

Doc.: QC \_4.14.2 Rev. no.: 03 Rev. Date: 11.09.2023







## **Certificate of Analysis**

Product name: Oosafe® 100 mm Dish Product type: Oosafe® Plasticware IVD

Product code: OOPW-HD10
Batch/LOT No.: 08973

Product expiry date: 2028-10

TESTING METHOD	ACCEPTANCE CRITERIA	RESULTS	CONCLUSION	DOCUMENT NO.
Mouse Embryo Assay Test (MEA)	Over 80% embryo development to the expanded blastocyst stage within 96 hours	Passed	Non- embryotoxic	SPAR-3511-0124
Human Sperm Survival Assay (HSSA)	≥75% sperm motility after 24 hours proven	Passed	Stable human sperm motility	S7027-0124SPAR
Limulus Amoebocyte Lysate (LAL)	<0.03 EU/device	Passed	Do not contain endotoxin	E3719-0124SPAR

Quality Management system according to ISO 13485:2016

Sterilized by irradiation according to ISO 11137-1

Sterilization method: E-Beam Sterility assurance level: 10<sup>-6</sup>

## **GOosafe with SparMED!**

Manuela Jagieniak Quality Control Department SparMED ApS

Issue date: 01.02.2024

