMPLE Some probes, some respiratory therapy equipment.

Note 1 to entry: There can be national regulations with alternative wording of the definition for this term.

[SOURCE: ISO 11139:2018/DAmd 1:2023, 3.369]

3.10
temperature band
range of temperatures expressed as the minimum and the maximum temperatures which prevail during the specified period of a cycle

[SOURCE: ISO 11139:2018, 3.293]

3.11
washing
removal of contaminants from surfaces by means of an aqueous fluid

[SOURCE: ISO 11139:2018, 3.321]

3.12
washing temperature
minimum temperature of the washing temperature band

[SOURCE: ISO 11139:2018, 3.322]

3.13
washing time
period for which the cycle variables are maintained within the values specified for washing

EXAMPLE Temperature of the load, detergent concentration in the chamber.

[SOURCE: ISO 11139:2018, 3.323]

4 Performance requirements

4.1 General

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

— 4.3.2 (which refers to chemical disinfection, see *Scope* of this document);