

PESUMASIN-DESINFITSEERIMISSEADMED. OSA 5:
NÕUDED TOIMIMISNÄITAJATELE JA
PUHASTUSTÕHUSUSE KATSEMEETODITE
KRITEERIUMID

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 15883-5:2021 sisaldab Euroopa standardi EN ISO 15883-5:2021 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15883-5:2021 consists of the English text of the European standard EN ISO 15883-5:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 18.08.2021.	Date of Availability of the European standard is 18.08.2021.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.080.10

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardimis- ja Akrediteerimiskeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardimis- ja Akrediteerimiskeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autoriõiguse kaitse kohta, võtke palun ühendust Eesti Standardimis- ja Akrediteerimiskeskusega: Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation and Accreditation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation and Accreditation.

If you have any questions about standards copyright protection, please contact the Estonian Centre for Standardisation and Accreditation: Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

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.



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

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

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.

This document is a preview generated by EVS

Contents

	Page
Foreword	iv
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Performance requirements	3
4.1 General.....	3
4.2 Test soil considerations.....	3
4.3 Load considerations.....	4
4.4 Cleaning efficacy test criteria.....	5
4.4.1 General.....	5
4.4.2 Visual examination.....	5
4.4.3 Assay criteria.....	5
4.4.4 Process residuals.....	7
5 Testing for conformity	7
5.1 Cleaning test method validation.....	7
5.1.1 General.....	7
5.1.2 Load soiling method.....	7
5.1.3 Detection method(s).....	7
5.1.4 Analyte assay method.....	8
5.2 Washer-disinfector requirements.....	8
5.3 Cleaning type test.....	8
5.3.1 Principle.....	8
5.3.2 Reagents/materials.....	8
5.3.3 Procedure.....	8
5.3.4 Acceptance criteria.....	8
5.4 Cleaning performance qualification test.....	9
5.4.1 Principle.....	9
5.4.2 Reagents/materials.....	9
5.4.3 Procedure.....	9
5.4.4 Acceptance criteria.....	9
5.5 Process residuals.....	9
5.5.1 General.....	9
5.5.2 Risk analysis.....	10
5.5.3 Cytotoxicity.....	10
5.5.4 Sampling methods.....	10
5.5.5 Acceptance criteria.....	10
Annex A (informative) Examples of test soils	11
Annex B (normative) Protein-based test soil performance assessment	16
Annex C (informative) Examples of test methods for the detection and assessment of residual proteinaceous contamination	38
Annex D (informative) Examples of test methods for the detection of haemoglobin for the assessment of cleaning efficacy	43
Annex E (informative) Test soil performance assessment – Sample results sheets	47
Bibliography	54

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](#);
- examples of protein detection methods were revised and transferred across from ISO 15883-1:2006 to informative [Annex C](#);
- examples of haemoglobin detection methods were added to informative [Annex D](#);

— extensive 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.

Introduction

Testing of cleaning efficacy is a key aspect of establishing satisfactory performance of a washer-disinfector (WD). This testing includes type testing under simulated use conditions. In addition to type testing, performance qualification testing is performed under clinical use conditions.

The cleaning efficacy of washer-disinfectors has historically been demonstrated by referring to different test soils and methods that have been used in several different countries. This document gives requirements for standardized methods for demonstration of cleaning efficacy, including examples of test soils. The individual requirements for the various types of washer-disinfectors and processing procedures can vary, but this document provides the basis for the demonstration of cleaning efficacy.

Cleaning efficacy testing is performed in the WD and with associated accessories in two phases:

- type testing, under simulated use conditions, with defined test soils and their analytes, soiling methods and test surfaces/medical devices/product representative of design and intended applications;
- performance qualification testing under clinical conditions with load(s) that are soiled with the most challenging soil from clinical use.

This document excludes the verification of cleaning of product that could have been exposed to prions, the causative agent in transmissible spongiform encephalopathies such as Creutzfeldt-Jakob disease (CJD).

Washer-disinfectors —

Part 5:

Performance requirements and test method criteria for demonstrating cleaning efficacy

1 Scope

This document specifies procedures and test methods used to demonstrate the cleaning efficacy of washer-disinfectors (WD) and their accessories intended to be used for cleaning of reusable medical devices.

NOTE 1 The requirements can be used for washer-disinfectors intended for use with other articles used in the context of medical, dental, laboratory, pharmaceutical and veterinary practice.

NOTE 2 This document does not apply to the activities to be performed by the manufacturers of reusable medical devices.

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

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15883-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

action level

value from monitoring that necessitates immediate intervention

[SOURCE: ISO 11139:2018, 3.5]

1) Under preparation. Stage at the time of publication: ISO/DIS 15883-1:2020.