

Certificate of Analysis

Date of issue: 18.08.2017

Product ID: Oosafe® Plasticware: OOPW – AT10

LOT No.: 07791

Expiry date: 04.2022

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!

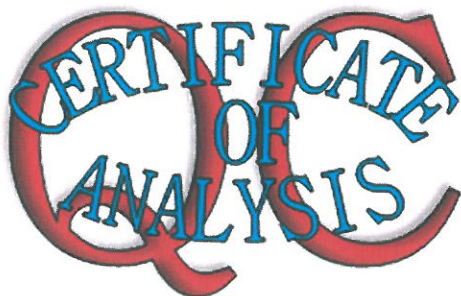
Date: 18.08.2017

Qi Wei

Quality Control Manager

SparMED ApS





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ELI Accession Number: S3058-0817SPAR

Date of completion: 08-09-2017

Lot number: 07791, 07730

Order numbers: OOPW-AT10, OOPW-CW05, OOPW-TF05

Description of test article(s): Oosafe® Andrology Tube, Center Well Dish, 35mm Dish

Assay system requested by customer: 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
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Test Article	Specification	Initial	Result % 24hr	SMI Value	Pass/Fail
Test Article	SMI \geq 0.75	97%	94%	0.98	Pass
Control	\geq 70%	97%	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 94% forward progressive motility at 24-hours.

Signature
Study Director

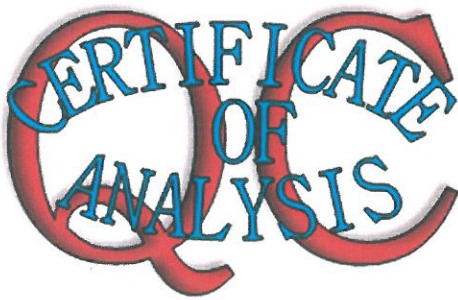
08-09-2017

Date

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Quality Reviewer

08-09-2017

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ELI Accession Number: E7970-0817SPAR

Date of completion: 08-07-2017

Lot numbers: 07710, 07791, 07730

Reference numbers: OOPW-IC02, OOPW-HD10
OOPW-OT10, OOPW-AT10
OOPW-CT01, OOPW-TF03
OOPW-CW05, OOPW-ST03
OOPW-SC01, OOPW-TF05

Description of test article(s): Oosafe® ICSI/IMSI Dish for Sperm Selection, 100mm Dish, OPU Tube, Andrology Tube, Centrifuge Tube, 35mm Dish, Center Well Dish, 60mm Dish, Sperm Collection Cup, 35mm 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 (λ) = 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 λ .06	+	+	Undiluted	-	-	+	+
λ .03	+	+	1:2	-	-	+	+
$\frac{1}{2}\lambda$.015	-	-	1:4	-	-	+	+
$\frac{1}{4}\lambda$.0075	-	-	1:8	-	-	+	+
NWC	-	-	1:16	-	-	+	+

SparMED requires a pass limit of <20 EU/device

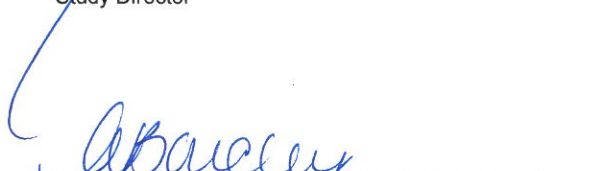
Summary of observations: The error for the Gel-Clot assay is +/- one two-fold dilution. The test article in this assay indicates an Endotoxin Concentration of <0.03125 EU/device.



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08-07-2017

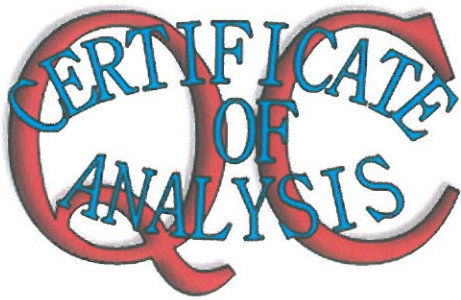
Date



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08-07-2017

Date



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ELI Accession Number: SPAR-7191-0717

Date of completion: 08-01-2017

Lot number: 07791

Reference number: OOPW-AT10

Description of test article(s): Oosafe® Andrology Tube, 5ml

Assay system requested by customer: 1mL 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 a 1mL drop of culture medium overlaid with oil in a IVF CENT. TUBE Reference number 137860:

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% 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.



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