



Kitazato Corporation

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

PRODUCT: ICSI Injection Pipettes

LOT#: 403013

EXPIRY DATE: 2027-03-25

Year-Month-Date

REF: 95230

CODE: MT-INJ-2S50-30

APPROVED BY:

Kazumi Shibata  
Quality Control

2024-04-08

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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 28.0 kGy and a maximum dose of 35.6 kGy on 3/30/2024. The validated sterile assurance level is  $10^{-6}$ .

ASSAY	SPECIFICATION	RESULT
Endotoxin <sup>1</sup>	≤ 0.5 EU/device	<0.03125
MEA (2-cell) <sup>2</sup>		
-Control	≥ 80%	86
-This Lot	≥ 80%	86

<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.