



Kitazato Corporation

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

PRODUCT: Kitazato ET Catheter

LOT #: S41126

EXPIRY DATE: 2027.10

REF: 223325

Year / Month



APPROVED BY:

Kazumi Shibata
Quality Control
2024.12.05

CERTIFICATE OF ANALYSIS

Indication for Use: The Kitazato ET Catheter is used to place embryo into the uterine cavity through the cervix.

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 ¹	<20 EU/device (<0.5 EU/ml)	Pass
Mouse Embryo Assay (One Cell) ²		
-Control	≥ 80%	95.2%
-This Lot	≥ 80%	100.0%

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

² 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) 10⁻⁶ in accordance with ISO11137 or ISO11135.