CERTIFICATE OF ANALYSIS

Product: Blastomere Biopsy Pipettes

Catalog #: SBB-20X-20

Lot Number: R11062FE

Expiration Date: 2026-11-25

Sterilization: The products were gamma irradiated at a minimum dose of 26.9 kGy and a maximum dose of 37.1 kGy on Dec. 2, 2023. The validated sterile assurance level is 10^{-6}.

Assays	Specification	Results
Endotoxin Assay (LAL Test)[1]	≤0.5 EU/device	<0.03125 EU/device
Mouse Embryo Assay (MEA)[2]	% expanded to blastocysts	
Control	≥80%	100%
This Lot	≥80%	95%

[1] Utilizes the LAL gel clot assay with a sensitivity of 0.03125EU/mL

[2] For a valid assay, at least 80% of 2-cell stage control embryos should develop to expanded blastocyst within 72 hours. The product is considered non-toxic if ≥80% of the embryos exposed to it develop to expanded and/or hatching blastocysts within 72 hours.

All assays were performed by an independent laboratory.

Approved by: Date: 12/11/2023

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