

Certificate of Analysis

Product: **Oosafe® Class IIA Medical Device Disinfectant-Wipes**

Product code: **OOMDW-120**

Batch/LOT No.: **83605-MD**

Production date: **09-2018**

Expiry date: **09-2021**

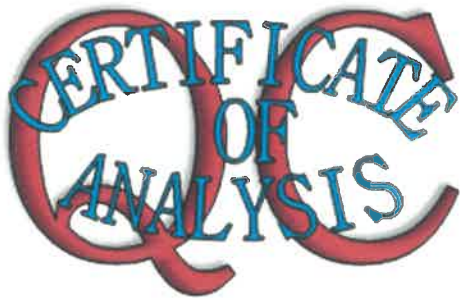
Analyses / Method	Specification	Result
Color / Visual	Clear liquid inside wipes	Clear liquid inside wipes
Odor / Olfactive	Odorless	Odorless
pH-rate (2% active substance in water) / pH meter (DIN EN 1262)	7,0 – 9,0	8,6
Density, 20 °C, gr/cm ³ / DIN 51757	1,001 – 1,010	1,005
Quaternary Ammonium Compounds	1,9 – 2,2 %	2,0 %
Water		The rest

GOosafe with SparMED!

Simona Laurinaviciute
Quality Control Department
SparMED ApS

Date: 15 Oct 2018





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ELI Accession Number: SPAR-9469-0918

Date of completion: 09-28-2018

Lot number: 83605-MD

Reference number: OOMDW-120

Description of test article: Oosafe Class IIA Medical Device Disinfectant

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

Control assay method and results: 15 one cell (B6C3F1 X B6D2F1) embryos were cultured in triplicate micro drops of culture medium; control incubator ELI-203:

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-248 previously cleaned with 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

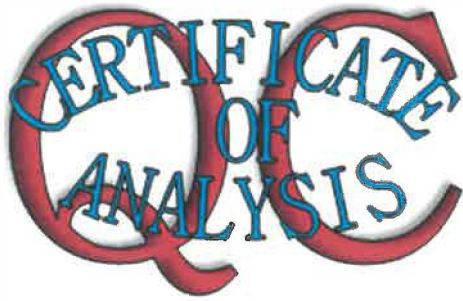
Summary of observations: All test and control embryos were selected randomly from a common pool of freshly collected embryos. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 100 percent of the embryos cultured in culture medium in the incubator that had been cleaned with the test article developed to the expanded blastocyst stage within 96-hours.

Signature
Study Director

Date

Signature
Quality Reviewer

Date



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ELI Accession Number: S3542-0918SPAR **Date of completion:** 09-26-2018

Lot number: 83605-MD

Reference number: OOMDW-120

Description of test article: Oosafe Class IIA Medical Device Disinfectant Wipes

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-248)	97 %	97 %
Control (incubator ELI-068)	97 %	97 %

Summary of observations: All test and control sperm was prepared from the same donor. The incubator ELI-068 (the control sperm) had a 97% forward progressive motility at 24-hours. The incubator ELI-248 (that was cleaned with the test article) had a 97% forward progressive motility at 24-hours.



 Signature
 Study Director

09-27-2018

 Date



 Signature
 Quality Reviewer

09-27-2018

 Date