

## Certificate of Analysis

**Date of issue:** 22 Aug 2018

**Product ID:** Oosafe® Plasticware: OOPW-FW04

**LOT No.:** 07947

**Expiry date:** 2023-03

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

**Quality Assurance:**

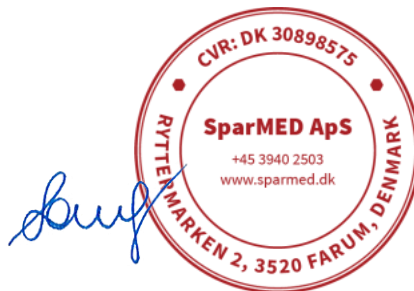
Analyses	Results
Proven non-embryotoxic by Mouse Embryo Assay Test. Over 80% embryo development to the expanded blastocyst stage within 96 hours.	Passed
Proved stable human sperm motility: $\geq 75\%$ sperm motility after 24 hours proven.	Passed
Proven non-toxic by Limulus Amebocyte Lysate (LAL) test.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

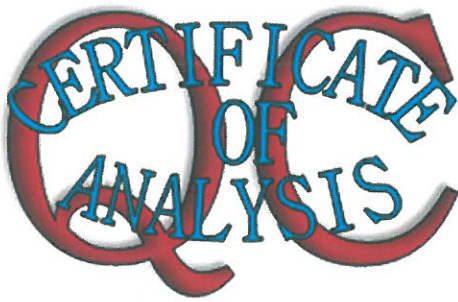
Quality control according to the ISO 13485:2012

**GOosafe with SparMED!**

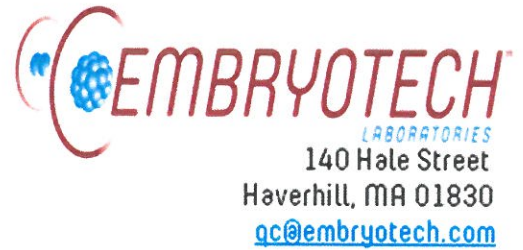
**Date:** 22 August 2018

Simona Laurinavičiute  
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: E8702-0818SPAR

Date of completion: 08-03-2018

Lot number: 07947

Reference number: OOPW-FW04

Description of test article(s): Oosafe® 4 Well Dish, Non-Treated Surface

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 154

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

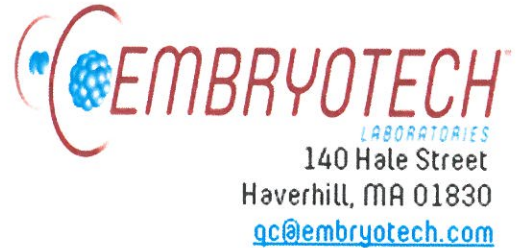
08-06-2018  
Date

Signature  
Quality Reviewer

08-06-2018  
Date



SparMED Aps  
Ryttermarken 2  
3520 Farum  
Denmark



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

ELI Accession Number: S3470-0818SPAR

Date of completion: 08-15-2018

Lot number: 07947

Order number: OOPW-FW04

Description of test article(s): Oosafe® 4 Well Dish, Non-Treated Surface

Assay system requested by customer: Sperm wash medium with 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
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Test Article	Specification	Initial	Result % 24hr	SMI Value	Pass/Fail
Test Article	SMI $\geq$ 0.75	98%	98%	1.00	Pass
Control	$\geq$ 70%	98%	98%	N/A	Pass

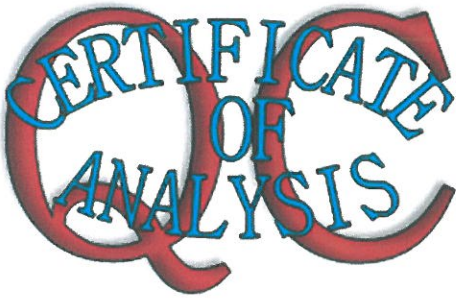
Summary of observations: All test and control sperm was prepared from the same donor and incubated in the same incubator at 32°C and 5% CO<sub>2</sub>. The control sperm had a 98% forward progressive motility at 24-hours. The test article sperm had a 98% forward progressive motility at 24-hours.

S. Rosemwald  
Signature  
Study Director

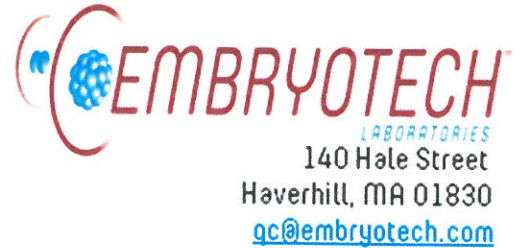
08-15-2018  
Date

M. Futin  
Signature  
Quality Reviewer

08-15-2018  
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-9200-0818

Date of completion: 08-07-2018

Lot number: 07947

Reference number: OOPW-FW04

Description of test article(s): Oosafe® 4 Well Dish, Non-Treated Surface

Assay system requested by customer: 0.5mL of culture medium was placed into each well of the test article and overlaid with oil. 21 one cell mouse embryos were placed in the test article (5-6 per well) and cultured for 96-hours.

Control assay method and results: 15 one cell (B6C3F1 X B6D2F1) embryos were cultured in in a 4 Well Dish:

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 the test article using culture medium:

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>. 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

08-07-2018

Date

M. Wald

Signature  
Quality Reviewer

08-07-2018

Date