



Kitazato Corporation

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

PRODUCT: Partial Zona Dissection Pipettes

LOT#: 011047

EXPIRY DATE: 2023-11-25

Year / Month / Date

REF: 95400

CODE: MT-PZD-30-55

APPROVED BY:

Kazumi Shibata
Quality Assurance

2020-12-18

CERTIFICATE OF ANALYSIS

Indication for Use: MT-PZD is used to create a slit in a part of embryo to enable assisted hatching.

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 26.5 kGy and a maximum dose of 37.7 kGy on 2020-11-27. The validated sterile assurance level is 10^{-6} .

ASSAY	SPECIFICATION	RESULT
Endotoxin ¹	≤ 0.5 EU/device	< 0.03125
MEA (2-cell) ²		
-Control	$\geq 80\%$	100%
-This Lot	$\geq 80\%$	100%

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

² 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.