

DIN EN 17846:2024-01 (E)

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)

Contents	Page
European foreword.....	3
Introduction	4
1 Scope	5
2 Normative references.....	5
3 Terms and definitions	6
4 Requirements	6
5 Test methods	7
5.1 Principle	7
5.2 Materials and reagents.....	7
5.2.1 Test organism	7
5.2.2 Culture media and reagents	8
5.3 Apparatus and glassware	10
5.3.1 General.....	10
5.3.2 Usual microbiological laboratory equipment.....	10
5.4 Preparation of test organism suspensions and product test solutions.....	14
5.4.1 Test organism suspensions	14
5.4.2 Product test solution.....	15
5.5 Procedure for assessing the sporicidal activity against <i>C. difficile</i> of the product	16
5.5.1 General.....	16
5.5.2 Method	18
5.6 Experimental data and calculation	21
5.6.1 Explanation of terms and abbreviations	21
5.6.2 Calculation	21
5.7 Verification of methodology.....	27
5.7.1 General.....	27
5.7.2 Control of weighted mean counts.....	27
5.7.3 Basic limits test microorganisms for sporicidal activity	27
5.8 Expression of results and precision	27
5.8.1 Overview of the different suspensions / test mixtures	27
5.8.2 V_C -values	28
5.8.3 Limiting test organism and sporicidal concentration	28
5.8.4 Precision, repetitions	29
5.9 Interpretation of results - conclusion	29
5.10 Test report.....	29
Annex A (informative) Referenced strain in national collections	32
Annex B (informative) Neutralizers	33
Annex C (informative) Graphical representations of the test method.....	35
Annex D (informative) Example of a typical test report.....	37
Bibliography.....	42