

# Certificate of Analysis

**Product name: Oosafe® Andrology Tube, 5 ml**

**Product type: Oosafe® Plasticware IVD**

**Product code: OOPW-AT10**

**Batch/LOT No.: 09112**

**Product expiry date: 2030-06**

| 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-1391-25-08 |
| Human Sperm Survival Assay (HSSA) | ≥75% sperm motility after 24 hours proven                                    | Passed  | Stable human sperm motility | SPAR-1393-25-08 |
| Limulus Amoebocyte Lysate (LAL)   | <0.03 EU/device  | Passed  | Do not contain endotoxin    | SPAR-1394-25-08 |

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>**

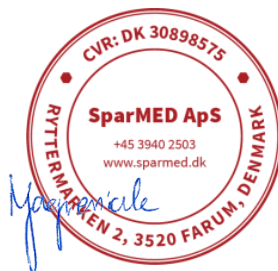
**GOosafe with SparMED!**

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Quality Control Department

SparMED ApS

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**Sparmed ApS**

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