

## Certificate of Analysis

**Date of issue:** 12 Feb 2018

**Product ID:** Oosafe® Plasticware: OOPW-TF03

**LOT No.:** 07827

**Expiry date:** 2022-08

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

**Quality Assurance:**

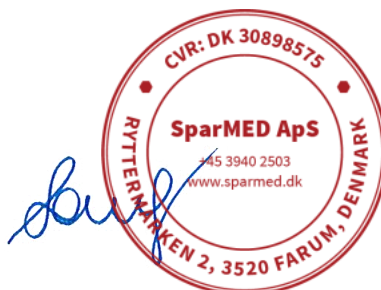
Analyses	Results
Proven non-embryotoxic by Mouse Embryo Assay Test. Over 80% embryo development to the expanded blastocyst stage within 96 hours.	Passed
Proved stable human sperm motility: ≥75% sperm motility after 24 hours proven.	Passed
Proven non-toxic by Limulus Amebocyte Lysate (LAL) test. Pass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

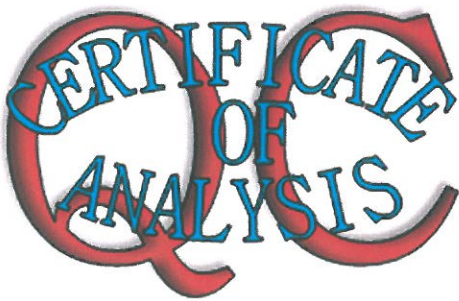
Quality control according to the ISO 13485:2012

**GOosafe with SparMED!**

**Date:** 12 Feb 2018

Simona Laurinaviciute  
Quality Control Department  
SparMED ApS





SparMED Aps  
Ryttermarken 2  
3520 Farum  
Denmark



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

ELI Accession Number: S3174-1117SPAR

Date of completion: 11-29-2017

Lot number: 07830, 07826, 07828, 07827

Order numbers: OOPW-HD10, OOPW-ST03,  
OOPW-CW03, OOPW-TF03

Description of test article(s): Oosafe® 100mm Dish,  
Oosafe® 60mm Dish Label Area Grip,  
Oosafe® Center Well Dish with 2 Compartments,  
Oosafe® 35mm Dish High Wall


**Assay system requested by customer:** Sperm wash medium was added to the test articles OOPW-ST03, OOPW-CW03, and OOPW-HD10 and incubated for 30 minutes. Post incubation the sperm wash medium was extracted from the test articles and pooled into OOPW-TF03. Sperm was added to the test article and incubated for 24 hours. 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%	83%	0.87	Pass
Control	$\geq$ 70%	96%	95%	N/A	Pass

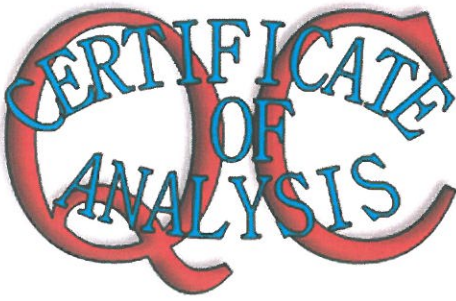
**Summary of observations:** All test and control sperm was prepared from the same donor and incubated in the same incubator at 32°C and 5% CO<sub>2</sub>. The control sperm had a 95% forward progressive motility at 24-hours. The test article sperm had a 83% forward progressive motility at 24-hours.

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

11.30.2017  
\_\_\_\_\_  
Date

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

11-30-2017  
\_\_\_\_\_  
Date



SparMED Aps  
Ryttermarken 2  
3520 Farum  
Denmark



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

ELI Accession Number: E8200-1117SPAR

Date of completion: 11-22-2017

Lot number(s): 07828, 07830  
07822, 07832  
07826, 07827  
07825

Reference number(s): OOPW-CW03, OOPW-HD10  
OOPW-OT10, OOPW-SW03  
OOPW-ST03, OOPW-TF03  
OOPW-SW02

Description of test article(s): Oosafe® Center Well Dish with 2 Compartment, 100mm Dish, OPU Tube, 6 Well Dish with Straw Holder, 60mm Dish, & 35mm Dish

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 ( $\lambda$ ) = 0.03125 EU/mL

Control Standard Endotoxin (CSE): Lot number 148

LAL Reagent Water (LRW): Lot number AAJ207283

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	-	-	+	+

SparMED requires a pass limit of <20 EU/device

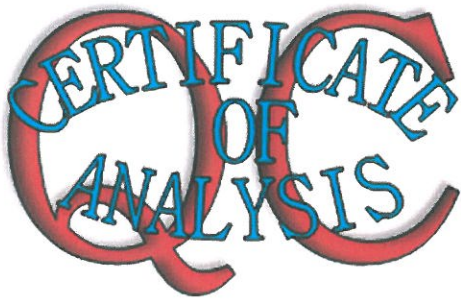
Summary of observations: The error for the Gel-Clot assay is +/- one two-fold dilution. The test article in this assay indicates an Endotoxin Concentration of <0.03125 EU/device.

Signature  
Study Director

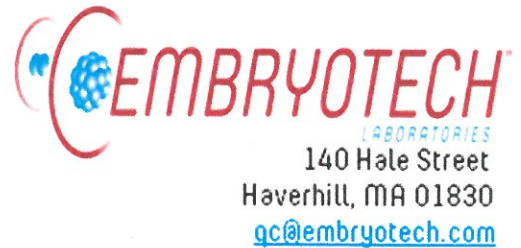
11-27-2017  
Date

Signature  
Quality Reviewer

11-27-2017  
Date



SparMED Aps  
Ryttermarken 2  
3520 Farum  
Denmark



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

ELI Accession Number: SPAR-7886-1117

Date of completion: 11-26-2017

Lot number: 07827

Reference number: OOPW-TF03

Description of test article(s): Oosafe® 35mm Dish, High Wall

**Assay system requested by customer:** 100µl of culture medium was placed in the test article and overlaid with oil. One cell mouse embryos were placed in the 100µl 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 35mm dish with 100µl of culture medium overlaid with oil:

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 100µl 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

11-30-2017

Date

Signature  
Quality Reviewer

11-30-2017

Date