

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



ID: COA-07655

## Certificate of Analysis

**Date of issue:** 07.08.2016  
**Product ID:** Oosafe® Plasticware: OOPW-HD10  
**LOT No.:** 07655  
**Expiry Date:** 06/2021  
**Storage conditions:** 20<sup>0</sup>C, dry room, no exposal to sun-light  
**Quality Assurance:**

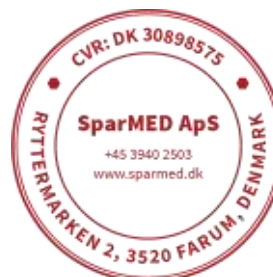
Proven non-embryotoxic by Mouse Embryo Assay Test. 100% embryo development to the expanded blastocyst stage within 96hours. **PASS**  
Proved stable human sperm motility: ≥70% sperm motility after 24hours proven. **PASS**  
Proven non-toxic by Limulus Amebocyte Lysate (LAL) test. Pass criteria <0.03 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 "C. Nielsen".

Camilla Inesa Nielsen  
Regulatory Affairs Manager





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ELI Accession Number: SPAR-5284-0816

Date of completion: 08-06-2016

Lot number: 07655

Reference number: OOPW-HD10

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

**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 1mL drop of culture medium overlaid with oil in a Central Well Dish Lot 07603:

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 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% 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.

Signature  
 Study Director

08-08-2016  
 Date

Signature  
 Quality Reviewer

08-08-2016  
 Date



SparMED Aps  
Ryttermarken 2  
3520 Farum  
Denmark



ELI Accession Number: S2614-0816SPAR

Date of completion: 08-03-2016

Lot number: 07655

Order numbers: OOPW-HD10, OOPW-CW05, OOPW-TF03

Description of test article(s): Oosafe® 100mm Dish, Center Well Dish with 2 Compartments, Label Area Grip and 35mm Dish, High Wall

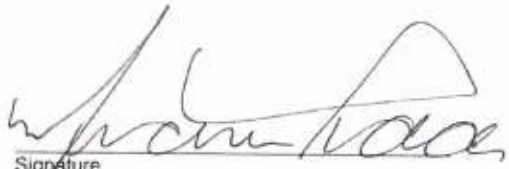
Assay system requested by customer: 1mL of sperm wash medium with sperm was added to the test articles (3 test articles pooled) and incubated for 24-hours. Post incubation the sperm wash medium with sperm was extracted from the test articles and pooled. The forward progressive motility was read and recorded at 24-hours.

**Results:**


Test method: SOP/TSG/ELI/008	Specification	Initial	Result % 24hr	SMI Value	Pass/Fail
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Test Article	SMI $\geq$ 0.75	96%	96%	1.00	Pass
Control	$\geq$ 70%	96%	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% CO<sub>2</sub>. The control sperm had a 96% forward progressive motility at 24-hours. The test article sperm had a 96% forward progressive motility at 24-hours.

  
Signature  
Study Director

08-04-2016  
Date

  
Signature  
Quality Reviewer

08-05-2016  
Date



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ELI Accession Number: E7226-0816SPAR

Date of completion: 08-02-2016

Lot number: 07655

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

Description of test article(s): Oosafe® 100mm Dish, Center Well Dish with 2 Compartments, Label Area Grip and 35mm Dish, High Wall

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

Control assay materials: Lysate: Lot number 515-08-746, Sensitivity ( $\lambda$ ) = 0.03125 EU/mL

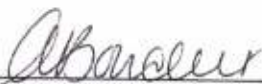
Control Standard Endotoxin (CSE): Lot number 148

LAL Reagent Water (LRW): Lot number AZA182110

Results:

Control Standard Series			Test Sample Dilutions	NPC		PPC	
2 $\lambda$ .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.

  
\_\_\_\_\_  
Signature  
Study Director

08-03-2016  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
Signature  
Quality Reviewer

08-03-2016  
\_\_\_\_\_  
Date