Manufacturer:
Sparmed ApS/CVR.No.: 30898575
Toppevadvej 34-38, 3660 Stenløse, Denmark

ID: *COA-07506*

Certificate of Analysis

Date of issue: 10.08.2015

Product ID: Oosafe® Plasticware: OOPW-SC01

LOT No.: 07506

Expiry Date: 11/2018

Storage conditions: 20^{0}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: Katrine Nobel
Quality Control Manager

Stamp: CVR: DK 30898575 SparMED ApS +45 3940 2503 www.sparmed.dk RYTTERMARKEN 2, 3520 FARUM, DENMARK

RNase Test Data and Results

Date: 3/10/2014
Company: SPARMED ApS
Date received: 3/7/2014

Project #: 112118A
Contact: ONUR OZTURK
Technician: Laura Gloss

PO#: 080314-01
Phone: 4539402503

Products tested:	**Product code:**	**Lot #:**
Oosafe 60 mm Dish	**OOPW-ST01**	**07506**
Oosafe Center Well Dish	**OOPW-CW01**	**07506**
Oosafe Sperm Collection Cup	**OOPW-SC01**	**07506**

Extraction:
Extract solution: DEPC Treated Water
Lot #: DW14A21
Volume: 1000µl

Number of test items exposed to extract solution: 10
Special extraction instructions: Extracted products according to extraction protocol #155.

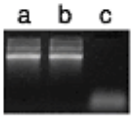
Procedure and Controls:
RNA: 6.0 kb Poly (A)-tailed
RNA lot #: 1307019
Salts: $MgCl_2$ and NaCl
Salt lot #: S13G12

RNA standard pool: 5µl of RNA + 20µl 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 ungloved 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 #: DD007
Electrophoresis: 20 minutes @ 80 volts

Photographic Results:



Lane (a) **product samples**, (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 samples 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 samples are 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.

Laura Gloss
Lab Technician

3/11/2014
Date

Carl Tsang
Q.A.

3/11/2014
Date

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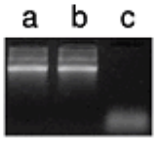
RNase FREE CERTIFICATE OF ANALYSIS

3/11/2014
The following samples obtained from **SPARMED ApS** on **3/7/2014** are free of any detectable RNase contamination.

PRODUCTS TESTED	PRODUCT CODE	LOT NUMBER
Oosafe 60 mm Dish	**OOPW-ST01**	**07506**
Oosafe Center Well Dish	**OOPW-CW01**	**07506**
Oosafe Sperm Collection Cup	**OOPW-SC01**	**07506**

Products were tested for RNase activity by the following protocol:
Products were 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) **product samples** (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 samples. The products can therefore be considered RNase free.

Comments:
The Test Sensitivity is 10^{-9} Kunitz Units/ µl.

Certified by: Laura Gloss, 3/11/2014

Q.A. Carl Tsang, 3/11/2014

CERTIFICATE OF ANALYSIS

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

EMBRYOTECH™ laboratories

ELI accession number: S1847-0314SPAR **Date of completion:** 03-06-2014

Reference number: OOPW-SC01, OOPW-CW01, OOPW-ST01 **Lot number:** 07506

Description of test article(s): Oosafe® Sperm Collection Cup, Center Well Dish, 60mm Dish

Assay system requested: Human Sperm was placed in each test article and incubated at room temperature for 24-hours. Post incubation the sperm was pooled from each test article and a 10µl sample was extracted for analysis.

Test Assay materials 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: SOP/TSG/ELI/008	Specification	Result % Initial	Result % 24hr	SMI Value	Pass/Fail
Test Article	SMI ≥ 0.75	94%	94%	1.00	Pass
Control	≥ 70%	94%	94%	N/A	Pass

Summary of observations: The motility remained consistent in the tube containing the test media while on the bench at room temperature. Both the test article and control showed no sign of affecting motility during the course of the assay.

signature
Study Director

03-07-2014
date

signature
Quality Reviewer

03-07-2014
date

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CERTIFICATE OF ANALYSIS

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ELI Accession Number: SPAR-3841-1115 **Date of completion:** 11-17-2015

Lot numbers: 07603, 07506 **Reference numbers:** OOPW-FW04, OOPW-HD10 OOPW-CT01, OOPW-SC01

Description of test article(s):
Oosafe® 4 Well Dish, 100mm Dish, Centrifuge Tube and Sperm Collection Cup

Assay system requested by customer: 1mL of culture medium was placed in each of the test articles (3) (OOPW-HD10, OOPW-CT01, OOPW-SC01) and incubated at 37°C for 30-minutes. Post incubation the culture medium was extracted from each test article and pooled. 0.5mL of the extracted culture medium was expelled into each well of the test article (4-well NonTreated dish); 1-cell mouse embryos were then added to each well of the test article and cultured for 96-hours.

Control assay method and results: 15 1-cell ($B_6C_3F_1$ X $B_6D_2F_1$) embryos were cultured in 0.5mL drops in a non-treated 4-Well Dish using culture medium:

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 1-cell stage control embryos to develop to expanded blastocyst within 96-hours.

Test assay method and results: 21 1-cell ($B_6C_3F_1$ X $B_6D_2F_1$) embryos were cultured in one of the test articles using the extracted culture medium:

21 / 21 (100 %)	1-cell to 2-cell within 24 hr
19 / 21 (90 %)	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% CO_2. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 90 percent of the embryos cultured in the test article developed to the expanded blastocyst stage within 96-hours.

signature
Study Director

11-17-2015
date

signature
Quality Reviewer

11-18-2015
date

CERTIFICATE OF ANALYSIS

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EMBRYOTECH LABORATORIES
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ELI Accession Number: E6685-1115SPAR

Date of completion: 11-13-2015

Lot number: 07506
Lot number: 07603

Order numbers: OOPW-IC01, OOPW-SC01, OOPW-ST01
Order numbers: OOPW-CT01, OOPW-CW05, OOPW-FW04, OOPW-HD10, OOPW-IC03, OOPW-TF02, OOPW-TF03

Description of test article(s): Oosafe® ICSI Dish, Sperm Collection Cup, 60mm Dish, Centrifuge Tube, Center Well Dish, 4 Well Dish-NonTreated, 100mm Dish, ICSI/IMSI Dish, 35mm Dish

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

LAL lot number: 513-05-647
CSE lot number: 143
LRW lot number: AYE162370

Sensitivity (λ) = 0.03 EU/mL

Control Standard Series			Test Sample Dilutions	NPC		PPC	
2 λ .06	+	+	Undiluted	-	-	+	+
λ .03	+	+	1:2	-	-	+	+
½λ .015	-	-	1:4	-	-	+	+
¼λ .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

11-18-2015
date

signature
Quality Reviewer

11-19-2015
date

Amended: 11-18-2015