SLOVENSKI STANDARD
SIST EN ISO 15883-1:2025

01-maj-2025

Nadomešča:
SIST EN ISO 15883-1:2009
SIST EN ISO 15883-1:2009/A1:2014

Čistilno-dezinfekcijske naprave - 1. del: Osnovne zahteve, termini, definicije in preskusi (ISO 15883-1:2024)

Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2024)

Reinigungs-Desinfektionsgeräte - Teil 1: Allgemeine Anforderungen, Begriffe und Prüfverfahren (ISO 15883-1:2024)

Laveurs désinfecteurs - Partie 1: Exigences générales, termes et définitions et essais (ISO 15883-1:2024)

Ta slovenski standard je istoveten z: **EN ISO 15883-1:2025**

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment

SIST EN ISO 15883-1:2025 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15883-1

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Supersedes EN ISO 15883-1:2009, EN ISO 15883-1:2009/A1:2014

English Version

Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2024)

Laveurs désinfecteurs - Partie 1: Exigences générales, termes et définitions et essais (ISO 15883-1:2024)

Reinigungs-Desinfektionsgeräte - Teil 1: Allgemeine Anforderungen, Begriffe und Prüfverfahren (ISO 15883-1:2024)

This European Standard was approved by CEN on 12 July 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

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European foreword

This document (EN ISO 15883-1:2025) 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 15883-1:2009, EN ISO 15883-1:2009/A1:2014.

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 15883-1:2024 has been approved by CEN as EN ISO 15883-1:2025 without any modification.

Annex ZA
(informative)

Relationship between this European Standard 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)	5.1.2.5, 5.4.2, 5.4.3, 5.19, 5.22, 5.27.1, 5.28	The selected clauses 5.1.2.5, 5.4.2, 5.4.3, 5.19, 5.22, 5.27.1 and 5.28 partly cover the requirement. Covered in respect of reducing the risks related to use error by reducing the risks related to the ergonomic features of the washer-disinfectors (WD). Aspects related to the environment in which the WD is intended to be used are not covered. Aspects related to manufacturing are also not covered.
5 (b)	5.20, 8.3	The selected clauses 5.20 and 8.3 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.
7	9.2	The selected clause 9.2 partly covers the requirement. Covered with respect to packaging to protect the device during transport and storage. Aspects related to the design and manufacture are not covered.
10.2	5.1.2.6, 5.1.2.7, 5.4.1.2, 5.4.5.1, 5.4.5.3, 5.5.1, 5.24.4, 5.25	The selected clauses 5.1.2.6, 5.1.2.7, 5.4.1.2, 5.4.5.1, 5.4.5.3, 5.5.1, 5.24.4 and 5.25 partly cover the requirement. Covered

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		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 packaging are not covered.
10.3, first part only	5.1.1.1, 5.1.1.2	The selected clauses 5.1.1.1 and 5.1.1.2 partly cover the requirement. Covered in respect with the safety use of WD with materials and substances 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.
10.4.1, first sentence only	5.1.2.6, 5.1.2.7, 5.4.1.2, 5.4.5.3	The selected clauses 5.1.2.6, 5.1.2.7, 5.4.1.2 and 5.4.5.3 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. WD devices are not intended to administer medicinal products, that's why the second part of this requirement is not covered.
11.1, first sentence only	4.2, 4.3, 5.3, 5.4, 5.5.1, 5.6.1, 5.9, 5.11, 5.12.6, 5.24.4, 5.24.5, 5.26	The selected clauses 4.2, 4.3, 5.3, 5.4, 5.5.1, 5.6.1, 5.9, 5.11, 5.12.6, 5.24.4, 5.24.5 and 5.26 partly cover the requirement. Covered in respect of reducing the risks of infection to patients, users and, where applicable, other persons by effective cleaning and disinfection of the

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		load. Aspects related to the WD manufacturing processes are not covered.
11.1 (d)	5.1.3, 5.3.1, 5.3.5, 5.5.1, 5.6.2	The selected clauses 5.1.3, 5.3.1, 5.3.5, 5.5.1 and 5.6.2 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	5.1.1, 5.1.3.2, 5.1.3.4, 5.6.3, 5.25.1, 5.26, 5.28.3	The selected clause 5.1.1 partly covers the requirement. Covered with respect of design of WD to facilitate its safe cleaning and disinfection. The other clauses 5.1.3.2, 5.1.3.4, 5.6.3, 5.25.1, 5.26 and 5.28.3 also cover this requirement. Aspects related to the (re-) sterilisation of the WD are not covered.
14.1, first sentence only	5.1.3, 5.28	The selected clauses 5.1.3 and 5.28 cover the requirement in respect of load carrier(s) and trolleys used with WD.
14.2 (a)	5.1.2.5, 5.1.3, 5.4.2, 5.4.3, 5.10, 5.12.3, 5.22.3, 5.22.4, 5.27.1	The selected clauses 5.1.2.5, 5.1.3, 5.4.2, 5.4.3, 5.10, 5.12.3, 5.22.3, 5.22.4 and 5.27.1 cover the requirement in respect of reducing the risks of injury, in connection with WD physical features, dimensional and ergonomic features.
14.2 (b)	5.2, 5.29	The selected clause 5.29 covers the requirement in respect of reducing the risks connected with reasonably foreseeable environmental conditions. The clause 5.2 covers other

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		important aspects related to external influences.
18.8	5.4.1.6, 5.4.5.4, 5.7.2, 5.18.2.10, 5.19.8, 5.20.1 c), 5.20.2 a), 5.21 (a), 5.21 d), 5.21 j), 5.22.3	The selected clauses 5.4.1.6, 5.4.5.4, 5.7.2, 5.18.2.10, 5.19.8, 5.20.1 c), 5.20.2 a), 5.21 (a), 5.21 d), 5.21 j) and 5.22.3 cover the requirement in respect of preventing unauthorized access on the device.
21.3	5.10, 5.12.2, 5.12.3	The selected clauses 5.10, 5.12.2 and 5.12.3 cover the requirement in respect of the design of indicators and symbols.
23.4 q)	7, 8.2 a), 8.2 b), 8.2 g), 8.2 h)	The selected clauses 7, 8.2 a), 8.2 b), 8.2 g) and 8.2 h) cover the requirement in respect of documentation provided for installation.
23.4 k)	6.1.3, 7, 8.2, 8.3	The selected clauses 6.1.3, 7, 8.2 and 8.3 cover the requirement in respect of documentation provided for installation, operation and maintenance. Covered only in respect of validation before use.

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 7000	ISO 7000:2019	Graphical symbols for use on equipment — Registered symbols	For applicable standard edition see Column 2
ISO 10012	ISO 10012:2003	Measurement management systems — Requirements for measurement processes and measuring equipment	EN ISO 10012:2003
ISO 14644-3	ISO 14644-3:2019	Cleanrooms and associated controlled environments — Part 3: Test methods	EN ISO 14644-3:2019

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 14971	ISO 14971:2019	Medical devices — Application of risk management to medical devices	EN ISO 14971:2019 EN ISO 14971:2019/A11:2021
ISO 15883-2	ISO 15883-2:2024	Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.	EN ISO 15883-2:2025
ISO 15883-3	ISO 15883-3:2024	Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	EN ISO 15883-3:2025
ISO 15883-4	ISO 15883-4:2018	Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes	EN ISO 15883-4:2018
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 15883-6	ISO 15883-6:2011	Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment	EN ISO 15883-6:2015
ISO 15883-7	ISO 15883-7:2016	Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment	EN ISO 15883-7:2016
IEC 60417-DB	IEC 60417-DB:2002	Graphical symbols for use on equipment	For applicable standard edition see Column 2
IEC 60584-1:2013	IEC 60584-1:2013	Thermocouples — Part 1: EMF specifications and tolerances	EN 60584-1:2013

Column 1 Reference in Clause 2	**Column 2 International Standard Edition**	**Column 3 Title**	**Column 4 Corresponding European Standard Edition**
IEC 60751:2008	IEC 60751:2008	Industrial platinum resistance thermometer and platinum temperature sensors	EN 60751:2008
IEC 61010-2-040:2020	IEC 61010-2-040:2020	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials	EN IEC 61010-2-040:2021
IEC 61326-1:2020	IEC 61326-1:2020	Electrical equipment for measurement, control and laboratory use. EMC requirements – Part 1: General requirements	EN IEC 61326-1:2021
IEC 80416-1	IEC 80416-1:2008	Basic principles for graphical symbols for use on equipment — Part 1: Creation of graphical symbols for registration	EN 80416-1:2009
European Pharmacopoeia	None	European Pharmacopoeia, Assays – 2.5.30 Oxidising substances; Biological tests - 2.6.14 Bacterial endotoxins	None
United States Pharmacopeia	None	United States Pharmacopeia, Chemical tests <541> Titrimetry, Oxidation-Reduction (Redox) titrations; Biological tests <85> Bacterial endotoxins test	None

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.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 1(12) of Regulation (EU) 2017/745, the following Table ZA.3 details the relevant Essential Health and Safety Requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than the General Safety and Performance Requirements set out in Chapter II of Annex I of Regulation (EU) 2017/745 along with the corresponding clauses of this European Standard. Table ZA.3, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

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 the 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).

Table ZA.3 — Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this Document (according to article 1, item 12, of Regulation (EU) 2017/745)

Essential Health and Safety Requirements of Directive 2006/42/EC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1.2.1 Indents 5, 7, 9, 10, 11 and last paragraph	5.7.4, 5.12.1, 5.12.5, 5.12.7, 5.12.10, 5.19.14, 5.22	The selected clauses 5.7.4, 5.12.1, 5.12.5, 5.12.7, 5.12.10, 5.19.14 and 5.22 cover the requirement in respect withstanding the intended operating stress and prevent hazardous situations by failures of the equipment and/or the control system.
1.3.2 paragraph 4	5.1, 8.1 e), 8.3 g)	The selected clauses 5.1, 8.1 e) and 8.3 g) cover the requirement in respect to minimize the risk of breakdown by leaking of hazardous substances during normal operation.

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