

PRODUCT: Kitazato OPU Needle

LOT #: S41128

EXPIRY DATE: 2027.10

Year / Month

REF: 329350



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APPROVED BY:

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Quality Control  
2024.12.05

### CERTIFICATE OF ANALYSIS

**Indication for Use:** The Kitazato OPU Needle is intended to puncture into human body and pick up follicular fluid or oocyte from ovarian follicle.

The product has been manufactured by Kitazato Corporation in conformity with requirements of ISO13485 Quality management system. The quality of products was tested and evaluated by quality control procedures.

ASSAY	SPECIFICATION	RESULT
Endotoxin <sup>1</sup>	<20 EU/device (<0.5 EU/ml)	Pass
Mouse Embryo Assay (One Cell) <sup>2</sup>		
-Control	≥ 80%	85.7%
-This Lot	≥ 80%	81.0%

<sup>1</sup> Utilizes a Kinetic Chromogenic Assay with a sensitivity of 0.01 EU/ml.

<sup>2</sup> One cell mouse embryo testing is performed using fresh mouse embryos. Test results indicate the percentage of mouse embryos developing to fully expanded blastocysts after 96 hours.

The product has been sterilized by gamma irradiation or EO and validated to meet sterility assurance level (SAL) 10<sup>-6</sup> in accordance with ISO11137 or ISO11135.