

STN	Prístroje na umývanie a dezinfekciu Časť 3: Požiadavky a skúšky dezinfekčných umývačiek s tepelnou dezinfekciou nádob na ľudské výlučky (ISO 15883-3: 2024)	STN EN ISO 15883-3 84 7130
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Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2024)

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

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NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 15883-3

March 2025

ICS 11.080.10

Supersedes EN ISO 15883-3:2009

English Version

**Washer-disinfectors - Part 3: Requirements and tests for
washer-disinfectors employing thermal disinfection for
human waste containers (ISO 15883-3:2024)**

Laveurs désinfecteurs - Partie 3: Exigences et essais
pour laveurs désinfecteurs destinés à la désinfection
thermique de récipients à déjections humaines (ISO
15883-3:2024)

Reinigungs-Desinfektionsgeräte - Teil 3:
Anforderungen an und Prüfverfahren für Reinigungs-
Desinfektionsgeräte mit thermischer Desinfektion für
Behälter für menschliche Ausscheidungen (ISO 15883-
3:2024)

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

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European foreword

This document (EN ISO 15883-3:2025) 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 15883-3:2009.

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 15883-3:2024 has been approved by CEN as EN ISO 15883-3:2025 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 [O] 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(a)	4.3.2	The selected clause 4.3.2 partly covers the requirement. Covered by reduction of risks related to use errors in connection to ergonomic features of the washer-disinfectors (WDs). Aspects related to the environment in which the WD is intended to be used are not covered.
5(b)	7 a), 7 b), 7 d)	The selected clauses 7 a), 7 b), 7 d) partly cover the requirement. Covered in respect of reducing the risks related to use error by considering the training of the user and technical knowledge. Aspects related to the experience, education and use environment, where applicable, and the medical and physical conditions of intended users are not covered.
10.2	4.3.2, 4.3.3, 5.3.2, 5.3.3	The selected clauses 4.3.2, 4.3.3, 5.3.2, 5.3.3 partly cover the requirement. 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 manufacturing and packaging are not covered.
10,4,1, first paragraph	4.3.2, 4.3.3, 5.3.2, 5.3.3	The selected clauses 4.3.2, 4.3.3, 5.3.2, 5.3.3 partly cover the requirement. Covered in respect with the risks posed by substances and processing residues, that may be released

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		<p>from the WD.</p> <p>Aspects related to the particles, including wear debris, and degradation products are not covered.</p>
11.1 (c)	4.3.2, 4.3.3, 5.3.2, 5.3.3	<p>The selected clauses 4.3.2, 4.3.3, 5.3.2, 5.3.3 partly cover the requirement. Covered in respect of reducing the risks of any microbial leakage from the device and/or microbial exposure during use.</p> <p>Aspects related to the WD manufacturing processes are not covered.</p>
11.1 (d)	4.6, 4.7	<p>The selected clauses 4.6, 4.7 partly cover the requirement. Covered with respect of design of WD to prevent microbial contamination of the device or its content.</p> <p>Aspects related to the WD manufacturing processes are not covered.</p>
11.2	5.2.1	<p>The selected clause 5.2.1 partly covers the requirement. Covered with respect of design of WD to facilitate its safe cleaning and disinfection.</p> <p>Aspects related to the WD re-sterilization are not covered.</p>
14.2 (a)	4.3.2, 4.3.3, 4.7	<p>The selected clauses 4.3.2, 4.3.3 and 4.7 partly cover the requirement in respect of reducing the risks of injury, in connection with WD physical features, dimensional and ergonomic features.</p> <p>Aspects related to the WD manufacturing are not covered.</p> <p>The risks of injury (<i>through spilling and discharge of aerosols, hot load</i>) are reduced through design (automatic and manual emptying, cooling).</p>

14.2 (e)	5.3.2, 5.3.3	<p>The selected clauses 5.3.2, 5.3.3 partly cover the requirement in respect of reducing the risks connected with accidental ingress of substances into the WD.</p> <p>Aspects related to the WD manufacturing are not covered.</p>
14.6	5.1.1	<p>The selected clause 5.1.1 partly covers the requirement. Covered with respect to ergonomics of the measurement, monitoring and display scales.</p> <p>Aspects related to the WD manufacturing are not covered.</p>
23.4 (k)	7 a) – e)	<p>The selected clause 7, first sentence and 7a) – 7e) cover the requirement.</p>

EN ISO 15883-3:2025 (E)**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 15883-1	ISO 15883-1:2024	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests	EN ISO 15883-1:2025
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
ISO 17664-2:2021	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	For applicable standard edition see Column 2

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 15883-3

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 pour déjections humaines*

**Second edition
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ISO 15883-3:2024(en)



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ISO 15883-3:2024(en)**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 15883-3:2006), which has been technically revised.

The main changes are as follows:

- revision of cross-references to clauses in ISO 15883-1:2024 and ISO 15883-5:2021;
- alignment of terms and definitions with ISO 11139:2018+Amd 1:2024;
- addition of [4.1.2](#) listing exemptions from the requirements of ISO 15883-5:2024;
- 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](#) and [4.5](#);
- addition of [4.7](#);
- 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.

ISO 15883-3:2024(en)

Introduction

This document is the third part in the ISO 15883 series of standards specifying the performance of washer-disinfectors (WD) and the general requirements for performance applicable to WD for human waste containers. The requirements given in this document apply to WD 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 WD for bedsteads and transport carts and the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

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

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 non-critical devices in the form of human waste containers by one operating cycle.

This document is intended to be used in conjunction with the general requirements specified in ISO 15883-1:2024, except for those specified in [4.1.1](#), and with the requirements of ISO 15883-5:2021, except for those specified in [4.1.2](#).

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 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 17664-2:2021, *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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN