

DIN EN 12791:2018-01 (E)

Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2) (includes Amendment :2017)

Contents	Page
European foreword	3
1 Scope	4
2 Normative references	4
3 Terms and definitions	4
4 Requirements	4
5 Test methods	4
5.1 Principle	4
5.2 Materials and reagents	5
5.2.1 Test organism	5
5.2.2 Culture media and reagents	5
5.3 Apparatus and glassware	7
5.3.1 General	7
5.3.2 Usual microbiological laboratory equipment	7
5.4 Product test solutions	8
5.5 Procedure for assessing the microbicidal activity of the product on volunteers' hands	9
5.5.1 General	9
5.5.2 Preparatory handwash	10
5.5.3 Test procedure with volunteers	10
5.5.4 Incubation and counting of the test mixture	12
5.6 Experimental data and calculation	12
5.6.1 Determination of VC-values	12
5.6.2 Calculation of the individual Ig reduction (Ig R; Ig prevalue minus Ig postvalue)	13
5.7 Verification of the methodology	14
5.7.1 Acceptance criteria for test results	14
5.7.2 Control of weighted mean counts	14
5.8 Statistical evaluation (significance testing), expression of results and precision	14
5.9 Conclusion	15
5.10 Test report	15
Annex A (informative) Standard surgical handrub/-wash procedure	17
Annex B (informative) Quality control of soft soap	18
Annex C (informative) Examples of reporting of results and significance testing	19
Annex D (informative) WILCOXON'S matched-pairs signed-ranks test	30
Bibliography	31