

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