

## **CERTIFICATE OF ANALYSIS**

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

**LOT NUMBER(S):** 206562, 206563, 206564, 206565, 206566, 206567, 206568,

206569, 206570

**EXPIRY DATE:** 2022-03-31

**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 trophectoderm) during assisted

reproductive techniques (ART).

**QUALITY ASSURANCE:** Sterilised by gamma irradiation using dose between 25 and

35kGy to a SAL of 10<sup>-6</sup>

Assay Test. Pass criteria:

1-cell MEA ≥ 80% hatched blastocysts at 120 hrs: 100% 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: 30 April 2019

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m Only}$  Caution: US Federal law restricts this device to sale by or on the order of a physician.

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