

## Certificate of Analysis

**Date of issue:** 09.02.2017

**Product ID:** Oosafe<sup>®</sup> Plasticware: OOPW-HD10

**LOT No.:** 07730

**Expiry date:** 12/2021

**Storage Conditions:** 20°C, dry room, no exposal to sun-light

**Quality Assurance:**

Analyses	Results
Proven non-embryotoxic by Mouse Embryo Assay Test. Over 80% embryo development to the expanded blastocyst stage within 96hours.	Passed
Proved stable human sperm motility: $\geq 75\%$ sperm motility after 24hours proven.	Passed
Proven non-toxic by Limulus Amebocyte Lysate (LAL) test. Pass criteria $< 0.03$ EU/device	Passed
Sterilization by gamma irradiation. Delivered irradiation dose: 8.6kGy-9.5kGy. Specified irradiation dose: 8.0kGy-10.0kGy	Passed

Quality control according to the ISO 13485:2012

**GOosafe with SparMED!**

**Date:** 09.02.2017

Qi Wei

Quality Control Manager

SparMED ApS





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ELI Accession Number: SPAR-6219-0217

Date of completion: 02-06-2017

Lot number: 07719

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 in the test article and overlaid with oil. 21 one cell mouse embryos (7 per drop) were placed in each drop and cultured for 96-hours.

Control assay method and results: 15 one cell (B6C3F1 X B6D2F1) embryos were cultured in 100µl drop of culture medium overlaid with oil in a 35mm Dish:

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 the test article using culture medium:

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% CO<sub>2</sub>. 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.

  
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Signature  
Study Director

02-07-2017  
Date

  
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Signature  
Quality Reviewer

02-07-2017  
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ELI Accession Number: SPAR-6219-0217

Date of completion: 02-06-2017

Lot number: 07730

Reference number: OOPW-HD10

Description of test article(s): Oosafe® 100mm Dish

**Assay system requested by customer:** 1mL of culture medium was placed in the test article and overlaid with oil. 21 one cell mouse embryos (7 per drop) were placed in each drop and cultured for 96-hours.

**Control assay method and results:** 15 one cell (B<sub>6</sub>C<sub>3</sub>F<sub>1</sub> X B<sub>6</sub>D<sub>2</sub>F<sub>1</sub>) embryos were cultured in 100µl drop of culture medium overlaid with oil in a 35mm Dish:

15 / 15 (100 %)  
15 / 15 (100 %)

1-cell to 2-cell within 24 hr  
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.*

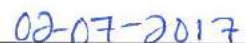
**Test assay method and results:** 21 one cell (B<sub>6</sub>C<sub>3</sub>F<sub>1</sub> X B<sub>6</sub>D<sub>2</sub>F<sub>1</sub>) embryos were cultured in a 1mL drop of culture medium overlaid with oil in the test article:

21 / 21 (100 %)  
21 / 21 (100 %)


1-cell to 2-cell within 24 hr  
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<sub>2</sub>. 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.

  
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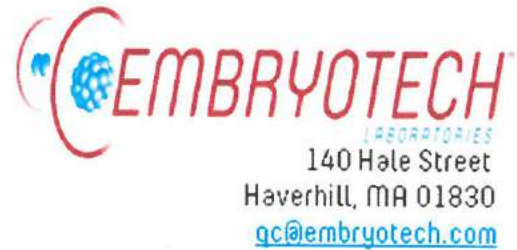
  
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ELI Accession Number: S2842-0217SPAR

Date of completion: 02-08-2017

Lot number: 07730, 07719

Order numbers: OOPW-SW03, OOPW-CT01

Description of test article(s): Oosafe® 6 Well Dish with Straw Holder, Centrifuge Tube


**Assay system requested by customer:** Sperm wash medium with sperm was added to the test articles (2 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
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Test Article	Specification	Initial	Result % 24hr	SMI Value	Pass/Fail
Test Article	SMI $\geq$ 0.75	94%	91%	0.97	Pass
Control	$\geq$ 70%	94%	94%	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% CO<sub>2</sub>. The control sperm had a 94% forward progressive motility at 24-hours. The test article sperm had a 91% forward progressive motility at 24-hours.

  
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02-08-2017  
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ELI Accession Number: S2842-0217SPAR

Date of completion: 02-08-2017

Lot number: 07719, 07730

Order numbers: OOPW-TF03, OOPW-HD10

Description of test article(s): Oosafe® 35mm Dish, High Wall, 100mm Dish

Assay system requested by customer: Sperm wash medium with sperm was added to the test articles (2 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:	Specification		Result %	SMI	Pass/Fail
SOP/TSG/ELI/008		Initial	24hr	Value	

Test Article	Specification	Initial	Result % 24hr	SMI Value	Pass/Fail
Test Article	SMI $\geq$ 0.75	94%	94%	1.00	Pass
Control	$\geq$ 70%	94%	94%	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% CO<sub>2</sub>. The control sperm had a 94% forward progressive motility at 24-hours. The test article sperm had a 94% forward progressive motility at 24-hours.

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ELI Accession Number: E7574-0217SPAR

Date of completion: 02-02-2017

Lot number(s): 07719  
07730

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

Description of test article(s): Oosafe® 35mm Dish, High Wall  
Oosafe® 100mm Dish

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

Control assay materials: Lysate: Lot number 515-12-761, Sensitivity ( $\lambda$ ) = 0.03125 EU/mL  
Control Standard Endotoxin (CSE): Lot number 148  
LAL Reagent Water (LRW): Lot number AAJ207283

Results:

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 <0.03125 EU/device.

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02-03-2017  
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