

Doc.: QC_4.14.1 Rev. no.: 05 Rev. Date: 11.03.2024





Certificate of Analysis

Product name: Oosafe® Medical Device Disinfectant

Product type: Class IIa Product code: OOMD

Batch/LOT No.: 60985.1-MD Production date: 2025-05 Product expiry date: 2028-05

TESTING METHOD	ACCEPTANCE CRITERIA	RESULTS	DOCUMENT NO.
Color / Visual	Clear liquid	Clear liquid	QC_4.1-0625
Odor / Olfactive	Mild	Mild	COA/F01
ph (2% active substance in water)/ ph meter	7.0-8.5	7.7	COA/F01
Density, 20 °C, gr/cm³ / Density measuring device	1.01-1.10	1.08	COA/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-1147-25-06
Human Sperm Survival Assay (HSSA)	≥75% sperm motility after 24 hours proven	Passed	Stable human sperm motility	SPAR-1148-25-06

Quality Management system according to ISO 13485:2016

GOosafe with SparMED!

Manuela Jagieniak Quality Control Department SparMED ApS

Issue date: 08.07.2025

