



NSAI
Standards

Irish Standard
I.S. EN 17126:2018

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

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I.S. EN 17126:2018

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National Foreword

I.S. EN 17126:2018 is the adopted Irish version of the European Document EN 17126:2018, Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area - Test method and requirements (phase 2, step 1)

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EUROPEAN STANDARD

EN 17126

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2018

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English Version

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants 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 sporicide des désinfectants chimiques utilisés dans le domaine médical - Méthodes d'essai et exigences (phase 2, étape 1)

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

This European Standard was approved by CEN on 28 August 2018.

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Contents	Page
European foreword.....	4
Introduction	5
1 Scope.....	6
2 Normative references.....	6
3 Terms and definitions	6
4 Requirements.....	6
5 Test method	7
5.1 Principle	7
5.2 Materials and reagents.....	8
5.2.1 Test organisms.....	8
5.2.2 Culture media and reagents.....	8
5.3 Apparatus and glassware	14
5.3.1 General.....	14
5.3.2 Usual microbiological laboratory equipment.....	14
5.4 Preparation of test organism suspensions and product test solutions.....	16
5.4.1 Test organism suspensions (test and validation suspension).....	16
5.4.2 Product test solutions.....	21
5.5 Procedure for assessing the sporicidal activity of the product.....	21
5.5.1 General.....	21
5.5.2 Dilution-neutralization method	23
5.5.3 Membrane filtration method	25
5.5.4 Modified method for ready-to-use products.....	27
5.6 Experimental data and calculation.....	29
5.6.1 Explanation of terms and abbreviations	29
5.6.2 Calculation.....	30
5.7 Verification of methodology.....	34
5.7.1 General.....	34
5.7.2 Control of weighted mean counts.....	34
5.7.3 Basic limits	34
5.8 Expression of results and precision	35
5.8.1 Reduction.....	35
5.8.2 Control of active and non-active product test solution (5.4.2).....	35
5.8.3 Limiting test organism and sporicidal concentration	35
5.8.4 Precision, repetitions	36
5.9 Interpretation of results - conclusion.....	36
5.9.1 General.....	36
5.9.2 Sporicidal activity for surface disinfection products.....	36
5.9.3 Sporicidal activity for instrument disinfection products.....	36
5.9.4 Sporicidal activity for textile disinfection products.....	36
5.9.5 Qualification for certain fields of application.....	36
5.10 Test report.....	36
Annex A (informative) Referenced strains in national collections.....	39
Annex B (informative) Neutralizers and Rinsing Liquids.....	40

Annex C (informative) Graphical representation of test procedures	42
C.1 Dilution-neutralization method	42
C.2 Membrane filtration method	44
C.3 Dilution-neutralization method (modified method for ready-to-use products)	46
C.4 Membrane filtration method (modified method for ready-to-use products)	48
Annex D (informative) Example of a typical test report	50
Annex E (informative) Precision of the test result	54
Annex F (informative) Graphical representation of spore preparation	55
Annex G (informative) Guide for preparation of reference test solution	56
Annex H (informative) Example for a titration Peracetic acids and hydrogen peroxide	57
H.1 General	57
H.2 Equipment	57
H.3 Procedure	57
Bibliography	59

European foreword

This document (EN 17126:2018) 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 European Standard specifies a suspension test for establishing whether a chemical disinfectant has a sporicidal 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 found by this test corresponds to the chosen experimental conditions.

1 Scope

This document specifies a test method and the minimum requirements for sporicidal activity of chemical disinfectant 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 instrument disinfection by immersion, and surface disinfection by wiping, spraying, flooding or other means.

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.

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 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.

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 shall demonstrate at least 4 decimal log (lg) reduction, when tested in accordance with Table 1 and Clause 5.

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