

Certificate of Analysis

Product name: Andrology Tube, 5 ml
Product type: Oosafe® Plasticware IVD
Product code: OOPW-AT10
Batch/LOT No.: 08999
Product expiry date: 2029-06

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-4670-0724
Human Sperm Survival Assay (HSSA)	≥75% sperm motility after 24 hours proven	Passed	Stable human sperm motility	S8118-0724SPAR
Limulus Amoebocyte Lysate (LAL)	<0.03 EU/device	Passed	Do not contain endotoxin	E4124-0724SPAR

Quality Management system according to ISO 13485:2016

Sterilized by irradiation according to ISO 11137-1

Sterilization method: E-Beam

Sterility assurance level: 10⁻⁶

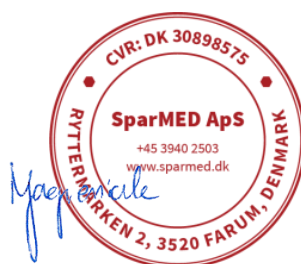
GOosafe with SparMED!

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SparMED ApS

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Sparmed ApS

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