KITAZATO®
Kitazato Corporation
http://www.kitazato.co.jp/

PRODUCT: Repro Plate

REF: 83016,83017
CODE: Repro Plate-K2(6well)

LOT#: 10629
EXPIRY DATE: 2024-06-29
Year / Month / Date

APPROVED BY: Kazumi Shibata
Quality Control
2021-07-30

CERTIFICATE OF ANALYSIS

Indication for Use: Repro Plate is used to place vitrification or thawing media on the wells.

Storage: Store between 15-30 °C.

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

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
Appearance	Particle Free, No Cracks	Pass
Endotoxin[1]	≤ 0.5 EU/unit (EU/mL)	0.003
Sterility[2]	No Microbial Growth	Pass
MEA (One Cell)[3]		
-Control	≥ 80%	97%
-This Lot	≥ 80%	100%

[1] Bacteria Endotoxins Test, Photometric Techniques in accordance with the USP, EP and JP
[2] Sterility Tests, Direct Inoculation in accordance with the USP, EP and JP
[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 in culture medium.