

Certificate of Analysis

Date of issue: 21 Nov 2018

Product ID: Oosafe® Plasticware: OOPW-ST03

LOT No.: 07962

Expiry date: 2023-07

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

Quality Assurance:

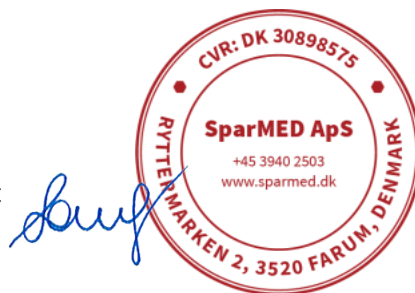
Analyses	Results
Proven non-embryotoxic by Mouse Embryo Assay Test. Over 80% embryo development to the expanded blastocyst stage within 96 hours.	Passed
Proved stable human sperm motility: $\geq 75\%$ sperm motility after 24 hours proven.	Passed
Proven non-toxic by Limulus Amebocyte Lysate (LAL) test. 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: 21 Nov 2018

Simona Laurinavičiute
Quality Control Department
SparMED ApS





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ELI Accession Number: S3526-0918SPAR

Date of completion: 09-19-2018

Lot number(s): 07963, 07960,
07962

Reference numbers: OOPW-CW05, OOPW-HD10,
OOPW-ST03

Description of test article(s): Oosafe® Center Well Dish with 2 Compartments,
Oosafe® 100mm Dish, Oosafe® 60mm Dish

Assay system requested by customer: 1mL of sperm wash medium was added to the test articles (3 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 % 24hr	SMI Value	Pass/Fail
SOP/TSG/ELI/008					
Test Article	SMI ≥ 0.75	98%	92%	0.94	Pass
Control	≥ 70%	98%	98%	N/A	Pass

Test method:	Specification	Initial	Result % 24hr	SMI Value	Pass/Fail
SOP/TSG/ELI/008					
Test Article	SMI ≥ 0.75	98%	92%	0.94	Pass
Control	≥ 70%	98%	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 92% forward progressive motility at 24-hours.

Signature
Study Director

Date

Signature
Quality Reviewer

Date



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ELI Accession Number: SPAR-9409-0918

Date of completion: 09-17-2018

Lot number: 07962

Reference number: OOPW-ST03

Description of test article(s): Oosafe® 60mm Dish

Assay system requested by customer: 1mL of culture medium was placed in the test article and overlaid with oil. One cell mouse embryos were placed in the 1mL drop of the culture medium 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:

15 / 15 (100 %)	1-cell to 2-cell within 24 hr
14 / 15 (93 %)	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 a 1mL drop of culture medium overlaid with oil in the test article:

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. 93 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.

S. Rosemwald

Signature
Study Director

09-17-2018

Date

[Signature]

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ELI Accession Number: E8775-0918SPAR

Date of completion: 09-13-2018

Lot number(s): 07963, 07961
 07960, 07962
 07964

Reference number(s): OOPW-CW05, OOPW-TF03
 OOPW-HD10, OOPW-ST03
 OOPW-IC03

Description of test article(s): Oosafe® Center Well Dish, 35mm Dish, 100mm Dish, 60mm Dish, ICSI/IMSI Dish for Sperm Selection

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 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.


 Signature
 Study Director

09-14-2018
 Date


 Signature
 Quality Reviewer

09-14-2018
 Date