KITAZATO®

Kitazato Corporation

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

PRODUCT: Kitazato IUI Catheter

REF: 131182

LOT #: S20208

EXPIRY DATE: 2025.01

Year / Month

(01) 0 4580303 26666 3 (17) 250100 (10) S20208

APPROVED BY: Kazumi Shibata
Quality Control
2022.03.15

CERTIFICATE OF ANALYSIS

Indication for Use: Kitazato IUI Catheter is used for the introduction of washed spermatozoa 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
Human Sperm Survival Assay (HSSA)[2]		
-Control	≥70%	95%
-This Lot	≥70%	90%
Mouse Embryo Assay (One Cell)[3]		
-Control	≥ 80%	100%
-This Lot	≥ 80%	94%

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

[2] Motility at 24-hours using human sperm.

[3] 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.