

Certificate of Compliance

Certified EN ISO13485: 2016 Date : 2022-02-11

Product Number : L122900 Lot Number : 2022002

Product Name : 1000 μ l Filter universal Pipette Tips, Filter, Racked

Manufacture Date : 2022-02-09 Expiration Date : 2025-01

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. All lots are sterilized and certified for proper dosage levels. 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.

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:PassHydrophilic Test:Pass



