

Certificate of Analysis

Date of issue: 6 Nov 2018

Product ID: Oosafe® Plasticware: OOPW-FW03

LOT No.: 07967

Expiry date: 2023-08

Storage Conditions: 20°C – 30°C, dry room, no exposal to sun-light

Quality Assurance:

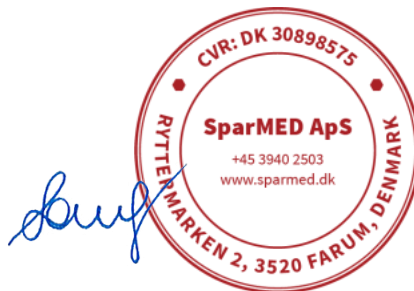
Analyses	Results
Proven non-embryotoxic by Mouse Embryo Assay Test. Over 80% embryo development to the expanded blastocyst stage within 96 hours.	Passed
Proved stable human sperm motility: $\geq 75\%$ sperm motility after 24 hours proven.	Passed
Proven non-toxic by Limulus Amebocyte Lysate (LAL) test.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

Quality control according to the ISO 13485:2012

GOosafe with SparMED!

Date: 6 Nov 2018

Simona Laurinavičiute
Quality Control Department
SparMED ApS





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ELI Accession Number: SPAR-9696-1018

Date of completion: 11-03-2018

Lot number: 07967

Reference number: OOPW-FW03

Description of test article(s): Oosafe® 4 Well Dish, Treated Surface

Assay system requested by customer: 0.5mL of culture medium was placed each well of the test article and overlaid with oil. 21 one cell mouse embryos (5-6 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 0.5mL drops of culture medium overlaid with oil in a 4-well 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% 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

Date

Signature
Quality Reviewer

Date



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ELI Accession Number: E8878-1018SPAR

Date of completion: 10-30-2018

Lot number(s): 07968, 07967
07966, 07965

Reference number(s): OOPW-CT01, OOPW-FW03
OOPW-OT10, OOPW-AT10

Description of test article(s): Oosafe® Centrifuge Tube, 4-Well Dish, OPU Tube, Andrology Tube

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

Control assay materials: Lysate: Lot number 516-07-792, Sensitivity (λ) = 0.03125 EU/mL

Control Standard Endotoxin (CSE): Lot number 154

LAL Reagent Water (LRW): Lot number AB10092197

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

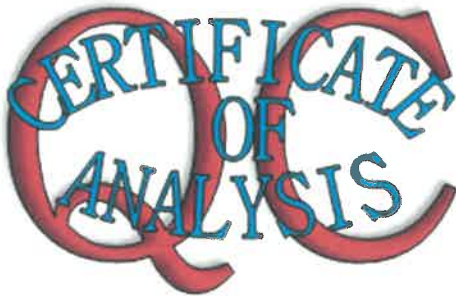
Summary of observations: The error for the Gel-Clot assay is +/- one two-fold dilution. The test article in this assay indicates an Endotoxin Concentration of <0.03125 EU/device.

Signature
Study Director

10-31-2018
Date

Signature
Quality Reviewer

10-31-2018
Date



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ELI Accession Number: S3592-1018SPAR

Date of completion: 10-31-2018

Lot number(s): 07968, 07966,
07965, 07967

Reference numbers: OOPW-CT01, OOPW-OT10,
OOPW-AT10, OOPW-FW03

Description of test article(s): Oosafe® Centrifuge Tube, Oosafe® OPU Tube,
Oosafe® Andrology Tube, Oosafe® 4 Well Dish, Treated Surface

Assay system requested by customer: 1mL of sperm wash medium was added to the test articles (4 test articles pooled) and incubated for 30-minutes. Post incubation the sperm wash medium was extracted from the test articles and pooled. 200µl of the pooled extracted medium was placed in the well of a 4-well dish with the sperm and incubated for 24-hour incubation. The forward progressive motility was read and recorded at 24-hours.

Results:

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

Test Article	Specification	Initial	Result %	SMI	Pass/Fail
Control	SMI ≥ 0.75	99%	96%	0.98	Pass
	≥ 70%	99%	98%	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 98% forward progressive motility at 24-hours. The test article sperm had a 96% forward progressive motility at 24-hours.

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