SVENSK STANDARD
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Kemiska desinfektionsmedel och antiseptiska medel – Kvantitativt test för icke-porösa ytor utan mekanisk aktivitet för utvärdering av den virusavdödande effekten av kemiska desinfektionsmedel inom medicinområdet – provningsmetod och krav

Chemical disinfectants and antiseptics – Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area – Test method and requirements (phase 2/step 2)

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The European Standard EN 16777:2018 has the status of a Swedish Standard. This document contains the official version of EN 16777:2018.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Rengöring, desinfektion och sterilisering, SIS/TK 349.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 16777

December 2018

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English Version

Chemical disinfectants and antiseptics - Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2/step 2)

Antiseptiques et désinfectants chimiques - Essai quantitatif de surface non poreuse sans action mécanique pour l'évaluation de l'activité virucide des désinfectants chimiques utilisés dans le domaine médical - Méthode d'essai et exigences (phase 2/étape 2)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Versuch auf nicht porösen Oberflächen ohne mechanische Einwirkung zur Bestimmung der viruziden Wirkung im humanmedizinischen Bereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

This European Standard was approved by CEN on 24 September 2018.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN 16777:2018) 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 June 2019, and conflicting national standards shall be withdrawn at the latest by June 2019.

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.

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Introduction

This document describes a surface test method for establishing whether a product proposed as a disinfectant in the fields described in Clause 1 has or does not have virucidal activity on non-porous surfaces.

The laboratory test closely simulates practical conditions of application. Chosen conditions (contact time, temperature, organisms on surfaces etc.) reflect parameters which are found in practical situations including conditions which may influence the action of disinfectants. Each use concentration found from this test corresponds to defined experimental conditions.

The conditions are intended to cover general purposes and to allow reference between laboratories and product types. Each utilization concentration of the chemical disinfectant or antiseptic found by this test corresponds to defined experimental conditions.

However for special applications the recommendations of use of a product can differ and therefore additional test conditions might be needed, which cannot be covered by this document.

1 Scope

This document specifies a test method and the minimum requirements for virucidal activity of chemical disinfectants that form a homogeneous physically stable preparation when diluted with hard water – or in the case of ready-to-use products - with water.

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

This document 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 on viruses in the conditions in which they are used.

NOTE 2 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 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 14476, *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)*

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*

EN 10088-1, *Stainless steels — Part 1: List of stainless steels*

EN 10088-2, *Stainless steels — Part 2: Technical delivery conditions for sheet/plate and strip of corrosion resisting steels for general purposes*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885 and EN 14476 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

4 Requirements for virucidal activity on surfaces

The product shall demonstrate at least a decimal log (lg) reduction of 4 in virus titre of the adenovirus and murine norovirus test strains when tested in accordance with Table 1 and Clause 5. As described in EN 14885, to claim virucidal activity against enveloped virus the product shall pass both EN 14476 and this standard with vaccinia virus and to claim limited spectrum virucidal activity the product shall pass both EN 14476 and this standard with adenovirus and murine norovirus. However, to claim the virucidal activity the product shall pass standards EN 14476 with poliovirus, adenovirus and murine norovirus and this standard with adenovirus and murine norovirus, because poliovirus is not resistant to drying.

Table 1 — Minimum and additional test conditions

Minimum spectrum of test organisms	**Virucidal activity**[a] adenovirus murine norovirus **Limited spectrum virucidal activity**[b] adenovirus murine norovirus **Virucidal activity against enveloped viruses**[c] vaccinia virus
Test temperature	between 18 °C and 25 °C
Additional temperature	between 4 °C and 30 °C
Contact time	according to the manufacturer's recommendation, but not longer than 5 min or 60 min[d]
Interfering substances a) clean b) dirty	0,3 g/l bovine serum albumin and/or 3,0 g/l bovine serum albumin plus 3,0 ml erythrocytes
Additional conditions[e]	Further contact time(s), interfering substance(s) or virus(es)

[a] Poliovirus (as used in the corresponding suspension test) cannot be used for surfaces, because of drying problems.

[b] The test for "limited spectrum virucidal activity" will cover all enveloped viruses (Annex A) and norovirus, rotavirus and adenovirus.

[c] The test for "virucidal activity against enveloped viruses" will cover all enveloped viruses only (Annex A).

[d] The contact times for surface disinfectants stated in this table are chosen on the basis of the practical