

Certificate of Analysis

Product: Oosafe® Class IIA Medical Device Disinfectant

Product code: OOMD-00050, OOMD-01000, OOMD-05000, OOMDW-120

Batch/LOT No.: 60735

Production date: 03/2017

Expiry date: 03/2020

Analyses / Method	Specification	Result
Appearance / Visual	Clear liquid (inside wipes)	Clear liquid (inside wipes)
Odor / Olfactive	Mild to odorless	Mild
pH-Rate (2% active substance in water) / pH meter (DIN EN 1262)	6.5 – 8.5	6.8
Density, 20 °C, gr/cm ³ / DIN 51757	1.001 – 1.010	1.006
Quaternary Ammonium Compounds / QUAT test stripe		2.6 mg/g
Sodium nitrite		≤ 0.1 mg/g
Additives		3.2 mg/g
Water		The rest

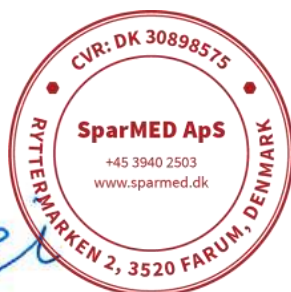
GOosafe with SparMED!

Qi Wei

Quality Control Manager

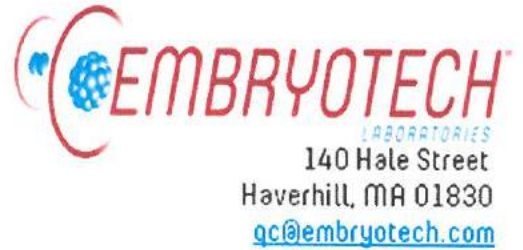
SparMED ApS

Date: 29.05.2017






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ELI Accession Number: S2967-0517SPAR

Date of completion: 05-24-2017

Lot number: 60735

Reference number: OOMD

Description of test article: Oosafe® Disinfectant

Assay system requested by customer: An incubator was cleaned with the test article. Post cleaning a prepared sperm sample was placed in the cleaned incubator for 24-hours. The forward progressive motility was read and recorded at 24-hours.

Results:

	<u>Initial motility</u>	<u>24hour motility</u>
Test Article (incubator ELI-103)	98 %	98 %
Control (incubator ELI-243)	98 %	98 %

Summary of observations: The motility of the sperm remained consistent in the incubator ELI-103 (that was cleaned with the test article) and the incubator ELI-243 (the control sperm).



Signature
Study Director

05-24-2017
Date

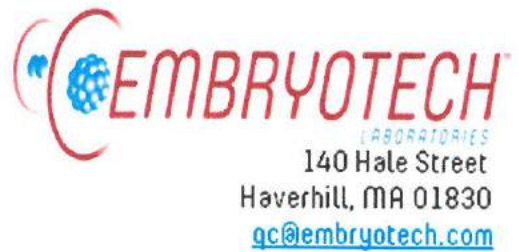


Signature
Quality Reviewer

05-24-2017
Date



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ELI Accession Number: SPAR-6802-0517

Date of completion: 05-23-2017

Lot number: 60735

Reference number: OOMD

Description of test articles: Oosafe® Disinfectant

Assay system requested by customer: An incubator was cleaned with the test article. Post cleaning a culture plate was set up and one-cell mouse embryos were cultured in the cleaned incubator with the test article for 96-hours.

Control assay method and results: 15 one cell (B6C3F1 X B6D2F1) embryos were cultured in triplicate micro drops of culture medium in control incubator ELI-181:

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 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 triplicate micro drops of culture medium while in incubator ELI-103 cleaned with 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. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 100 percent of the embryos cultured in an incubator previously cleaned with the test article developed to the expanded blastocyst stage within 96-hours.

Signature
Study Director

05-23-2017

Date

Signature
Quality Reviewer

05-23-2017

Date