SLOVENSKI STANDARD
SIST EN 13727:2012/kFprA1:2013

01-julij-2013

Kemična razkužila in antiseptiki - Kvantitativni suspenzijski preskus za vrednotenje baktericidnega delovanja v medicini - Preskusna metoda in zahteve (faza 2, stopnja 1) - Dopolnilo A1

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)

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

Ta slovenski standard je istoveten z: **EN 13727:2012/FprA1**

ICS:

11.080.20	Dezinfektanti in antiseptiki	Disinfectants and antiseptics

SIST EN 13727:2012/kFprA1:2013 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
EN 13727:2012

FprA1

June 2013

ICS

Will supersede EN 13727:2012

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)

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This draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 216.

This draft amendment A1, if approved, will modify the European Standard EN 13727:2012. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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Foreword

This document (EN 13727:2012/FprA1:2013) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This document is currently submitted to the Unique Acceptance Procedure.

1 Modifications to Foreword

Add the following to the list of modifications to the previous version of the standard:

- "The neutralisation time was shortened to 10 s for products with contact times of 10 min or less."

Replace the 9th paragraph with the following one:

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

Modify the last paragraph to include Former Yugoslav Republic of Macedonia and Turkey as follows:

"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."

2 Modification to 5.4.2 Product test solutions

Replace the second last sentence of the 2nd paragraph with the following one:

"Ready to use products may be tested at 97 % (see 5.5.4.)."

3 Modification to 5.5.4.1 General

Replace the 1st sentence of the 1st paragraph with the following one:

"Ready to use products may be tested according to the following modified test procedure, if the product does not pass the procedure in 5.5.2 or 5.5.3."

4 Modification to 5.6.1.2 V_C-values

*Delete the word "*hygienic*" in b).*

5 Modification to 5.6.2.2 Determination of V_C-values

Add the following in b) after "1 ml":

"(or other volumes for membrane filtration and/or handwash products)" *so that the first paragraph reads:*

"For counting the test suspension *N* (**5.4.1.6**), the validation suspensions *N*V and *N*VB (**5.4.1.6**) and for all countings of the dilution-neutralisation method (**5.5.2.6**), determine and record the V_C-values according to the number of plates used per 1 ml (or other volumes for membrane filtration and/or handwash products) sample (**5.6.1.2**)."

6 Modifications to 5.6.2.3 Calculation of N and N_0

Add the following NOTE after the Formula (1) and before the paragraph starting with "Round off the results":

"NOTE 1 For the modified method (5.5.4), the lower dilution is 10-7 and the higher dilution is 10-8."

Renumber the second NOTE of this paragraph as "NOTE 2".

7 Modifications to 5.6.2.4 Calculation of Na

*Replace the formula in the example **a1** with the following one:*

$$N_a^{-1} = \frac{(< 14 + 16) \times 10}{2} \times 10^1 = 150 \times 10^1 = < 1500 = 1{,}5 \times 10^3$$

Replace *the formula in the example **a2** with the following one:*

$$N_a^{-2} = \frac{(> 165 + > 165) \times 100}{2} \times 10 = > 1650 \times 10^2 = 165000 = 1{,}6 \times 10^5$$

8 Modification to 5.8.2 Control of active and non-active product test solution (5.4.2)

Add the word "hygienic" *before* "handwash" *in the two occurrences.*

9 Modification to 5.9.2 Bactericidal activity for handrub and handwash products

Replace list item d) with the following one:

"d) 5 lg reduction within max. 5 min under dirty conditions (surgical handwash)."