

Manufacturer:
Sparmed ApS/CVR.No.: 30898575
Ryttermarken 2, 3520 Farum, Denmark



ID: COA-07655

Certificate of Analysis

Date of issue: 07.08.2016
Product ID: Oosafe® Plasticware: OOPW-TF03
LOT No.: 07655
Expiry Date: 06/2021
Storage conditions: 20⁰C, dry room, no exposal to sun-light
Quality Assurance:

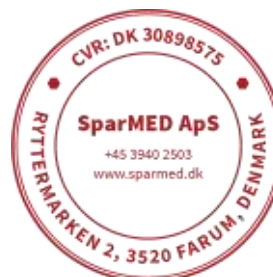
Proven non-embryotoxic by Mouse Embryo Assay Test. 100% embryo development to the expanded blastocyst stage within 96hours. **PASS**
Proved stable human sperm motility: ≥70% sperm motility after 24hours proven. **PASS**
Proven non-toxic by Limulus Amebocyte Lysate (LAL) test. Pass criteria <0.03 EU/device **PASS**
Proven RNase DNase test FREE- **PASS**
Sterilization by gamma irradiation. Delivered irradiation dose: 8.6kGy-9.5kGy. Specified irradiation dose: 8.0kGy-10.0kG- **PASS**

Quality control according to the ISO 13485:2012

Final approval:
Stamp:

A handwritten signature in blue ink, appearing to read 'C. Nielsen'.

Camilla Inesa Nielsen
Regulatory Affairs Manager





SparMED Aps
Ryttermarken 2
3520 Farum
Denmark



ELI Accession Number: SPAR-5284-0816 Date of completion: 08-06-2016

Lot number: 07655 Reference number: OOPW-TF03

Description of test article(s): Oosafe® 35mm Dish, High Wall

Assay system requested by customer: 100µl of culture medium was placed into the test article and overlaid with oil. One-cell mouse embryos were then placed into the test article and cultured for 96-hours.

Control assay method and results: 15 one cell (B6C3F1 X B6D2F1) embryos were cultured in 1mL drop of culture medium overlaid with oil in a Central Well Dish Lot 07603:

15 / 15 (100 %) 1-cell to 2-cell within 24 hr
15 / 15 (100 %) 1-cell to expanded blastocyst within 96 hr

For a valid assay, Embryotech™ requires at least 70% of one cell stage control embryos to develop to expanded blastocyst within 96-hours.

Test assay method and results: 21 one cell (B6C3F1 X B6D2F1) embryos were cultured in a 100µl drop of culture medium overlaid with oil in the test article:

21 / 21 (100 %) 1-cell to 2-cell within 24 hr
21 / 21 (100 %) 1-cell to expanded blastocyst within 96 hr

Summary of observations: All test and control embryos were selected randomly from a common pool of freshly collected embryos and were cultured in the same incubator at 37°C and 5.0% CO₂. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 100 percent of the embryos cultured in the test article developed to the expanded blastocyst stage within 96-hours.

Signature
Study Director

08-08-2016
Date

Signature
Quality Reviewer

08-08-2016
Date



SparMED Aps
Ryttermarken 2
3520 Farum
Denmark



140 Hale Street
Haverhill, MA 01830
qc@embryotech.com

ELI Accession Number: S2614-0816SPAR

Date of completion: 08-03-2016

Lot number: 07655

Order numbers: OOPW-HD10, OOPW-CW05, OOPW-TF03

Description of test article(s): Oosafe® 100mm Dish, Center Well Dish with 2 Compartments, Label Area Grip and 35mm Dish, High Wall

Assay system requested by customer: 1mL of sperm wash medium with sperm was added to the test articles (3 test articles pooled) and incubated for 24-hours. Post incubation the sperm wash medium with sperm was extracted from the test articles and pooled. The forward progressive motility was read and recorded at 24-hours.

Results:

| | | | | | |
|---------------------------------|---------------|---------|------------------|--------------|-----------|
| Test method: SOP/TSG/ELI/008 | Specification | Initial | Result % 24hr | SMI Value | Pass/Fail |
|---------------------------------|---------------|---------|------------------|--------------|-----------|

| Test Article | Specification | Initial | Result % 24hr | SMI Value | Pass/Fail |
|--------------|-----------------|---------|------------------|--------------|-----------|
| Test Article | SMI \geq 0.75 | 96% | 96% | 1.00 | Pass |
| Control | \geq 70% | 96% | 96% | N/A | Pass |

Summary of observations: All test and control sperm was prepared from the same donor and incubated in the same incubator at 32°C and 5% CO₂. The control sperm had a 96% forward progressive motility at 24-hours. The test article sperm had a 96% forward progressive motility at 24-hours.


Signature
Study Director

08-04-2016
Date


Signature
Quality Reviewer

08-05-2016
Date



SparMED Aps
Ryttermarken 2
3520 Farum
Denmark



140 Hale Street
Haverhill, MA 01830
qc@embryotech.com

ELI Accession Number: E7226-0816SPAR

Date of completion: 08-02-2016

Lot number: 07655

Reference number(s): OOPW-HD10, OOPW-CW05, OOPW-TF03

Description of test article(s): Oosafe® 100mm Dish, Center Well Dish with 2 Compartments, Label Area Grip and 35mm Dish, High Wall

Assay system requested by customer: Endotoxin titer and interference screening using the Gel-Clot method.

Control assay materials: Lysate: Lot number 515-08-746, Sensitivity (λ) = 0.03125 EU/mL


Control Standard Endotoxin (CSE): Lot number 148

LAL Reagent Water (LRW): Lot number AZA182110

Results:

| Control Standard Series | | | Test Sample Dilutions | NPC | | PPC | |
|----------------------------|---|---|-----------------------|-----|---|-----|---|
| 2 λ .06 | + | + | Undiluted | - | - | + | + |
| λ .03 | + | + | 1:2 | - | - | + | + |
| $\frac{1}{2}\lambda$.015 | - | - | 1:4 | - | - | + | + |
| $\frac{1}{4}\lambda$.0075 | - | - | 1:8 | - | - | + | + |
| NWC | - | - | 1:16 | - | - | + | + |


Summary of observations: The error for the Gel-Clot assay is +/- one two-fold dilution. The test article in this assay indicates an Endotoxin Concentration of <0.03125 EU/device.



Signature
Study Director

08-03-2016

Date



Signature
Quality Reviewer

08-03-2016

Date