

Certificate of Compliance

Certified EN ISO13485: 2016 Date : 2022-01-17

Product Number : L211075 Lot Number : 2022001

Product Name : 75 cm² Cell Culture Flask, Vent Cap, TC, Sterile

Manufacture Date : 2022-01-15 Expiration Date : 2024-12

Materials:

Virgin Polystyrene, meets USP, Class VI requirements for plastic containers.

Sterilization:

Products certified sterile have been validated for the proper E-Beam radiation dosage based on ISO 11137. This validation procedure is verified to insure all sterilized product receives adequate doses of E-Beam. Products meet a minimum Sterility Assurance Level (SAL) of 10⁻⁶.

Non-Pyrogenic:

Products certified non-pyrogenic have been tested and have met the criteria established in the *Pharmacopoeia of China* (Ch.P). The acceptance level for product is ≤ 0.05 EU/ml.

Cell Attachment and Growth Characteristics:

The product has been tested for the attribute of Cell Attachment and Growth utilizing an attachment-dependent mammalian cell line in a serum supplemented media, Attachment and Growth Performance.

RNase/DNase Testing:

The product has been tested and is free of any detectable RNase/DNase contamination.

Quality Control Testing:

Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

Test:	Results:
Visual Attributes:	Pass
Hydrophilic Test:	Pass

