

Chemické dezinfekčné a antiseptické prípravky Kvantitatívna skúška na neporéznom povrchu na vyhodnotenie bakteriocídnej a kvasinkocídnej a/alebo fungicídnej aktivity chemických dezinfekčných prípravkov používaných v zdravotníckej oblasti bez mechanického pôsobenia Skúšobná metóda a požiadavky (fáza 2, krok 2)

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Chemical disinfectants and antiseptics - Quantitative test for the evaluation of bactericidal and yeasticidal and/or fungicidal activity of chemical disinfectants in the medical area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)

Táto norma obsahuje anglickú verziu európskej normy. This standard includes the English version of the European Standard.

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English Version

Chemical disinfectants and antiseptics - Quantitative test for the evaluation of bactericidal and yeasticidal and/or fungicidal activity of chemical disinfectants in the medical area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)

Antiseptiques et désinfectants chimiques - Essai quantitatif pour l'évaluation de l'activité bactéricide et levuricide et/ou fongicide des désinfectants chimiques utilisés en médecine sur des surfaces non poreuses sans action mécanique - Méthode d'essai et exigences (phase 2, étape 2) Chemische Desinfektionsmittel und Antiseptika -Quantitativer Versuch zur Bestimmung der bakteriziden und levuroziden und/oder fungiziden Wirkung chemischer Desinfektionsmittel im humanmedizinischen Bereich auf nicht porösen Oberflächen ohne mechanische Einwirkung -Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

This European Standard was approved by CEN on 25 January 2021.

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

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European foreword

This document (EN 17387:2021) 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of an identical text or by endorsement, at the latest by February 2022, and conflicting national standards shall be withdrawn at the latest by February 2022.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.

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.

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Introduction

This document describes a surface test method for establishing whether a chemical disinfectant in the area and fields described in the scope (Clause 1) has or does not have bactericidal and/or fungicidal or yeasticidal activity on non-porous surfaces without mechanical action.

The laboratory test closely simulates practical conditions of application. Chosen conditions (contact time, temperature, and microorganisms on surfaces...) reflect parameters which are found in practical situations including conditions which can influence the action of disinfectants.

However, for some applications the recommendations of use of a product can differ and therefore additional test conditions need to be used.

This document is not intended to be used when product is applied via an automatic airborne disinfection method; in such cases, see EN 17272.

1 Scope

This document specifies a test method and the minimum requirements for bactericidal and yeasticidal and additionally fungicidal 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.

NOTE Dilutions are necessary as three concentrations in the active to non-active range are tested.

This document applies to products that are used in the medical area for disinfecting non-porous surfaces without mechanical action.

This document applies to areas and situations where disinfection or antisepsis 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.

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

Using this document, it is possible to determine the activity of products like commercial formulations or active substances on bacteria and/or fungi in the conditions in which they are used and therefore it corresponds to a phase 2, step 2 test.

This method excludes the evaluation of the activity of products against mycobacteria and bacterial spores.

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 14885, Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics

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