DIN EN 13727:2015-12 (E)

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) (includes Amendment A2:2015)

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 8
5.1 Principle 8
5.2 Materials and reagents 8
5.2.1 Test organisms 8
5.2.2 Culture media and reagents 9
5.3 Apparatus and glassware 11
5.3.1 General 11
5.3.2 Usual microbiological laboratory equipment 12
5.4 Preparation of test organism suspensions and product test solutions 13
5.4.1 Test organism suspensions (test and validation suspension) 13
5.4.2 Product test solutions 15
5.5 Procedure for assessing the bactericidal activity of the product 15
5.5.1 General 15
5.5.2 Dilution-neutralization method 17
5.5.3 Membrane filtration method 19
5.5.4 Modified method for ready-to-use products 21
5.6 Experimental data and calculation 23
5.6.1 Explanation of terms and abbreviations 23
5.6.2 Calculation 23
5.7 Verification of methodology 28
5.7.1 General 28
5.7.2 Control of weighted mean counts 28
5.7.3 Basic limits 29
5.8 Expression of results and precision 29
5.8.1 Reduction 29
5.8.2 Control of active and non-active product test solution (5.4.2) 29
5.8.3 Limiting test organism and bactericidal concentration 30
5.8.4 Precision, repetitions 30
5.9 Interpretation of results - conclusion 30
5.9.1 General 30
5.9.2 Bactericidal activity for handrub and handwash products 30
5.9.3 Bactericidal activity for instrument disinfection products 30
5.9.4 Bactericidal activity for surface disinfection products 31
5.9.5 Qualification for certain fields of application 31
5.10 Test report 31

Annex A (informative) Referenced strains in national collections 33

Annex B (informative) Neutralizers and rinsing liquids 34

Annex C (informative) Graphical representation of test procedures 36

Annex D (informative) Example of a typical test report 44

Annex E (informative) Precision of the test result 48

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC 51

Bibliography 52