# SVENSK STANDARD
# SS-EN 17111:2018

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SWEDISH STANDARDS INSTITUTE

**Kemiska desinfektionsmedel och antiseptiska medel – Kvantitativ provning med bärare för utvärdering av den virucida aktiviteten för instrument inom hälso- och sjukvården – Provningsmetod och krav (fas 2, steg 2)**

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

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Europastandarden EN 17111:2018 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 17111:2018.

The European Standard EN 17111:2018 has the status of a Swedish Standard. This document contains the official version of EN 17111:2018.



*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 17111**

October 2018

ICS 11.080.20

English Version

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

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

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

This European Standard was approved by CEN on 18 June 2018.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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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EUROPEAN COMMITTEE FOR STANDARDIZATION
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 17111:2018) has been prepared by Technical Committee CEN/TC 216 “Chemical desinfectants 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 April 2019, and conflicting national standards shall be withdrawn at the latest by April 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.

According to the CEN-CENELEC Internal Regulations, the national standards organisations 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey 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 virucidal activity in the fields described in the scope.

The laboratory test closely simulates practical conditions of application including pre-drying viruses 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. Each utilization concentration of the chemical disinfectant found by this test corresponds to defined experimental conditions.

# 1 Scope

This document specifies a test method and the minimum requirements for virucidal 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 document applies to products that are used in the medical area for disinfecting instruments by immersion.

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 under 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 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 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

The product, when diluted with hard water or – in the case of ready-to-use products – with water, and tested in accordance with Clause 5 under simulated clean conditions (0,3 g/l bovine albumin solution) or simulated dirty conditions (3 g/l bovine albumin solution, plus 3 ml/l washed sheep erythrocytes)

according to its practical applications and under the minimum test conditions shall demonstrate at least a 4 decimal log (lg) reduction.

**Table 1 — Minimum and additional test conditions**

| **Test Conditions** | **Virucidal activity against enveloped viruses**[b] (**Pre-cleaning products** with a combined cleaner/disinfectant) | **Virucidal activity**[a] (**Instrument disinfection** when temperature is < 40 °C) | **Virucidal activity** (**Instrument disinfection** when temperature is ≥ 40 °C) |
|---|---|---|---|
| **Minimum spectrum of test organisms** | modified vaccinia virus Ankara or vaccinia virus strain Elstree | Adenovirus and murine norovirus | murine parvovirus |
| **additional** | Any relevant test organism | | |
| **Test temperature** | according to the manufacturer's recommendation, but at / between | | |
| | 20 °C | 20 °C and < 40 °C | ≥ 40 °C and 70 °C |
| **Contact time** | according to the manufacturer's recommendation, but no longer than | | |
| | 60 min | 60 min | 60 min |
| **Interfering substance** | | | |
| clean conditions | 0,3 g/l bovine albumin solution and/or | 0,3 g/l bovine albumin solution and/or | 0,3 g/l bovine albumin solution and/or |
| dirty conditions | 3,0 g/l bovine albumin solution plus 3,0 ml/l washed sheep erythrocytes | 3,0 g/l bovine albumin solution plus 3,0 ml/l washed sheep erythrocytes | 3,0 g/l bovine albumin solution plus 3,0 ml/l washed sheep erythrocytes |
| Additional conditions[c] | any relevant substance | any relevant substance | any relevant substance |

[a] Poliovirus (as used in the corresponding suspension test) cannot be used for surfaces, because of drying problems. To claim the virucidal activity the product shall pass standards EN 14476 with polio-, adeno- and murine norovirus.

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

[c] For the additional conditions, the concentration defined as a result can be lower than the one obtained under the minimum test conditions.