



CERTIFICATE OF ANALYSIS

PRODUCT DESCRIPTION: EZ-Tip® (Vial) Denudation and Transfer Pipette

LOT NUMBER(S): 209132, 209144, 209145, 209146, 209169, 209170, 209171, 209183, 209184, 209185

EXPIRY DATE: 2022-09-30

INDICATIONS FOR USE: The EZ-Tip pipettes are for denudation, i.e. removing the cumulus from an oocyte prior to Intracytoplasmic sperm injection (ICSI) and in vitro fertilization (IVF), and for handling gametes, embryos and biopsied cells (polar bodies, blastomeres and trophoctoderm) during assisted reproductive techniques (ART).

QUALITY ASSURANCE: Sterilised by gamma irradiation using dose between 25 and 35kGy to a SAL of 10^{-6}

Assay Test. Pass criteria:
1-cell MEA \geq 80% hatched blastocysts at 120 hrs **95% PASS**

Limulus Amoebocyte Lysate Test (LAL). Pass criteria
<20Eu/device. **PASS**

STORAGE CONDITIONS: Temperature 10-30°C
Humidity 20-80% RH
Keep away from direct sunlight (UV)

Quality Assurance:

Date: 22 November 2019

R_xOnly *Caution: US Federal law restricts this device to sale by or on the order of a physician.*

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