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Chemical disinfectants and antiseptics - Quantitative
suspension test for the evaluation of virucidal activity in
the medical area - Test method and requirements
(Phase 2/Step 1)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 14476:2013+A1:2015 sisaldab Euroopa standardi EN 14476:2013+A1:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 14476:2013+A1:2015 consists of the English text of the European standard EN 14476:2013+A1:2015.
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English Version

Chemical disinfectants and antiseptics - Quantitative
suspension test for the evaluation of virucidal activity in
the medical area - Test method and requirements (Phase
2/Step 1)

Antiseptiques et désinfectants chimiques - Essai
quantitatif de suspension pour l'évaluation de l'activité
virucide dans le domaine médical - Méthode d'essai et
prescriptions (Phase 2/Étape 1)

Chemische Desinfektionsmittel und Antiseptika -
Quantitativer Suspensionsversuch zur Bestimmung der
viruziden Wirkung im humanmedizinischen Bereich -
Prüfverfahren und Anforderungen (Phase 2, Stufe 1)

This European Standard was approved by CEN on 5 July 2013 and includes Amendment 1 approved by CEN on 27 July 2015.

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European foreword

This document (EN 14476:2013+A1:2015) 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of an identical text or by endorsement, at the latest by March 2016 and conflicting national standards shall be withdrawn at the latest by March 2016.

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 supersedes A1 EN 14476:2013 A1.

This document includes Amendment 1 approved by CEN on 2015-07-27.

The start and finish of text introduced or altered by amendment is indicated in the text by tags A1 A1.

A1 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 EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document. A1

The document was revised to adapt it to the latest state of science, to correct errors and ambiguities, to harmonise the structure and wording with other existing tests of CEN/TC 216 or in preparation and to improve the readability of the standard and thereby make it more understandable. The following list is a list of significant technical changes since the last edition:

- The scope was expanded for the following fields of application within the medical area, i.e. products for textile disinfection.
- “Obligatory test conditions” were replaced by “minimum test conditions” (test temperatures and contact times can be chosen within limits) that have to be performed to pass the test.
- An additional modified method is described to test ready-to-use products in a higher concentration than 80 %, i.e. 97 %;

A1

- For the hygienic handrub and handwash method a test for virucidal activity against enveloped viruses with *Vacciniavirus* was added.
- The relationship between this European Standard and the MDD was added (Foreword and Annex ZA).
- The value of v_n in C.1 was corrected (0,001 instead of 0,0001). A1

Data obtained using the former version of EN 14476 may still be used.

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

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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Introduction

This European Standard specifies a suspension test for establishing whether a chemical disinfectant or an antiseptic has a virucidal activity in the area and fields described in the scope.

This laboratory test takes into account practical conditions of application of the product including contact time, temperature, test organisms and interfering substances, i.e. conditions which may influence its action in practical situations. Each utilisation concentration of the chemical disinfectant or antiseptic found by this test corresponds to the chosen experimental conditions.

1 Scope

This European Standard specifies a test method and the minimum requirements for virucidal activity of chemical disinfectant and antiseptic products that form a homogeneous physically stable preparation when diluted with hard water – or in the case of ready-to-use products, i. e, products that are not diluted when applied, – with water. Products can only be tested at a concentration of 80 % (97 %, with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substance.

This European Standard applies to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, instrument disinfection by immersion, surface disinfection by wiping, spraying, flooding or other means and textile disinfection.

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 1 The method described is intended to determine the activity of commercial formulations or active substances under the conditions in which they are used.

NOTE 2 This method corresponds to a phase 2, step 1 test.

NOTE 3 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 14885, *Chemical disinfectants and antiseptics — Application of European Standards for chemical disinfectants and antiseptics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885 and the following apply.

3.1

cytotoxicity

morphological alteration of cells and/or their destruction or their reduced sensitivity to virus multiplication caused by the product

3.2

plaque forming units

PFU

number of infectious virus particles per unit volume (ml)