SLOVENSKI STANDARD
SIST EN ISO 15883-3:2025

01-maj-2025

Nadomešča:
SIST EN ISO 15883-3:2009

Čistilno-dezinfekcijske naprave - 3. del: Zahteve in preskusi za čistilno-dezinfekcijske naprave s toplotno dezinfekcijo za zbiralnike človeških izločkov (ISO 15883-3:2024)

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

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

Ta slovenski standard je istoveten z: **EN ISO 15883-3:2025**

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment

SIST EN ISO 15883-3:2025 **en,fr,de**

EUROPEAN STANDARD

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)

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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.

CEN members are the national standards bodies of 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 United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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 [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(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

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

14.2 (e)	5.3.2, 5.3.3	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. Aspects related to the WD manufacturing are not covered.
14.6	5.1.1	The selected clause 5.1.1 partly covers the requirement. Covered with respect to ergonomics of the measurement, monitoring and display scales. Aspects related to the WD manufacturing are not covered.
23.4 (k)	7 a) – e)	The selected clause 7, first sentence and 7a) – 7e) cover the requirement.

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.