STN	**Prístroje na umývanie a dezinfekciu Časť 2: Požiadavky a skúšky dezinfekčných umývačiek s tepelnou dezinfekciou kritických a semikritických zdravotníckych pomôcok (ISO 15883-2: 2024)**	**STN EN ISO 15883-2** 84 7130

Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices (ISO 15883-2:2024)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 05/25

Obsahuje: EN ISO 15883-2:2025, ISO 15883-2:2024

Oznámením tejto normy sa ruší
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English Version

Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices (ISO 15883-2:2024)

Laveurs désinfecteurs - Partie 2: Exigences et essais pour laveurs désinfecteurs destinés à la désinfection thermique des dispositifs médicaux critiques et semi-critiques (ISO 15883-2:2024)

Reinigungs-Desinfektionsgeräte - Teil 2: Anforderungen und Prüfverfahren von Reinigungs-Desinfektionsgeräten mit thermischer Desinfektion für kritische und semikritische Medizinprodukte (ISO 15883-2:2024)

This European Standard was approved by CEN on 11 November 2024.

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 15883-2:2025 E

EN ISO 15883-2:2025 (E)

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Annex ZA (informative) **Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered** **4**

European foreword

This document (EN ISO 15883-2:2025) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2025, and conflicting national standards shall be withdrawn at the latest by September 2025.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 15883-2:2009.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 15883-2:2024 has been approved by CEN as EN ISO 15883-2:2025 without any modification.

Annex ZA
(informative)

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

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
5	4.1.4, 4.1.5	Clauses 4.1.4 and 4.1.5 only partly covered in respect of reducing the risks related to use error by reducing the risks related to the ergonomic features of the washer-disinfectors (WDs). Aspects related to the environment in which the WD is intended to be used are not covered. Aspects related to manufacturing are not covered. Aspects related to the ***letter b)*** are not covered as well.
10.2	4.1.4, 4.1.5, 5.1.2, 5.2, 5.3	All clauses only partly covered in respect with the minimizing the risk posed by contaminants and residues to patients and the persons involved in use of the WD. Aspects related to the manufacture and packaging are not covered. Aspects related to the *transport and storage* are not covered as well.
10.3	4.5	Clause 4.5 only partly covers the requirement. Covered in respect with the safety use of WD with the water with which it enters into contact during intended use. WD devices are not intended to administer medicinal products, that's why the second part of this requirement is not covered. Aspects related to the

		manufacture are not covered.
14.1	4.1.4	Clause 4.1.4 only partly covers the requirement. Covered in respect to the first sentence only (combination and connection to the WD)
14.2 (a)	4.1.5, 4.1.7, 5.1.2, 4.1.6, 5.2 and 5.3	All selected clauses only partly cover the requirement. Covered in respect of reducing the risks of injury, in connection with WD physical and ergonomic features. Aspects related to the WD manufacturing processes are not covered.
23.4 (k)	7 a) – 7 e)	The selected clauses 7 a) – 7 e) only partly cover the requirement. Cover in respect of information to be supplied and needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer. Aspects related to the *methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices*, are not covered.

Table ZA.2 — Normative references from Clause 2 of this document and their corresponding European publications

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 4017	ISO 4017:2022	Fasteners — Hexagon head screws — Product grades A and B	EN ISO 4017:2022
ISO 5356-2	ISO 5356-2:2012 ISO 5356-2:2021/Amd 1:2019	Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors	EN ISO 5356-2:2012 EN ISO 5356-2:2012/A1:2019
ISO 5361	ISO 5361:2023	Anaesthetic and respiratory equipment — Tracheal tubes and connectors	EN ISO 5361:2023
ISO 5362	ISO 5362:2024	Anaesthetic reservoir bags	EN ISO 5362:2024
ISO 5367	ISO 5367:2023	Anaesthetic and respiratory equipment - Breathing sets and connectors	EN ISO 5367:2023
ISO 15883-1	ISO 15883-1:2024	Washer-disinfectors — Part 1: General requirements, definitions and tests	EN ISO 15883-1:2025
ISO 17664-1:2021	ISO 17664-1:2021	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	EN ISO 17664-1:2021
ISO 15883-5:2021	ISO 15883-5:2021	Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy	EN ISO 15883-5:2021
EN 10088-2	none	Stainless steels - Part 2: Technical delivery conditions for sheet/plate and strip of corrosion resisting steels for general purposes	EN 10088-2:2024

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

International Standard

ISO 15883-2

Washer-disinfectors —

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

Laveurs désinfecteurs —

Partie 2: Exigences et essais pour laveurs désinfecteurs destinés à la désinfection thermique des dispositifs médicaux critiques et semi-critiques

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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).

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

The main changes are as follows:

— change of 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+Amd 1:2024;

— revision of cross-references to relevant clauses in ISO 15883-1:2024 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 the 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 second 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 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 comprising glass components;

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

Requirements for WD 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 WD, 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 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 the ISO 17664 series).

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

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.

International Standard **ISO 15883-2:2024(en)**

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 critical and semi-critical medical devices, such as surgical instruments, anaesthetic equipment, and any non-critical devices used in conjunction with critical and semi-critical medical devices, such as bowls, dishes and receivers, utensils and glassware.

This document is intended to be used in conjunction with the general requirements specified in ISO 15883-1:2024, except those specified in 4.1.1.

NOTE The specified performance requirements of this document cannot 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, *Fasteners — 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 and respiratory equipment — Anaesthetic reservoir bags*

ISO 5367, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 15883-1:2024, *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 17664-1:2021, *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*

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