

Certificate of Compliance

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

Product Number : L191010 Lot Number : 2022001

Product Name : 10ml Serological Pipette, Individually Wrapped, Sterile

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

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.

RNase/DNase Testing:

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

Accurate scale line:

Take the maximum scale volume of water, weigh the water. The weight deviation is not more than 2%.

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 |

