

Manufacturer:
Sparmed ApS/CVR.No.: 30898575
Ryttermarken 2, 3520 Farum, Denmark



ID: COA-07710

Certificate of Analysis

Date of issue: 29.10.2016
Product ID: Oosafe® Plasticware: OOPW-IC02
LOT No.: 07710
Expiry Date: 09/2021
Storage conditions: 20⁰C, 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:
Stamp:

A handwritten signature in blue ink, appearing to read "Inesa".

Camilla Inesa Nielsen
Regulatory Affairs Manager





SparMED Aps
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140 Hale Street
Haverhill, MA 01830
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ELI Accession Number: SPAR-5714(R1)-1016

Date of completion: 10-28-2016

Lot number: 07710

Reference number: OOPW-IC02

Description of test article(s): Oosafe® ICSI/IMSI Dish for Sperm Selection

Assay system requested by customer: Three 20µl drops of the culture medium were 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 1mL drop of culture medium overlaid with oil in a Central Well Dish Lot 07551:

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:

20 / 21 (95 %)

1-cell to 2-cell within 24 hr

20 / 21 (95 %)

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. 95 percent of the embryos cultured in the test article developed to the expanded blastocyst stage within 96-hours.

Signature
Study Director

10-28-2016
Date

Signature
Quality Reviewer

10-28-2016
Date



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140 Hale Street
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ELI Accession Number: E7381-1016SPAR

Date of completion: 10-20-2016

Lot number(s): 07715
07710, 07722

Reference number(s): OOPW-ST03, OOPW-IC03
OOPW-IC02, OOPW-CW03

Description of test article(s):

Oosafe® 60mm Dish, Label Area Grip, ICSI/IMSI Dish for Sperm Selection,
Center Well Dish with 2 Compartments Label Area Grip

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 AZA182110

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	-	-	+	+

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

10-20-2016

Date



Signature
Quality Reviewer

10-20-2016

Date



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Denmark**



140 Hale Street
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ELI Accession Number: S2721-1016SPAR

Date of completion: 10-21-2016

Lot numbers: 07715
07710, 07722

Reference numbers: OOPW-ST03, OOPW-IC03
OOPW-IC02, OOPW-CW03

Description of test article(s):

Oosafe® 60mm Dish, Label Area Grip, ICSI/IMSI Dish for Sperm Selection, Center Well Dish with 2 Compartments Label Area Grip

Assay system requested by customer: 1mL of sperm wash medium with sperm was added to the test articles (4 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	SMI \geq 0.75	99%	98%	0.99	Pass
Control	\geq 70%	99%	99%	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 99% forward progressive motility at 24-hours. The test article sperm had a 98% forward progressive motility at 24-hours.

Signature
Study Director

10-24-2016
Date

Signature
Quality Reviewer

10-24-2016
Date