Keemilised desinfektsioonivahendid ja antiseptikumid. Kvantitatiivne ülekandekatse meditsiini valdkonnas kasutatavate instrumentide bakteritsiidse toime hindamiseks. Katsemeetod ja nõuded (2.faas, 2.etapp)

Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 14561:2006 sisaldab Euroopa standardi EN 14561:2006 ingliskeelset teksti. Käesolev dokument on jõustatud 29.06.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 14561:2006 consists of the English text of the European standard EN 14561:2006. This document is endorsed on 29.06.2006 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This European Standard specifies a test method and the minimum requirements for bactericidal 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.	**Scope:** This European Standard specifies a test method and the minimum requirements for bactericidal 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.

ICS 11.080.20

Võtmesõnad: disinfectants, disinfections, effects, efficiency, hygiene

EUROPEAN STANDARD

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English Version

Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)

Désinfectants et antiseptiques chimiques - Essai quantitatif de porte germe pour l'évaluation de l'activité bactéricide pour instruments utilisés en médecine humaine - Méthode d'essai et prescriptions (phase 2, étape 2)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Keimträgerversuch zur Prüfung der bakteriziden Wirkung für Instrumente im humanmedizinischen Bereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

This European Standard was approved by CEN on 29 August 2005.

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

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Foreword

This European Standard (EN 14561:2006) 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 November 2006, and conflicting national standards shall be withdrawn at the latest by November 2006.

Other methods to evaluate the efficacy of chemical disinfectants and antiseptics for different applications in the medical field are in preparation.

A collaborative trial will be undertaken to provide a precision annex to this standard.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive(s).

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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

This European Standard specifies a carrier test for establishing whether a chemical disinfectant for use on instruments (surgical instruments, anaesthesia material, endoscopes etc.) has a bactericidal activity in the fields described in the scope.

The laboratory test closely simulates practical conditions of application including pre-drying bacteria on a carrier, contact time, temperature, test organisms and interfering substances, i.e. conditions which may influence the action of chemical disinfectants in practical situations.

The obligatory conditions are intended to cover general purposes and to allow reference between laboratories and product types. Each utilization concentration of the chemical disinfectant found by this test corresponds to defined experimental conditions. However, for some applications the recommendations of use of a product may differ and therefore additional test conditions need to be used.

1 Scope

This European Standard specifies a test method and the minimum requirements for bactericidal 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 instruments by immersion – even if they are not covered by the EEC/93/42 Directive on Medical Devices.

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 kindergardens 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 (see Annex E).

2 Normative references

The following referenced documents are indispensable for the application of this European Standard. 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, sporicidal and fungicidal activity*

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

3.1
product
chemical agent or formulation used as a chemical disinfectant or antiseptic

3.2
bactericide
product that kills vegetative bacteria under defined conditions

NOTE The adjective derived from "bactericide" is "bactericidal".

3.3
bactericidal activity
capability of a product to produce a reduction in the number of viable bacterial cells of relevant test organisms under defined conditions

3.4
clean conditions
conditions representative of surfaces which have been cleaned satisfactorily and/or are known to contain minimal levels of organic and/or inorganic substances