

CERTIFICATE OF ANALYSIS

LOT NUMBER: 21377VD35, 21378VD40, 21379VD30

PRODUCT NAME: V-DENUPET

REFERENCE: V-DEN-135, V-DEN-140, V-DEN-300

EXPIRY DATE: 04.03.2024

INDICATIONS FOR USE: V-DENUPET is used for the removal of cumulus oocyte complexes (COC) from oocyte prior to Intracytoplasmic Sperm Injection (ICSI) and In Vitro Fertilization (IVF) as well as for the handling of oocytes and embryos during assisted reproductive techniques (ART). V-DENUPET is not intended for biopsy of cells from oocytes or embryos.

STORAGE CONDITIONS: Keep away from sunlight and heat. Store at 15 – 25 °C. Keep dry.

Rx only

TEST	SPECIFICATION	RESULT
GAMMA STERILIZATION	25 - 45 kGy	PASSED
ENDOTOXIN	< 0.05 EU/device	PASSED
MEA 1-cell to expanded blastocyst in 96 h	≥ 80 %	PASSED