



Kitazato Corporation

<http://www.kitazato.co.jp/>

PRODUCT: ICSI Injection Pipettes

LOT#: 306032  
EXPIRY DATE: 2026-06-25  
Year-Month-Date

REF: 95235  
CODE: MT-INJ-1S50-35

APPROVED BY: Kazumi Shibata  
Quality Control  
2023-07-10

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### CERTIFICATE OF ANALYSIS

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**Indication for Use:** MT-INJ is used for injecting sperm into oocyte.

**Caution:** Federal law restricts this device to sale by or on the order of a physician or practitioner trained in its use.

**Sterilization:** The products were gamma irradiated at a minimum dose of 27.4 kGy and a maximum dose of 37.6 kGy on 6/30/2023. The validated sterile assurance level is  $10^{-6}$ .

ASSAY	SPECIFICATION	RESULT
Endotoxin <sup>1</sup>	$\leq 0.5$ EU/device	<0.03125
MEA (2-cell) <sup>2</sup>		
-Control	$\geq 80\%$	95
-This Lot	$\geq 80\%$	95

<sup>1</sup> Uses the LAL with a sensitivity of 0.03125EU/mL

<sup>2</sup> 2-cell mouse embryo testing is performed using fresh mouse embryos. Test results indicate the percentage of mouse embryos developing to fully expanded blastocysts after 72 hours in culture medium.