

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



ID: COA-07603

## Certificate of Analysis

**Date of issue:** 14.03.2016  
**Product ID:** Oosafe® Plasticware: OOPW-ST02  
**LOT No.:** 07603  
**Expiry Date:** 10/2020  
**Storage conditions:** 20°C, 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 'Katrine Nobel'.



Katrine Nobel  
Quality Control Manager

# QC

## Certificate of Analysis

**REQUESTED BY:** SparMED ApS (Ryttermarken 2, Farum 03520 Denmark)

**ASSAY REQUESTED BY CUSTOMER:** MEA - Standard Mouse embryo assay

**OPERATION PROCEDURE:** SOP-MEA-00  
**TYPE OF ASSAY:** Direct  
**INTERNAL NUMBER:** MEA.006.184.2016  
**DATE:** 07/03/2016 - 11/03/2016

**DESCRIPTION OF TEST PRODUCT:** Oosafe 60mm Dish, Label Area Grip  
**REF:** OOPW-ST02  
**LOT NUMBER:** 07603  
**EXP. DATE:** 31/10/2020

### PROTOCOL:

Test "Oosafe 60mm Dish, Label Area Grip" dishes were prepared with previously tested medium in triplicate and equilibrated overnight prior to use. Fresh 1-cell stage mouse embryos were collected from F1 hybrid females (B6/CBA) crossed with males from the same genetic background, washed thoroughly and cultured at 37.3°C and optimal %CO<sub>2</sub> and %O<sub>2</sub> conditions in test dishes up to Day 5. Control group was prepared following the same set-up and conditions, and embryos cultured in parallel using previously tested dishes. Embryo development of test and control group was followed every 24 h and photos were taken and included in this report (annex I).

### CONTROL AND TEST ASSAY RESULTS:

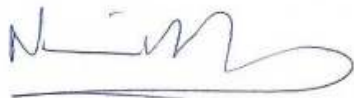
Embryo developmental rates of control and tested group.

| Embryo development rates                            |    |                               |                                 |  |                |
|---|----|-------------------------------|---------------------------------|--|----------------|
|   | n  | Day 2<br>Two-cell stage n (%) | Day 5<br>Blastocyst stage n (%) | Good Quality (morphology)<br>Blastocysts n (%) | Result         |
| Control   | 15 | 15 (100)                      | 15 (100)                        | 15 (100)                                       | <b>Passed*</b> |
| Oosafe 60mm Dish,<br>Label Area Grip<br>(Lot:07603) | 21 | 21 (100)                      | 21 (100)                        | 19 (90.48)                                     | <b>Passed*</b> |

**SUMMARY OF OBSERVATIONS:** All test and control embryos were selected randomly from a common pool and cultured at 37.3°C with a tri-gas atmosphere with optimal %CO<sub>2</sub> and %O<sub>2</sub>. Acceptance criteria of this standard test is ≥80% of mouse embryos must develop to the expanded blastocyst stage and pass a visual morphological examination of the inner cell mass (ICM) and trophectoderm (TE) cells.

\*More than 80% of the test group embryos developed to the expanded blastocyst stage within 5 days, fulfilling acceptance criteria for this test.

Nuno Costa-Borges, PhD



Scientific Director

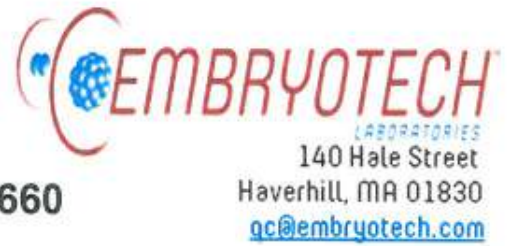
Gloria Calderón, PhD



Quality Assurance



**SparMED Aps**  
**Toppevadvej 34-38, DK-3660**  
**Stenlose, Denmark**



140 Hale Street  
 Haverhill, MA 01830  
[qc@embryotech.com](mailto:qc@embryotech.com)

**ELI Accession Number:** S2325-1215SPAR

**Date of completion:** 12-22-2015

**Lot number:** 07603

**Order numbers:** OOPW-IC02, OOPW-IC04, OOPW-IC05,  
 OOPW-ST02, OOPW-ST04, OOPW-ST05,  
 OOPW-CW04, OOPW-CW06, OOPW-CW07

**Description of test article(s):**

Oosafe® ICSI/IMSI Dish for Sperm Selection, 60mm Dish, Center Well Dish

**Assay system requested by customer:** 100µL of sperm wash medium was added to the test articles (9 test articles pooled) and incubated for 30-minutes. Post incubation the sperm wash medium was extracted from the test articles and pooled. The pooled extracted medium was placed in OOPW-CW07 with the sperm and incubated for 24-hour incubation.

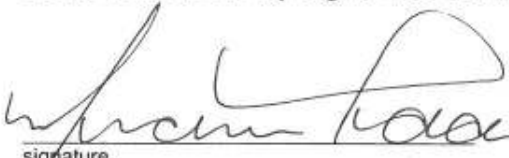
**Test Assay method and results:** A non-frozen donor sperm specimen was obtained and used for this assay. The sperm was prepared and the motile fraction separated using a sperm gradient and centrifuge cycle. The motility was noted at the beginning of the assay and again at 24-hours using a measure depth Makler Chamber System. Analyses were performed in sequence each time, with no more than 5-minutes between the test and the control samples.

**Results:**

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

|              |            |     |     |      |      |
|--------------|------------|-----|-----|------|------|
| Test Article | SMI ≥ 0.75 | 95% | 93% | 0.98 | Pass |
| Control      | ≥ 70%      | 95% | 95% | N/A  | Pass |

**Summary of observations:** The motility remained consistent in the test article extract and control while in an incubator atmosphere of 32°C and 5% CO<sub>2</sub>. Neither the test nor the control showed any signs that the motility was affected during the course of the assay.

  
 signature  
 Study Director

12-22-2015  
 date

  
 signature  
 Quality Reviewer

12-22-2015  
 date



SparMED Aps  
 Toppevadvej 34-38  
 DK-3660  
 Stenlose, Denmark



ELI Accession Number: E6767-1215SPAR

Date of completion: 12-18-2015

Lot number: 07603

Order number(s): OOPW-IC02, OOPW-IC04, OOPW-IC05,  
 OOPW-ST02, OOPW-ST04, OOPW-ST05,  
 OOPW-CW04, OOPW-CW06, OOPW-CW07

Description of test article(s):

Oosafe® ICSI/IMSI Dish for Sperm Selection, 60mm Dish, Center Well Dish

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

LAL lot number: 515-05-733

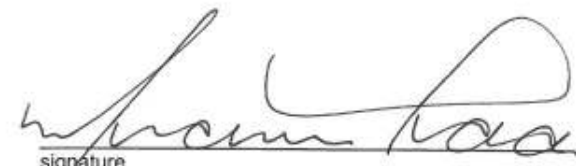
Sensitivity ( $\lambda$ ) = 0.03 EU/mL

CSE lot number: 143

LRW lot number: AZA182110

| Control Standard Series    |   |   | Test Sample Dilutions | NPC |   | PPC |   |
|----------------------------|---|---|-----------------------|-----|---|-----|---|
| 2 $\lambda$ .06            | + | + | Undiluted             | -   | - | +   | + |
| $\lambda$ .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 < 0.03 EU/device.

  
 signature  
 Study Director

12-22-2015  
 date

  
 signature  
 Quality Reviewer

12-22-2015  
 date



## RNase Test Data and Results

Date: 1/7/2016  
Company: Sparmed ApS  
Date received: 1/4/2016

Project #: 113376A  
Contact: Onur Ozturk  
Technician: Chase Wong

PO#: 122715  
Phone: 45- 39 40 2503

| Products tested:                         | Product code: | Lot #: |
|--|---------------|--------|
| Oosafe Sperm Collection Cup              | OOPW-SC01     | 07603  |
| Oosafe 35 MM DISH                        | OOPW-TF04     | 07603  |
| Oosafe 35 MM DISH                        | OOPW-TF05     | 07603  |
| Oosafe CENTER WELL                       | OOPW-CW04     | 07603  |
| Oosafe CENTER WELL                       | OOPW-CW06     | 07603  |
| Oosafe CENTER WELL                       | OOPW-CW07     | 07603  |
| Oosafe 60MM DISH                         | OOPW-ST02     | 07603  |
| Oosafe 60MM DISH                         | OOPW-ST04     | 07603  |
| Oosafe 60MM DISH                         | OOPW-ST05     | 07603  |
| Oosafe ICSI/MSI DISH for Sperm Selection | OOPW-IC02     | 07603  |

### Extraction:

Extract solution: DEPC Treated Water  
Lot #: DW15A6  
Volume: 200µl

Number of test items exposed to extract solution: 10  
Special extraction instructions: All items tested pooled

### Procedure and Controls:

RNA: 6.0 kb Poly (A)-tailed  
RNA lot #: 1310020  
Salts: MgCl<sub>2</sub> and NaCl  
Salt lot #: S15G2

RNA standard pool: 3µl of RNA + 12µl Salts.  
Volume of each standard reaction: 5µl  
Volume of extract added to the standard: 10µl  
Total volume: 15µl

Negative Control (-): RNA and salt standards with 10 µl of unexposed extract solution added

Positive Control (+): RNA and salt standards with 10 µl of extract solution exposed to RNase from a tip touched by un-gloved hands

Incubation periods: 1 hr @ 37°C, followed by 5 minutes at 65°C

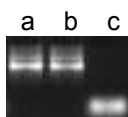
### Gel Electrophoresis:

2µl gel loading dye + 15µl reaction is loaded on a 1.2% agarose in ½ X TAE gel

Gel loading dye lot #: DD006

Electrophoresis: 20 minutes @ 80 volts

### Photographic Results:



Lane (a) Pooled products, (b) unexposed RNA standard as a negative control, (c) RNA standard exposed to RNase as a positive control.

### Conclusions:

There is no visible degradation in lanes (a) and (b). Lane (a) represents the product sample and lane (b) represents the negative control. Lane (c), which represents the RNA standard, exposed to RNase as a positive control shows degradation of the RNA. The results suggest that the product sample is free of detectable RNase contamination.

### Recommendations:

Based on this experimental procedure, we can show a definite risk of RNase contamination if your product is touched by un-gloved hands. We suggest that all operations are monitored and personnel are instructed in the importance of avoiding RNase contamination.



Chase Wong  
Lab Technician

1/11/2016  
Date



Carl Tsang  
Q.A.

1/11/2016  
Date



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### RNase FREE CERTIFICATE OF ANALYSIS

1/11/2016

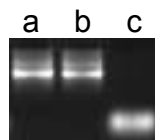
The following sample obtained from **Sparmed ApS** on 1/4/2016 is free of any detectable RNase contamination.

| <u>PRODUCTS TESTED</u>                    | <u>PRODUCT CODE</u> | <u>LOT NUMBER</u> |
|---|---------------------|-------------------|
| Oosafe Sperm Collection Cup               | OOPW-SC01           | 07603             |
| Oosafe 35 MM DISH                         | OOPW-TF04           | 07603             |
| Oosafe 35 MM DISH                         | OOPW-TF05           | 07603             |
| Oosafe CENTER WELL                        | OOPW-CW04           | 07603             |
| Oosafe CENTER WELL                        | OOPW-CW06           | 07603             |
| Oosafe CENTER WELL                        | OOPW-CW07           | 07603             |
| Oosafe 60MM DISH                          | OOPW-ST02           | 07603             |
| Oosafe 60MM DISH                          | OOPW-ST04           | 07603             |
| Oosafe 60MM DISH                          | OOPW-ST05           | 07603             |
| Oosafe ICSI/IMSI DISH for Sperm Selection | OOPW-IC02           | 07603             |

Product was tested for RNase activity by the following protocol:

Product was extracted in RNase free water. The extract was then added to an RNA standard. The RNA standard was incubated at 37° C for 1 hour then heated to 65° C for 5 minutes. RNA samples were then run on an agarose gel, photographed, and evaluated for degradation.

**FIGURE 1.**




Lane (a) **Pooled products**, (b) unexposed RNA standard as a negative control, (c) RNA standard exposed to RNase as a positive control.

**Conclusions:**

No visible degradation is present in the product sample. The product can therefore be considered RNase free.

**Comments:**

The Test Sensitivity is 10<sup>-9</sup> Kunitz Units/ µl.



Certified by: Chase Wong, 1/11/2016



Q.A. Carl Tsang, 1/11/2016

## DNase Test Data and Results

Date: 1/7/2016  
Company: Sparmed ApS  
Date Received: 1/4/2016

Project #: 113376B  
Contact: Onur Ozturk  
Technician: Chase Wong

PO#: 122715  
Phone: 45- 39 40 2503

| Products tested:                          | Product code: | Lot #: |
|---|---------------|--------|
| Oosafe Sperm Collection Cup               | OOPW-SC01     | 07603  |
| Oosafe 35 MM DISH                         | OOPW-TF04     | 07603  |
| Oosafe 35 MM DISH                         | OOPW-TF05     | 07603  |
| Oosafe CENTER WELL                        | OOPW-CW04     | 07603  |
| Oosafe CENTER WELL                        | OOPW-CW06     | 07603  |
| Oosafe CENTER WELL                        | OOPW-CW07     | 07603  |
| Oosafe 60MM DISH                          | OOPW-ST02     | 07603  |
| Oosafe 60MM DISH                          | OOPW-ST04     | 07603  |
| Oosafe 60MM DISH                          | OOPW-ST05     | 07603  |
| Oosafe ICSI/IMSI DISH for Sperm Selection | OOPW-IC02     | 07603  |

### Extraction:

Extract solution: DEPC Treated Water      Number of test items exposed to extract solution: 10  
Lot #: DW15A6      Special extraction instructions: All items tested pooled  
Volume: 200µl

### Procedure and Controls:

DNA: 1 kb Ladder      DNA standard pool: 3µl of DNA + 12µl Salts.  
DNA lot #: 1735579      Volume of each standard reaction: 5µl  
Salts: MgCl<sub>2</sub> and NaCl      Volume of extract added to the standard: 10µl  
Salt lot #: S15G2      Total volume: 15µl

Negative Control (-): DNA and salt standards with 10 µl of unexposed extract solution added

Positive Control (+): DNA and salt standards with 10 µl of extract solution exposed to DNase from a tip exposed to human saliva

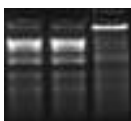
Incubation periods: 1 hr @ 37°C, followed by 5 minutes at 65°C

### Gel Electrophoresis:

2µl gel loading dye + 15µl reaction is loaded on a 1.2% agarose in ½ X TAE gel  
Gel loading dye lot #: DD006      Electrophoresis: 30 minutes @ 80 volts

### Photographic Results:

a   b   c



Lane (a) Pooled products, (b) unexposed DNA standard as a negative control, (c) DNA standard exposed to DNase as a positive control.

### Conclusions:

There is no visible degradation in lanes (a) and (b). Lane (a) represents the product sample and lane (b) represents the negative control. Lane (c), which represents the DNA standard, exposed to DNase as a positive control shows degradation of the DNA. The results suggest that the product sample is free of detectable DNase contamination.

### Recommendations:

Based on this experimental procedure, we can show a definite risk of DNase contamination if your product is exposed to saliva. We suggest that all operations are monitored and personnel are instructed in the importance of avoiding DNase contamination.

Chase Wong  
Lab Technician

1/11/2016  
Date

Carl Tsang  
Q.A.

1/11/2016  
Date



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**DNase FREE CERTIFICATE OF ANALYSIS**

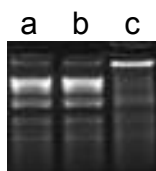
1/11/2016

The following sample obtained from **Sparmed ApS** on 1/4/2016 is free of any detectable DNase contamination.

| <u>PRODUCTS TESTED</u>                    | <u>PRODUCT CODE</u> | <u>LOT NUMBER</u> |
|---|---------------------|-------------------|
| Oosafe Sperm Collection Cup               | OOPW-SC01           | 07603             |
| Oosafe 35 MM DISH                         | OOPW-TF04           | 07603             |
| Oosafe 35 MM DISH                         | OOPW-TF05           | 07603             |
| Oosafe CENTER WELL                        | OOPW-CW04           | 07603             |
| Oosafe CENTER WELL                        | OOPW-CW06           | 07603             |
| Oosafe CENTER WELL                        | OOPW-CW07           | 07603             |
| Oosafe 60MM DISH                          | OOPW-ST02           | 07603             |
| Oosafe 60MM DISH                          | OOPW-ST04           | 07603             |
| Oosafe 60MM DISH                          | OOPW-ST05           | 07603             |
| Oosafe ICSI/IMSI DISH for Sperm Selection | OOPW-IC02           | 07603             |

Product was tested for DNase activity by the following protocol:  
 Product was extracted in DNase free water. The extract was then added to a DNA standard. The DNA standard was incubated at 37° C for 1 hour then heated to 65° C for 5 minutes. DNA samples were then run on an agarose gel, photographed, and evaluated for degradation.

**FIGURE 1.**



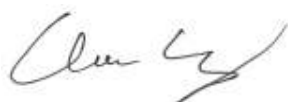
Lane (a) **Pooled products**, (b) unexposed DNA standard as a negative control, (c) DNA standard exposed to DNase as a positive control.

**Conclusions:**

No visible degradation is present in the product sample. The product can therefore be considered DNase free.

**Comments:**

The Test Sensitivity is 10<sup>-7</sup> Kunitz Units/ µl.



Certified by: Chase Wong, 1/11/2016



Q.A. Carl Tsang, 1/11/2016