Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2)

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

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NATIONAL FOREWORD

See Eesti standard EVS-EN 16616:2022+A1:2025 sisaldab Euroopa standardi EN 16616:2022+A1:2025 ingliskeelset teksti.	This Estonian standard EVS-EN 16616:2022+A1:2025 consists of the English text of the European standard EN 16616:2022+A1:2025.
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 15.10.2025.	Date of Availability of the European standard is 15.10.2025.
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.

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Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2)

Désinfectants chimiques et antiseptiques - Désinfection thermochimique du textile - Méthode d'essai et exigences (phase 2, étape 2)

Chemische Desinfektionsmittel und Antiseptika - Chemothermische Wäschedesinfektion - Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

This European Standard was approved by CEN on 27 June 2022 and includes Amendment 1 approved by CEN on 11 August 2025.

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

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European foreword

This document (EN 16616:2022+A1:2025) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

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of an identical text or by endorsement, at the latest by April 2026, and conflicting national standards shall be withdrawn at the latest by April 2026.

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 includes Amendment 1 approved by CEN on 11 August 2025.

This document supersedes ▌A1⟩ EN 16616:2022 ⟨A1▐.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ▌A1⟩ ⟨A1▐.

The document was revised to adapt it to the latest state of science, to correct errors and ambiguities, to harmonize the structure and wording with other tests of CEN/TC 216 existing or in preparation and to improve the readability of the document and thereby make it more understandable. The following is a list of significant technical changes since the last edition, EN 16616:2015:

— the scope is adapted to the scope of the WG 1;

— in Clause 4 the requirements for phase 2, step 1 tests are deleted;

— addition of water for the test and reference control (5.2.2.4);

— the example for washing machines in 5.3.2.18 of the previous version is switched to Annex D;

— addition of Potter S 1 apparatus (5.3.2.22);

— adaption of 5.4.3.1 to 5.4.3.3 to other current standards;

— review of 5.4.4 (editorial changes and better description);

— re-wording of the description of the neutralization (5.5.1.2) and addition of a reference to phase 2, step 1 tests;

— addition of an information on using a spectrophotometer for counting cell numbers of mycobacteria in 5.4.4.3 (NOTE);

— addition of the documentation and justification of the choice of the neutralizer in the test report (5.5.1.2);

— addition of a new NOTE in 5.5.2.1;

— addition of a NOTE and the reference to Annex G in 5.5.2.2;

— addition of the reference control (5.5.2.3);

— *R*II is deleted;

— a reference to phase 2, step 1 tests was added;

— correction and adaption to the current tests of Table 2 (5.6.1.1);

— addition of two paragraphs in 5.6.2.1 (former 5.6.2.3);

— in 5.6.2.2 the V_C-values will be expressed per carrier (former per ml);

— addition of N and N_0 in the calculation (5.6.2.3);

— in 5.6.2.4 the calculation is changed to values per carrier, the formula is corrected and the weighted mean is added in all calculations;

— in 5.6.2.5 the calculation is changed: only N_w will be calculated, *R*I is not counted and *R*II, *B* and *C* are no longer used in the standard;

— correction of the example in 5.7.2;

— adaption of 5.7.3 to the tests in the current version;

— addition of the requirements of the test report in 5.10;

— adaption of Annex A to EN 12353;

— correction of Annex C;

— addition of a new Annex D “Example of washing machine specification”;

— addition of a new Annex E “Preparation of hard water for using in the test and reference procedures”;

— addition of a new Annex F “Test report (example)”;

— addition of a new Annex G “Example for loading the washing machine”;

— document editorially revised, clauses not applied (from the old version) deleted;

— de-harmonization of the standard, Annex ZA deleted.

The changes of this revision have no impact on the test results obtained with reference to the version EN 16616:2015. Those results are still valid except the reduction of the reference control N_w was higher than 3 lg and/or the calculation of the results followed the wrong way of version 2015.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations 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.

Introduction

This document specifies a carrier test for establishing whether a single-wash disinfecting product or combination of products for the treatment of contaminated textile has or does not have necessary microbicidal activity. This document only intends to validate the disinfection part of the laundry process.

This laboratory test takes into account practical conditions of application of the product including contact time, temperature, test organisms and interfering substances, i.e. conditions which could influence its action in practice.

The conditions are intended to cover general purposes and to allow reference between microbiological laboratories and types of detergents and disinfectants. Each effective dosage of the chemical disinfectant found by this test corresponds only to the chosen experimental conditions. Where actual conditions vary additional testing in microbiological laboratories is needed to determine the effective dosage. Instructions for use are the responsibility of manufactures of detergents or disinfectants.

1 Scope

This document specifies a test method and the minimum requirements for the microbicidal activity of a specified disinfection process for the treatment of contaminated textile. This procedure is carried out by using a washing machine as specified in 5.3.2.18 and refers to the disinfection step without prewash. This procedure is not limited to certain types of textile. The suppliers' instructions are expected to be sufficient if they content the process parameters identified in the test (e.g. dosing disinfectant in whatever washing phase e.g. main wash, rinsing, disinfecting at 40 °C).

This document applies to areas and situations where disinfection is medically indicated. Such indications occur in patient care, for example:

— in hospitals, in community medical facilities, and in dental institutions;

— in clinics of schools, of kindergartens, and of nursing homes;

and could occur in the workplace and in the home.

It could also include services such as laundries and kitchens supplying products directly for the patients.

The method described is intended to determine the activity of a product or product combination under the conditions in which they are used. This is a phase 2, step 2 laboratory test that simulates the conditions of application of the product.

EN 14885 specifies in detail the relationship of the various tests to one another and to “use recommendations”.

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.

EN 12353, *Chemical disinfectants and antiseptics — Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

EN 13624, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area — Test method and requirements (phase 2, step 1)*

EN 13727, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity in the medical area — Test method and requirements (phase 2, step 1)*

EN 14348, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants — Test methods and requirements (phase 2, step 1)*

EN 14885, *Chemical disinfectants and antiseptics — Application of European Standards for chemical disinfectants and antiseptics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885 and the following apply.

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

— IEC Electropedia: available at https://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp