SVENSK STANDARD
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Kemiska desinfektionsmedel och antiseptiska medel – Kvantitativt suspensionsprov för utvärdering av den antibakteriella effekten inom hälso- och sjukvården – Provningsmetod och krav (fas 2, steg 1)

Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1)

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Europastandarden EN 13727:2012+A2:2015 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 13727:2012+A2:2015.

Denna standard ersätter SS-EN 13727:2012+A1:2013, utgåva 1.

The European Standard EN 13727:2012+A2:2015 has the status of a Swedish Standard. This document contains the official English version of EN 13727:2012+A2:2015.

This standard supersedes the Swedish Standard SS-EN 13727:2012+A1:2013, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB 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 Förlag AB, 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.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13727:2012+A2

October 2015

ICS 11.080.20

Supersedes EN 13727:2012+A1:2013

English Version

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal 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 bactéricide en médecine - Méthode d'essai et prescriptions (Phase 2, Étape 1)

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

This European Standard was approved by CEN on 14 October 2013 and includes Amendment 2 approved by CEN on 3 August 2015.

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
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN 13727:2012+A2:2015) 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 April 2016, and conflicting national standards shall be withdrawn at the latest by April 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 includes Amendment 1 approved by CEN on 2013-10-14 and Amendment 2 approved by CEN on 2015-08-03.

This document supersedes [A2] EN 13727:2012+A1:2013 [/A2].

The start and finish of text introduced or altered by amendment is indicated in the text by tags [A1] [/A1] and [A2] [/A2].

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.

[A2] *deleted text* [/A2]

[A1] Data obtained using the former version of EN 13727 may still be used, if a neutralization time of 10 s for all products with contact times of 10 min or shorter has been demonstrated to be sufficient. Data obtained by using the prEN 12054 should not be used as this project was abandoned in 2001. [/A1]

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.

Introduction

This European Standard specifies a suspension test for establishing whether a chemical disinfectant or an antiseptic has a bactericidal 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 utilization 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 bactericidal 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 - with water. Products can only be tested at a concentration of 80 % or less (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, surgical handrub, surgical handwash, instrument disinfection by immersion, and surface disinfection by wiping, spraying, flooding or other means.

This European Standard applies to areas and situations where disinfection or antisepsis 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 This method cannot be used to evaluate the activity of products against *Legionella* in watersystems against mycobacteria and against bacterial spores.

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 apply.

4 Requirements

The product shall demonstrate at least a 5 decimal log (lg) reduction (for hygienic hand wash at least a 3 lg reduction), when tested in accordance with Table 1 and Clause **5**.

Table 1 — Minimum and additional test conditions

Test Conditions	Hygienic handrub and handwash	Surgical handrub and handwash	Instrument disinfection	Surface disinfection
Minimum spectrum of test organisms	*P. aeruginosa,* *S. aureus,* *E. hirae,* *E. coli K12*	*P. aeruginosa,* *S. aureus,* *E. hirae,* *E. coli K12*	*P. aeruginosa,* *S. aureus,* *E. hirae,* when temperature is 40 °C or higher: only *E. faecium*	*P. aeruginosa,* *S. aureus,* *E. hirae*
additional	Any relevant test organism			
Test temperature	according to the manufacturer's recommendation, but between			
	20 °C and 20 °C	20 °C and 20 °C	20 °C and 70 °C	4°C and 30 °C
Contact time	according to the manufacturer's recommendation			
	but between		but no longer than	
	30 s and 60 s	1 min and 5 min	60 min	5 min or 60 min [a]
Interfering substance				
clean conditions	0,3 g/l bovine albumin solution (hygienic handrub) [b]	0,3 g/l bovine albumin solution (surgical handrub) [b]	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 erythrocytes (hygienic handwash) [c]	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes (surgical handwash) [c]	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes
additional	clean or dirty; any relevant substance	clean or dirty; any relevant substance	any relevant substance	any relevant substance

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

[a] The contact times for surface disinfectants stated in this table are chosen on the basis of the practical conditions of the product. The recommended contact time for the use of the product is within the responsibility of the manufacturer. Products intended to disinfect surfaces that are likely to come into contact with the patient and / or the medical staff and surfaces, which are frequently touched by different people, leading to the transmission of microorganisms to the patient, shall be tested with a contact time of maximum 5 min. The same applies where the contact time of the product shall be limited for practical reasons. Products for other surfaces than stated above may be tested with a contact time of maximum 60 min.

[b] hygienic and surgical handrub shall be tested as a minimum under clean conditions.

[c] hygienic and surgical handwash shall be tested as a minimum under dirty conditions.