

STN	Chemické dezinfekčné a antiseptické prípravky. Kvantitatívna skúšobná metóda na vyhodnotenie bakteriocídnej aktivity na neporéznych povrchoch s mechanickým účinkom zamestnaneckých obrúskov alebo mopov v lekárskej oblasti. Skúšobná metóda a požiadavky (fáza 2, krok 2).	STN EN 16615 85 7042
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Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test) - Test method and requirements

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

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/15

Obsahuje: EN 16615:2015

121239

Úrad pre normalizáciu, metrológiu a skúšobníctvo SR, 2015
Podľa zákona č. 264/1999 Z. z. v znení neskorších predpisov sa môžu slovenské technické normy
rozmnžovať a rozširovať iba so súhlasom Úradu pre normalizáciu, metrológiu a skúšobníctvo SR.

English Version

**Chemical disinfectants and antiseptics - Quantitative test method
for the evaluation of bactericidal and yeasticidal activity on non-
porous surfaces with mechanical action employing wipes 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 sur des surfaces non poreuses, avec action
mécanique à l'aide de lingettes dans le domaine médical
(essai à 4 zones) - Méthode d'essai et prescriptions (phase
2, étape 2)

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

This European Standard was approved by CEN on 3 January 2015.

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Foreword

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of an identical text or by endorsement, at the latest by October 2015 and conflicting national standards shall be withdrawn at the latest by October 2015.

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For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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Introduction

This European Standard specifies a carrier test for establishing whether a chemical disinfectant for use on surfaces administered with wipes has a bactericidal and yeasticidal 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 or need to be used.

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

1 Scope

This European Standard specifies a test method and the minimum requirements for bactericidal and yeasticidal 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 European Standard applies to products that are used in the medical area for disinfecting non-porous surfaces including surfaces of medical devices by wiping – regardless if they are covered by the 93/42/EEC Directive on Medical Devices or not.

This European Standard includes ‘ready-to-use wipes’ which are impregnated with a microbicidal solution.

This European Standard 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 may occur in the workplace and in the home. It may 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 14885, *Chemical disinfectants and antiseptics — Application of European Standards for chemical disinfectants and antiseptics*

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