



Certificate of Compliance

LLG-Serological pipettes, Type 1

Sterilization: Products labeled as sterile are irradiated and dosimetrically released upon ISO11137 recommended practices in effect at the time of validation. Sterilization records are reviewed and signed off by qualified personnel for product release. Products labeled sterile meet a minimum requirement of 10^{-6} SAL (Sterility Assurance Level).

Non-Pyrogenic: Products labeled non-pyrogenic have been validated per FDA guidelines on LAL (Limulus Amebocyte Lysate) testing for medical devices and Company guidelines. The acceptance level for product is less than 0.5 EU/ml.

RNase / DNase Testing: Products have been tested and are free of any detectable RNase /DNase contamination.

Cytotoxicity: Products are non-cytotoxic. Finished product is tested for cytotoxicity according to DIN EN ISO 10993.

Haemolicity: Products are non-haemolytic. The end product is tested for haemolicity according to DIN EN ISO 10993.

Accuracy: Each lot has been taken some samples random from total Lot as representative sample for graduation accuracy and they comply with our product specification. The volume of the lowest scale line (label 0.1mL) should be the volume of 0.10g ($\pm 2\%$) purity water, and the volume of last scale line (label 1.0mL) should be the volume of 1.00g ($\pm 2\%$) purity water.

Quality Control Testing: Products are Inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified personnel for product release.

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