

**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-CW05  
**LOT No.:** 07655  
**Expiry Date:** 06/2021  
**Storage conditions:** 20<sup>0</sup>C, dry room, no exposal to sun-light  
**Quality Assurance:**

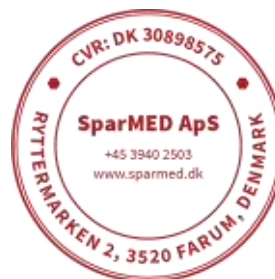
Proven non-embryotoxic by Mouse Embryo Assay Test. 100% embryo development to the expanded blastocyst stage within 96hours. **PASS**  
Proved stable human sperm motility: ≥70% sperm motility after 24hours proven. **PASS**  
Proven non-toxic by Limulus Amebocyte Lysate (LAL) test. Pass criteria <0.03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

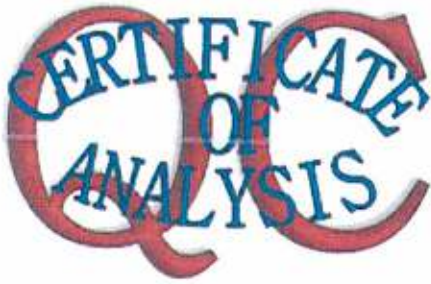
Quality control according to the ISO 13485:2012

**Final approval:**  
**Stamp:**

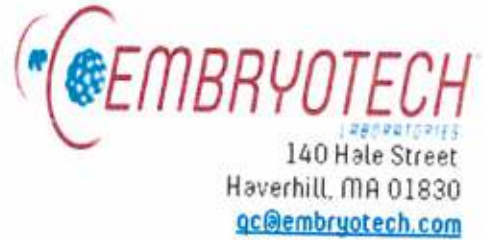
A handwritten signature in blue ink, appearing to read "C. Nielsen".

Camilla Inesa Nielsen  
Regulatory Affairs Manager





SparMED Aps  
Ryttermarken 2  
3520 Farum  
Denmark



ELI Accession Number: SPAR-5284-0816

Date of completion: 08-06-2016

Lot number: 07655

Reference number: OOPW-CW05

**Description of test article(s):**

Oosafe® Center Well Dish with 2 Compartments Label Area Grip

**Assay system requested by customer:** 1mL of culture medium was placed in the center well of 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 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



140 Hale Street  
Haverhill, MA 01830  
[qc@embryotech.com](mailto:qc@embryotech.com)

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.

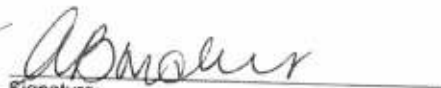
**Results:**

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



SparMED Aps  
Ryttermarken 2  
3520 Farum  
Denmark



140 Hale Street  
Haverhill, MA 01830  
[qc@embryotech.com](mailto:qc@embryotech.com)

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

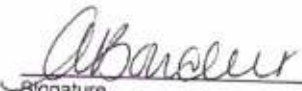
Control Standard Endotoxin (CSE): Lot number 148

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

08-03-2014  
Date

  
Signature  
Quality Reviewer

08-03-2016  
Date