

# DIN EN 16616:2015-10 (E)

## Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - 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 .....	5
4 Requirements .....	6
5 Test methods .....	7
5.1 Principle .....	7
5.2 Materials and reagents .....	7
5.2.1 Test organisms .....	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 .....	11
5.4 Preparation of test organism suspensions and product test solutions .....	14
5.4.1 Test organism suspensions (test and validation suspension) .....	14
5.4.2 Product test solutions for validation tests .....	19
5.5 Procedure for assessing the microbicidal activity of the product .....	19
5.5.1 General .....	19
5.5.2 Method .....	21
5.6 Experimental data and calculation .....	24
5.6.1 Explanation of terms and abbreviations .....	24
5.6.2 Calculation .....	24
5.7 Verification of methodology .....	26
5.7.1 General .....	26
5.7.2 Control of weighted mean counts .....	26
5.7.3 Basic limits .....	27
5.8 Expression of results and precision .....	27
5.8.1 Reduction .....	27
5.8.2 Repetitions .....	28
5.9 Interpretation of results - conclusion .....	28
5.9.1 General .....	28
5.9.2 Microbicidal activity .....	28
5.10 Test report .....	29
Annex A (informative) Referenced strains in national collections .....	30
Annex B (informative) Suitable neutralizers and rinsing liquids .....	32
B.1 General .....	32
B.2 Neutralizers .....	32
B.3 Neutralizer added to the agar for counting .....	33
Annex C (informative) Graphical representations of the test method .....	34
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC concerning medical devices .....	35
Bibliography .....	36