

Expert Opinion

EN 14561:2006

Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area (phase 2, step 2)

	Report Number	: SM2019059GATn-00
a)	Identification of the test laboratory	: Microbiology Department Schülke & Mayr GmbH D – 22840 Norderstedt
b)	Identification of the sample	
	Name of the product	: thermosept® ED
	Batch number	: 1330352
	Manufacturer	: Schülke & Mayr GmbH
	Date of supply	: 16.06.19
	Storage conditions	: room temperature, dark
	Diluent recommended by the manufacturer	: water
	Active substance(s) and its concentration(s)	: 100 g solution contain 20 g glutaraldehyde
c)	Test procedure and its validation	
	Procedure	: Dilution-Neutralisation
	Neutraliser	: 3.0% tryptone soya broth, 3.0% polysorbate 80, 0.3% lecithin, 3.0% saponin, 0.1% L-histidine ("CSL+TLSH")

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d) Test conditions

Period of the test	: 18.07.19-20.07.19
Appearance of the product and its dilutions	: clear liquids
Concentrations of the test product	: 0.5%, 1%, 1.5%
Test temperature	: 55°C ± 1°C
Diluent for the product	: sterile hard water
Contact time	: 5 min
Load substances	: 0.3 g/l bovine serum albumin (clean cond.)
Stability of the test products	: no precipitates
Incubation temperature	: 36°C ± 1°C
Bacterial strains used	: <i>Pseudomonas aeruginosa</i> (ATCC 15442) <i>Staphylococcus aureus</i> (ATCC 6538) <i>Enterococcus hirae</i> (ATCC 10541)

e) Test results

See Annex in test report

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f) Conclusion

In accordance with EN 14561, the product thermosept® ED (batch 1330352) displays a **bactericidal** effect against tested bacterial species *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Enterococcus hirae* at **55°C** under conditions of **low organic soiling** (0.3 g/l bovine serum albumin) at the following concentration-time relation:

0.5% - 5 min

Norderstedt, 16.08.2019

Schülke & Mayr GmbH

Research & Regulatory Affairs



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