

Certificate of Analysis

Product name: Oosafe® Medical Device Disinfectant

Product type: Class IIa

Product code: OOMDW-120

Batch/LOT No.: 40601-MD

Production date: 2024-02

Product expiry date: 2027-02

TESTING METHOD	ACCEPTANCE CRITERIA	RESULTS	DOCUMENT NO.
Color / Visual	Clear liquid	Clear liquid	QC_4.1-0324
Odor / Olfactive	odorless	odorless	PRD/F01
ph (2% active substance in water)/ ph meter	7,0-9,0	8,3	PRD/F01
Density, 20 °C, gr/cm ³ / Density measuring device	1,001-1,010	1,008	PRD/F01

TESTING METHOD	ACCEPTANCE CRITERIA	RESULTS	CONCLUSION	DOCUMENT NO.
Mouse Embryo Assay Test (MEA)	Over 80% embryo development to the expanded blastocyst stage within 96 hours	Passed	Non-embryotoxic	SPAR-3861-0324
Human Sperm Survival Assay (HSSA)	≥75% sperm motility after 24 hours proven	Passed	Stable human sperm motility	S7137-0324SPAR

Quality Management system according to ISO 13485:2016

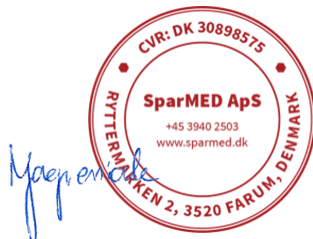
GOosafe with SparMED!

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Quality Control Department

SparMED ApS

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