

|            |                                                                                                                                                                                                                           |                         |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| <b>STN</b> | <b>Chemické dezinfekčné a antiseptické prípravky<br/>Kvantitatívna skúška nosiča na vyhodnotenie<br/>virulicídnej aktivity na nástrojoch používaných v<br/>medicíne<br/>Skúšobná metóda a požiadavky (fáza 2, krok 2)</b> | <b>STN<br/>EN 17111</b> |
|            |                                                                                                                                                                                                                           | 85 7045                 |

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)

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 02/19

Obsahuje: EN 17111:2018

**128125**

**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.

CEN members are the national standards bodies of 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 United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
 COMITÉ EUROPÉEN DE NORMALISATION  
 EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

## Contents

|                                                                                                                                       | Page      |
|---------------------------------------------------------------------------------------------------------------------------------------|-----------|
| <b>European foreword.....</b>                                                                                                         | <b>4</b>  |
| <b>Introduction .....</b>                                                                                                             | <b>5</b>  |
| <b>1 Scope.....</b>                                                                                                                   | <b>6</b>  |
| <b>2 Normative references.....</b>                                                                                                    | <b>6</b>  |
| <b>3 Terms and definitions .....</b>                                                                                                  | <b>6</b>  |
| <b>4 Requirements .....</b>                                                                                                           | <b>6</b>  |
| <b>5 Test method .....</b>                                                                                                            | <b>8</b>  |
| <b>5.1 Principle .....</b>                                                                                                            | <b>8</b>  |
| <b>5.2 Materials and reagents.....</b>                                                                                                | <b>8</b>  |
| <b>5.2.1 Test organisms.....</b>                                                                                                      | <b>8</b>  |
| <b>5.2.2 Culture media, reagents and cell cultures.....</b>                                                                           | <b>9</b>  |
| <b>5.3 Apparatus and glassware .....</b>                                                                                              | <b>12</b> |
| <b>5.3.1 General.....</b>                                                                                                             | <b>12</b> |
| <b>5.3.2 Usual microbiological laboratory equipment.....</b>                                                                          | <b>12</b> |
| <b>5.4 Preparation of test organism suspensions and product test solutions.....</b>                                                   | <b>14</b> |
| <b>5.4.1 Test organism suspensions (test suspension).....</b>                                                                         | <b>14</b> |
| <b>5.4.2 Product test solution.....</b>                                                                                               | <b>14</b> |
| <b>5.5 Procedure for assessing the virucidal activity of the product.....</b>                                                         | <b>15</b> |
| <b>5.5.1 General.....</b>                                                                                                             | <b>15</b> |
| <b>5.5.2 Method .....</b>                                                                                                             | <b>16</b> |
| <b>5.5.3 Cytotoxicity caused by product solutions .....</b>                                                                           | <b>18</b> |
| <b>5.5.4 Control of efficiency for suppression of disinfectant activity .....</b>                                                     | <b>19</b> |
| <b>5.5.5 Reference test for virus inactivation.....</b>                                                                               | <b>19</b> |
| <b>5.5.6 Titration of the virus control .....</b>                                                                                     | <b>19</b> |
| <b>5.5.7 Titration of test samples.....</b>                                                                                           | <b>19</b> |
| <b>5.6 Experimental data and calculation.....</b>                                                                                     | <b>20</b> |
| <b>5.6.1 Protocol of the results .....</b>                                                                                            | <b>20</b> |
| <b>5.6.2 Calculation of infectivity titre (TCID<sub>50</sub> – PFU) .....</b>                                                         | <b>20</b> |
| <b>5.7 Verification of the methodology .....</b>                                                                                      | <b>20</b> |
| <b>5.8 Explanation of terms and abbreviations .....</b>                                                                               | <b>21</b> |
| <b>5.9 Expression of results.....</b>                                                                                                 | <b>21</b> |
| <b>5.9.1 General.....</b>                                                                                                             | <b>21</b> |
| <b>5.9.2 Calculation of the virucidal activity of products .....</b>                                                                  | <b>21</b> |
| <b>5.10 Calculation .....</b>                                                                                                         | <b>21</b> |
| <b>5.10.1 Virucidal activity .....</b>                                                                                                | <b>21</b> |
| <b>5.10.2 Claims .....</b>                                                                                                            | <b>22</b> |
| <b>5.11 Test report.....</b>                                                                                                          | <b>22</b> |
| <b>Annex A (informative) Example of a typical test report.....</b>                                                                    | <b>24</b> |
| <b>Annex B (informative) Examples of viruses sorted according to their presence in the human body in case of virus infection.....</b> | <b>26</b> |
| <b>Annex C (normative) Detoxification of test mixtures by molecular sieving.....</b>                                                  | <b>28</b> |
| <b>C.1 Molecular sieving with Sephadex™ LH 20 .....</b>                                                                               | <b>28</b> |

|       |                                                                                                                                 |    |
|-------|---------------------------------------------------------------------------------------------------------------------------------|----|
| C.1.1 | Principle.....                                                                                                                  | 28 |
| C.1.2 | Sephadex suspension .....                                                                                                       | 28 |
| C.1.3 | Procedure .....                                                                                                                 | 28 |
| C.2   | Molecular sieving using MicroSpin™ S 400 HR.....                                                                                | 30 |
| C.3   | Determination of the residual virus titre by the large-volume-plating (LVP) method .....                                        | 30 |
| C.3.1 | General .....                                                                                                                   | 30 |
| C.3.2 | Example for the calculation of titres and the reduction according to the large-volume-plating Method .....                      | 31 |
|       | Annex D (informative) Calculation of the viral infectivity titre .....                                                          | 33 |
| D.1   | Quantal tests - Example of TCID <sub>50</sub> determination by the Spaerman-Kärber method .....                                 | 33 |
| D.2   | Plaque test.....                                                                                                                | 34 |
| D.3   | Biometrical evaluation of experimental approaches and assessment of the disinfecting effect on the virus (reduction [R]): ..... | 34 |
| D.3.1 | General .....                                                                                                                   | 34 |
| D.3.2 | Calculating the virus titre with 95 % confidence interval .....                                                                 | 35 |
| D.3.3 | Calculating the reduction and its 95 % confidence interval.....                                                                 | 35 |
| D.3.4 | Calculating the average reduction ( $R_{(mi)}$ ) and its 95 % confidence interval.....                                          | 36 |
| D.3.5 | Practical example .....                                                                                                         | 37 |
|       | Bibliography .....                                                                                                              | 40 |

**EN 17111:2018 (E)****European foreword**

This document (EN 17111:2018) 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 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.

## EN 17111:2018 (E)

### 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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN