



## Certificate of Analysis

**Product: DeNoody® Tips**

**Lot Number: 0833**

**Expiration Date: 2025-03**

**Sterilization:**

Product gamma radiated at a minimum to meet Sterility Assurance Level (SAL)  $10^{-6}$  monitored by review of dosimetry report for dose range and quarterly dose audit testing.

**Toxicity Testing (1-Cell MEA):**

The percent of embryos developing to the blastocyst stage were assessed at 96 hours. The MEA is considered acceptable if 80% or more of the embryos exposed to the product reach the blastocyst stage.

<u>Group</u>	<u>Percent blastocysts per one-cell embryo</u>
Control	100%
Product	95%

**Endotoxin Testing:**

Testing is performed using the Limulus Amoebocyte Lysate (LAL) test with units per device less than 20 to be considered acceptable.

Results:

<0.00500 Endotoxin Units (EU) per device.