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English Version

Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeastcidal and/or fungicidal and/or tuberculocidal and/or mycobactericidal activity on non-porous surfaces with mechanical action employing wipes or mops in the medical area (4- field test) - Test method and requirements (phase 2, step 2)

Antiseptiques et désinfectants chimiques - Méthode d'essai quantitative pour l'évaluation de l'activité bactéricide et levuricide et/ou fongicide et/ou tuberculocide et/ou mycobactéricide sur des surfaces non poreuses, avec action mécanique à l'aide de lingettes ou de serpillières dans le domaine médical (essai à 4 zones) - Méthode d'essai et exigences (phase 2, étape 2)

Chemische Desinfektionsmittel und Antiseptika - Quantitatives Prüfverfahren zur Bestimmung der bakteriziden und levuroziden und/oder fungiziden und/oder tuberkuloziden und/oder mykobakteriziden Wirkung auf nicht-porösen Oberflächen mit mechanischer Einwirkung mit Hilfe von Tüchern oder Mopps im humanmedizinischen Bereich (4-Felder-Test) - Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

This European Standard was approved by CEN on 23 February 2026.

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European foreword

This document (EN 16615:2026) 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of an identical text or by endorsement, at the latest by October 2026, and conflicting national standards shall be withdrawn at the latest by October 2026.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 supersedes EN 16615:2015.

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 standard and thereby make it more understandable.

The following is a list of significant technical changes since the last edition:

- Annex ZA was deleted, the document was de-harmonized;
- N_0 was deleted;
- Harmonization of the text with EN 13727;
- Implementation of different applications forms;
- Implementation different swab material;
- Implementation of the definition of room temperature;
- Water control always be carried out with hard water (= process and method validation);
- Polysorbate 80 should be weighed 1 g instead 1 ml;
- Implementation of Apparatus Pre-cleaning of surfaces with 2-Propanol instead of n-Propanol;
- Correction of calculation and editorial mistakes;
- Implementation of additional test-surfaces;
- Implementation of standard wiping cloth (wipe) and specified wiping cloth;
- Implementation of fungicidal, tuberculocidal and mycobactericidal activity;
- Water control: Test field 1 to be taken into account for calculation of the water control;
- Implementation of Annex E and Annex G.

The changes of this revision have no impact on the test results obtained with reference to the version EN 16615:2015. Those results are still valid but additional data requirements concerning number of required test runs and test parallels per tested organisms/ claimed group of target organisms should be respected.

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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 chemical disinfectant for use on surfaces administered with wipes has a bactericidal and yeasticidal and/or fungicidal and/or tuberculocidal and/or mycobactericidal activity in the fields described in the scope.

The laboratory test closely simulates practical conditions of application such as contact time, temperature and interfering substances, including pre-drying specified test organisms on a test-surface as carrier and wiping the product on the test-surface with a wipe. The conditions are intended to cover general purposes. However, if for some applications the recommendations of use of a product differ additional test conditions may be used or may need to be used.

Each utilization concentration of the product found by this test corresponds to defined experimental conditions.

EN 16615:2026 (E)**1 Scope**

This document specifies a test method and the minimum requirements for bactericidal and yeasticidal and/or fungicidal and/or tuberculocidal and/or mycobactericidal activity of chemical disinfectant products that form a homogeneous, physically stable preparation when diluted with hard water – or in the case of ready-to-use products – with water.

This document is applicable to products that are used in the medical area for disinfecting non-porous surfaces including surfaces of medical devices by wiping or mopping – regardless if they are covered by the Medical Device Regulation [7] or not.

Due to the new methods of application of surface disinfectants like pre-impregnated wipes this document was established to cover the different application methods.

This document is applicable for four methods of application of products for wiping and/or mopping:

- a) soaking any non-specified wipe or mop with product;
- b) spraying the product on any non-specified wipe and / or mop or a specified wipe or mop;
- c) impregnation of specified wipes or mops by the user with the product according to the manufacturer's recommendation;
- d) pre-impregnation of specified wipes or mop by the manufacturer as ready-to-use wipes or mops.

In all types of application, the water control is done with the standard wipe (5.3.2.17.1), because it is a process or method control.

This document does not apply to products that are sprayed on or flooding surfaces, without wiping in the contact time. In this case, the methods of phase 2/ stage 2 without mechanical action apply.

The test-surface (5.3.2.16) was selected as standard surface to cover all non-porous surfaces. This document does not apply to the testing of the influence of different surfaces.

This document is applicable 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 can occur in the workplace and in the home. It can also include services such as laundries and kitchens supplying products directly for the patients.

NOTE This method corresponds to a phase 2, step 2 test.

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 12353:2021, *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 14885, *Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics*

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