

# DIN EN 12791:2016-06 (E)

## Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2)

---

<b>Contents</b>		<b>Page</b>
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 .....	9
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 .....	11
5.5.4	Incubation and counting of the test mixture .....	12
5.6	Experimental data and calculation .....	13
5.6.1	Determination of VC-values .....	13
5.6.2	Calculation of the individual lg reduction (lg R; lg prevalue minus lg 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 .....	15
5.8	Statistical evaluation (significance testing), expression of results and precision .....	15
5.9	Conclusion .....	15
5.10	Test report .....	16
Annex A (informative) Standard surgical handrub/-wash procedure .....		18
Annex B (informative) Quality control of soft soap .....		19
Annex C (informative) Examples of reporting of results and significance testing .....		20
Annex D (informative) WILCOXON'S matched-pairs signed-ranks test .....		31
Bibliography .....		32