

DIN EN ISO 15883-5



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Supersedes
DIN ISO/TS 15883-5:2006-02

**Washer-disinfectors –
Part 5: Performance requirements and test method criteria for
demonstrating cleaning efficacy (ISO 15883-5:2021);
English version EN ISO 15883-5:2021,
English translation of DIN EN ISO 15883-5:2021-11**

Reinigungs-Desinfektionsgeräte –
Teil 5: Leistungsanforderungen und Kriterien für Prüfverfahren zum Nachweis der
Reinigungswirksamkeit (ISO 15883-5:2021);
Englische Fassung EN ISO 15883-5:2021,
Englische Übersetzung von DIN EN ISO 15883-5:2021-11

Laveurs désinfecteurs –
Partie 5: Exigences de performance et critères des méthodes d'essai pour démontrer
l'efficacité du nettoyage (ISO 15883-5:2021);
Version anglaise EN ISO 15883-5:2021,
Traduction anglaise de DIN EN ISO 15883-5:2021-11

Document comprises 69 pages

Translation by DIN-Sprachendienst.

In case of doubt, the German-language original shall be considered authoritative.

A comma is used as the decimal marker.

National foreword

This document (EN ISO 15883-5:2021) 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” (Secretariat: DIN, Germany), with the active participation of German experts.

The responsible German body involved in its preparation was *DIN-Normenausschuss Medizin* (DIN Standards Committee Medicine), Working Committee NA 063-04-09 AA “Washer-disinfectors”.

The DIN documents corresponding to the documents referred to in this document are as follows:

ISO 10993-1	DIN EN ISO 10993-1
ISO 10993-5	DIN EN ISO 10993-5
ISO 10993-12	DIN EN ISO 10993-12
ISO 11737-1	DIN EN ISO 11737-1
ISO 14971	DIN EN ISO 14971
ISO 15883-1:—	DIN EN ISO 15883-1:—*
ISO 15883-4	DIN EN ISO 15883-4
ISO 15883-7	DIN EN ISO 15883-7
ISO 17664-1	DIN EN ISO 17664-1
ISO/IEC 17025	DIN EN ISO/IEC 17025

For current information on this document, please go to DIN’s website (www.din.de) and search for the document number in question.

Amendments

This standard differs from DIN ISO/TS 15883-5:2006-02 as follows:

- a) the number of the standard has been amended; the ISO/TS has become an EN ISO;
- b) new and previous terms and definitions have been aligned with ISO 11139:2018;
- c) considerations for the selection of an appropriate test soil and test load have been included;
- d) performance requirements to demonstrate the cleaning efficacy of a washer-disinfector have been consolidated and specified;
- e) the cleaning efficacy test and acceptance criteria for the type test and performance qualification test have been specified for a variety of analytes;

* In preparation.

- f) alert and action levels have been introduced for analytes to facilitate the interpretation of cleaning validation data;
- g) examples of test soils relevant to certain procedures, as referenced in published literature, and suitable assay methods for the detection or quantification of certain soil residuals have been included in Annex A;
- h) the immersion test protocol resulting from interlaboratory tests to evaluate the cleaning performance of a protein-based test is specified in Annex B, together with examples of worksheets to assist laboratories performing the test in Annex E;
- i) examples of protein detection methods have been revised and transferred from ISO 15883-1:2006 to the informative Annex C;
- j) examples of haemoglobin detection methods have been added to the informative Annex D;
- k) the Bibliography has been revised.

Previous editions

DIN ISO/TS 15883-5: 2006-02

National Annex NA
(informative)

Bibliography

DIN EN ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

DIN EN ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

DIN EN ISO 10993-12, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

DIN EN ISO 11737-1, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

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

DIN EN ISO 15883-1: —*, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

DIN EN ISO 15883-4, *Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*

DIN EN ISO 15883-7, *Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment*

DIN EN ISO 17664-1, *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*

DIN EN ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

English Version

Washer-disinfectors -
Part 5: Performance requirements and test method
criteria for demonstrating cleaning efficacy
(ISO 15883-5:2021)

Laveurs désinfecteurs -
Partie 5: Exigences de performance et
critères des méthodes d'essai pour
démontrer l'efficacité du nettoyage
(ISO 15883-5:2021)

Reinigungs-Desinfektionsgeräte -
Teil 5: Leistungsanforderungen und Kriterien
für Prüfverfahren zum Nachweis
der Reinigungswirksamkeit
(ISO 15883-5:2021)

This European Standard was approved by CEN on 28 February 2021.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 08 September 2021.

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, Turkey and United Kingdom.



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European foreword

This document (EN ISO 15883-5:2021) 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 February 2022, and conflicting national standards shall be withdrawn at the latest by February 2022.

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 CEN ISO/TS 15883-5:2005.

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 websites.

The original outline of the EN ISO 15883 series of standard was based on seven parts. Two of the parts were applicable to all washer-disinfectors: Part 1 defining the general requirements, terms and definitions and Part 5 defining tests for all washer-disinfectors (at the time of publication designated a technical specification). The other five parts described requirements for different types of washer-disinfectors. During the initial development of Part 1, cleaning requirements were defined but at the time could not be harmonized due to differences from country to country on the use of simulative test soils. At the time of publication in 2006, the development of a single internationally acceptable test method was not agreed, and the cleaning efficacy of washer-disinfectors could be demonstrated by referring to the various test soils and methods that were in use in a number of different countries at that time. The Technical Specification EN ISO/TS 15883-5 was therefore published as a reference for this purpose and it was noted in the document that it remained the intention of the Technical Committees to develop a single test method. Part 1 and 5 have now been subjected to major revisions and are designed to be used together.

The new EN ISO 15883-5 standard incorporates cleaning performance and conformity testing requirements originally included in EN ISO 15883-1, but also includes significant revisions in the international harmonization of the cleaning performance criteria for washer-disinfectors. The compilation of different country-specific test methods including acceptance criteria as in the previous TS is therefore no longer necessary. In total this new revision includes: new definitions (already included in EN ISO 11139:2018), performance requirements for test soils and cleaning efficacy test criteria, and updates to the testing for conformity including process residuals.

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, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 15883-5:2021 has been approved by CEN as EN ISO 15883-5:2021 without any modification.

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).

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 and associated equipment for processing of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This first edition of ISO 15883-5 cancels and replaces ISO/TS 15883-5:2005, which has been technically revised. The main changes compared to the previous edition are as follows:

- new and previous terms and definitions were harmonized with ISO 11139:2018;
- considerations for selection of an appropriate test soil and test load have been included;
- performance requirements to demonstrate cleaning efficacy of a washer-disinfector were consolidated and specified;
- cleaning efficacy test and acceptance criteria for the type test and performance qualification test have been specified for a variety of analytes;
- alert and action levels were introduced for analytes to facilitate interpretation of cleaning validation data;
- examples of test soils relevant to certain procedures, as referenced in published literature, and suitable assay methods for detection or quantification of certain soil residuals have been included in [Annex A](#);
- the immersion test protocol resulting from interlaboratory tests to evaluate cleaning performance of a protein-based test is specified in [Annex B](#), together with examples of worksheets to assist laboratories performing the test in an [Annex E](#);