

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







Certificate of Analysis

Product name: 100 mm Dish

Product type: Oosafe® Plasticware IVD

Product code: OOPW-HD10
Batch/LOT No.: 09012

Product expiry date: 2029-08

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-4947-0924
Human Sperm Survival Assay (HSSA)	≥75% sperm motility after 24 hours proven	Passed	Stable human sperm motility	S8215-0924SPAR
Limulus Amoebocyte Lysate (LAL)	<0.03 EU/device	Passed	Do not contain endotoxin	E4220-0924SPAR

Quality Management system according to ISO 13485:2016

Sterilized by irradiation according to ISO 11137-1

Sterilization method: E-Beam Sterility assurance level: 10⁻⁶

GOosafe with SparMED!

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SparMED ApS

Issue date: 24.09.2024

