Keemilised desinfektsioonivahendid ja antiseptikumid. Kvantitatiivne ülekandekatse meditsiini valdkonnas kasutatavate instrumentide puhul kasutatavate keemiliste desoainete mükobakteritsiidse või tuberkuloosivastase toime hindamiseks. Katsemeetod ja nõuded (2.faas, 2.etapp)

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 14563:2009 sisaldab Euroopa standardi EN 14563:2008 ingliskeelset teksti.	This Estonian standard EVS-EN 14563:2009 consists of the English text of the European standard EN 14563:2008.
Standard on kinnitatud Eesti Standardikeskuse 29.01.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 29.01.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 26.11.2008.	Date of Availability of the European standard text 26.11.2008.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.080.20

Võtmesõnad: chemicals, determination, disinfectants, effects, evaluations

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 14563

November 2008

ICS 11.080.20

English Version

Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments 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 mycobactéricide ou tuberculocide des désinfectants chimiques utilisés pour instruments en médecine humaine - Méthode d'essai et prescriptions (phase 2, étape 2)

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

This European Standard was approved by CEN on 18 October 2008.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 14563:2008: E

Contents

Page

Foreword

This document (EN 14563:2008) 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 May 2009, and conflicting national standards shall be withdrawn at the latest by May 2009.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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

For relationship with EU Directive 93/42/EEC, see informative annex ZA, which is an integral part of this document.

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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, 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 the 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 mycobactericidal or tuberculocidal activity in the area described in the scope.

The laboratory test closely simulates practical conditions of application including pre-drying mycobacteria 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 mycobactericidal or tuberculocidal 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, kindergartens and 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.

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

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

2 Normative references

The following referenced documents are indispensable for the application 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, mycobactericidal, sporicidal and fungicidal activity*

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

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN 14885 apply.

4 Requirements

The product, when tested in accordance with Clause 5 under simulated clean conditions (0,3 g/l bovine albumin solution) or simulated dirty conditions (3,0 g/l bovine albumin solution, plus 3,0 ml/l washed sheep erythrocytes) according to its practical applications and under the obligatory test conditions, (one or two selected test organisms, 20 °C, 60 min), shall demonstrate at least a decimal log (lg) reduction in counts of 4.

The mycobactericidal activity shall be evaluated using the following two test organisms: *Mycobacterium avium* and *Mycobacterium terrae*.

The tuberculocidal activity shall be evaluated using the following test organism: *Mycobacterium terrae*.