

# Certificate of Analysis

**Product name: Oosafe® Sperm Collection Cup**

**Product type: Oosafe® Plasticware IVD**

**Product code: OOPW-SC01**

**Batch/LOT No.: 08923**

**Production date: 2023-07**

**Product expiry date: 2028-07**

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-2970-1023
Human Sperm Survival Assay (HSSA)	≥75% sperm motility after 24 hours proven	Passed	Stable human sperm motility	S6839-1023SPAR
Limulus Amoebocyte Lysate (LAL)	<0.03 EU/device	Passed	Do not contain endotoxin	E3516-1023SPAR

Quality Management system according to ISO 13485:2016

**Sterilized by irradiation according to ISO 11137-1**

**Sterilization method: E-Beam**

**Sterility assurance level: 10<sup>-6</sup>**

**GOosafe with SparMED!**

Manuela Jagieniak

Quality Control Department

SparMED ApS

Issue date: 14.11.2023

*Manuela Jagieniak*



**Sparmed ApS**

Ryttermarken 2, 3520 Farum, DK ● +4539402503 ● info@sparmed.dk ● www.sparmed.dk

Corp. VAT no.: DK 30 89 85 75