

Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of sporicidal activity against *Clostridioides difficile* on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) - Test method and requirements (phase 2, step 2)

EESTI STANDARDI EESSÕNA

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English Version

Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of sporicidal activity against *Clostridioides difficile* on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) - Test method and requirements (phase 2, step 2)

Antiseptiques et désinfectants chimiques - Méthode d'essai quantitative pour l'évaluation de l'activité sporicide contre *Clostridioides difficile* sur des surfaces non poreuses, avec action mécanique à l'aide de lingettes dans le domaine médical (essai à 4 zones) - Méthode d'essai et prescriptions (phase 2, étape 2)

Chemische Desinfektionsmittel und Antiseptika - Quantitatives Prüfverfahren zur Bestimmung der sporiziden Wirkung gegen *Clostridioides difficile* auf nicht-porösen Oberflächen mit mechanischer Einwirkung mit Hilfe von Tüchern im humanmedizinischen Bereich (4-Felder-Test) - Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

This European Standard was approved by CEN on 4 September 2023.

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European foreword

This document (EN 17846:2023) 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of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by May 2024.

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Introduction

This document specifies a carrier test for establishing whether a chemical disinfectant for use on surfaces administered with wipes has a sporicidal activity against *Clostridioides difficile* in the fields described in the scope.

The laboratory test closely simulates practical conditions of application such as contact time, temperature and interfering substances, including pre-drying specified test organisms on a test-surface as carrier and wiping the product on the test-surface with a wipe. The conditions are intended to cover general purposes. However, if for some applications the recommendations of use of a product differ additional test conditions may be or need to be used.

Each utilization concentration of the product found by this test corresponds to specified experimental conditions.

1 Scope

This document specifies a test method and the minimum requirements for sporicidal activity against spores of *Clostridioides difficile* 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 is applicable to products that are used in the medical area for disinfecting non-porous surfaces including surfaces of medical devices by wiping – regardless if they are covered by the 93/42/EEC Directive on Medical Devices or not.

Due to the new methods of application of surface disinfectants like pre-impregnated wipes this document was established to cover the different application method.

The document is applicable for four method of application of products for wiping and/or mopping:

- a) soaking any non-specified wipe or mop with product;
- b) spraying the product on any non-specified wipe and / or mop or a specified wipe or mop;
- c) impregnation of specified wipes or mops by the user with the product according to the manufacturer's recommendation;
- d) pre-impregnation of specified wipes or mops by the manufacturer as ready-to-use wipes or mops.

In all types of application the water control has to be done with the standard wipe [5.3.2.17 a)], because it is a process or method control.

This document does not apply to products that are sprayed on or flooding surfaces, then left until the contact application phase 2, step 2 standards without mechanical action should be used and their methods performed.

The test surface (5.3.2.16) was selected as standard surface and should cover all non-porous surfaces. It was not intended to cover the influence of each different surface.

This document is applicable 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 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 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 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)*

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

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

3.1

pre-impregnated wipe ready-to-use wipe

wipe containing disinfectant added by the wipe manufacturer at the manufacturing site

3.2

impregnated wipe

wipe containing disinfectant added by the user

Note 1 to entry: Examples include a wipe soaked in disinfectant, a wipe sprayed with disinfectant.

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) or simulated dirty conditions (3,0 g/l bovine albumin + 3,0 ml/l sheep erythrocytes) according to its practical applications and under the following test conditions: temperature between 4 °C and 30 °C, contact time min. 1 min and max. either 30 min or 60 min¹⁾ shall demonstrate at least a decimal log (lg) reduction in counts of 4 on test field 1. The mean of the number of cfu per 25 cm² on the test fields 2 to 4 shall be equal or less than 50, the mean of the number of cfu on test fields 1 to 4 of the water control shall be equal or more than 10. Details on the precision and repetition are given in 5.8.4 and EN 14885.

The sporicidal activity against *Clostridioides difficile* spores shall be evaluated using the following test organism: *Clostridioides difficile* R027.

Where indicated, additional specific sporicidal activity shall be determined applying other contact times and test organisms in order to take into account intended specific use conditions.

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

1) See 5.5.1.1 b).