BSI Standards Publication

Washer-disinfectors

Part 1: General requirements, terms and definitions and tests

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National foreword

This British Standard is the UK implementation of EN ISO 15883-1:2025. It is identical to ISO 15883-1:2024. It supersedes BS EN ISO 15883-1:2009+A1:2014, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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UK Government is responsible for legislation. For information on legislation and policies relating to that legislation, consult the relevant pages of www.gov.uk.

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

This European Standard was approved by CEN on 12 July 2024.

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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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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of an identical text or by endorsement, at the latest by September 2025, and conflicting national standards shall be withdrawn at the latest by September 2025.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. ed in respect of reducing the risks related to use error by reducing the risks related to the omic 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. ts related to the ence, education and use nment, where applicable, he medical and physical conditions of intended users are not covered.
7	9.2	elected clause 9.2 partly the requirement. ed 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	selected clauses 5.1.2.6, ', 5.4.1.2, 5.4.5.1, 5.4.5.3, 5.24.4 and 5.25 partly 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 minir the risk posed by contaminants and residues to patients and the persons involved in use 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 by substances and proc residues, that may be rel from the WD. Aspects related to the particles, including wear debris, degradation products ar 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 5.3, 5.4, 5.5.1, 5.6.1, 5.9, 5.12.6, 5.24.4, 5.24.5 anc partly cover the require Covered in respect of rec the risks of infection to patients, users and, where appl other persons by eff cleaning and disinfection

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		ts related to the WD facturing 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, 5.5.1 and 5.6.2 partly cover the requirement. Covered with respect of design of WD to nt microbial nination 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. ed with respect of design D to facilitate its safe cleaning and disinfection. other clauses 5.1.3.2, , 5.6.3, 5.25.1, 5.26 and 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)	, 5.1.3, 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. ause 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 external influences.
18.8	5.4.1.6, 5.4.5.4, 5.7.2, 5.18 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.

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.

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,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 15883-1:2006), which has been technically revised. It also incorporates ISO 15883-1:2006/Amd 1:2014.

The main changes are as follows:

— alignment of terms and definitions with ISO 11139:2018 + Amd 1:2024;

— addition of requirements for load carrier(s);

— clarification of water quality requirements;

— elaboration of load dryness tests for external and internal surfaces of load items (see 6.12);

— relocation of former Annex C, *Test methods for the detection and assessment of residual proteinaceous contamination,* to ISO 15883-5:2021;

— redesignation of former Annex D, *Microbiological recovery medium for estimation of bacterial contamination of water,* as Annex C;

— increase in the minimum temperature limit for thermal disinfection and calculation of A_0 values from 65 °C to 70 °C (see Reference [48]);

— revision of 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.

This document is the first part of the ISO 15883 series of standards specifying the performance of washer-disinfectors (WD) and specifies the general requirements for performance applicable to all WD. The requirements given in this document are applicable to all WD specified in subsequent parts of the ISO 15883 series, except insofar as they are modified or added to by a subsequent part, in which case the requirements of that particular part apply.

Fields of application within the scope of ISO 15883 series 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.

WD are used only for processing the type of loads specified by the manufacturer of the WD.

In selecting the appropriate WD, references are made both to this document and to the relevant parts of ISO 15883 series. It is the user's responsibility to ensure that the choice of type of WD, operating cycle or quality of services or process chemicals is appropriate for any particular load.

This document has been prepared on the basis that each individual WD is subject to validation tests (e.g. installation qualification, operational qualification, and performance qualification on first installation) and that in use continued conformance is established by periodic tests.

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

Washer-disinfectors —

Part 1:
General requirements, terms and definitions and tests

1 Scope

This document specifies general performance requirements for washer-disinfectors (WD) and washer-disinfector accessories that are intended to be used for cleaning and disinfection of reusable medical devices. It specifies performance requirements for cleaning and disinfection as well as for the accessories that can be required to achieve the necessary performance. The methods and instrumentation required for validation, routine control and monitoring and requalification, periodically and after essential repairs, are also specified.

NOTE 1 The requirements can be applied to WD intended for use with other articles used in the context of medical, dental, pharmaceutical and veterinary practice.

The requirements for WD intended to process specific loads are specified in ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7. For WD intended to process loads of two or more different types, the requirements of the applicable parts of ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7 apply.

This document does not specify requirements intended for machines for use for laundry or general catering purposes.

This document does not include requirements for machines which are intended to sterilize the load, or which are designated as “sterilizers” and addressed in other standards.

The specified performance requirements of this document do not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

NOTE 2 Chemicals in some cleaning agents and disinfectants can react with prion protein in a manner that can inhibit its removal or inactivation. If the presence of prion protein is considered a possibility, then this can influence the choice of cleaning agent and disinfectant.

NOTE 3 This document can be used by prospective purchasers and manufacturers as the basis of agreement on the specification of a WD. The test methods for demonstration of conformity with the requirements of this document can also be employed by users to demonstrate continued conformity of the installed WD throughout its service life. Guidance on a routine test programme is given in Annex A.

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 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

ISO 14644-3, *Cleanrooms and associated controlled environments — Part 3: Test methods*

ISO 14971, *Medical devices — Application of risk management to medical devices*