

Certificate of Analysis

Product ID: Oosafe® ICSI/IMSI Dish for Sperm Selection

Product code: OOPW-IC03

LOT No.: 08055

Expiry date: 2025-04

Storage Conditions: 20-30°C, dry room, no exposure to sunlight

Quality Assurance:

| Analysis | Reference No. | Results | Completion date |
|--|----------------|---------|-----------------|
| Proven non-embryotoxic by Mouse Embryo Assay Test. Over 80% embryo development to the expanded blastocyst stage within 96 hours. | SPAR-4079-0620 | Passed | 06-06-2020 |
| Proved stable human sperm motility: ≥75% sperm motility after 24 hours proven. | S4478-0620SPAR | Passed | 05-06-2020 |
| Proven non-toxic by Limulus Amebocyte Lysate (LAL) test. Pass criteria <0.03 EU/device. | E0252-0620SPAR | Passed | 02-06-2020 |
| Sterilization by gamma irradiation. Delivered irradiation dose: 8.6 kGy-9.5 kGy. Specified irradiation dose: 8.0 kGy-10.0 kGy. | N/A | Passed | N/A |

Quality Control according to ISO 13485:2016

GOosafe with SparMED!

Florencia Garcia
Quality Control Department
SparMED ApS
Date: 03-08-2020

