

Certificate of Compliance

Shenzhen Medicalet Technology Co., Ltd
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Medicalet hereby certifies that the product identified below is inspected and released according to the requirements of product and quality specifications as maintained in our quality management system.

Product name: Single PCR 0.2 mL tube
Catalog Number: PCR000200
Manufacture Date: 2021-11-21
Expiration Date: 2024-11-22

Sterilization - Product labeled as sterile is irradiated and dosimetrically released upon ISO 11137 recommended practices in effect at the time of validation. Sterilization records are reviewed and signed off by qualified personnel for product release. Medicalet products labeled sterile meet a minimum requirement of 10^{-6} SAL (Sterility Assurance Level).

ATP free-This product has been tested and is free of ATP.

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.

DNase & RNase Free - This product has been tested and is free of any detectable DNase / RNase contamination.

Nucleic Acid - This product has been tested and is free of any detectable Nucleic Acid.

Trace Metal - All material is certified metal-free by material manufacturers before they are turned into production which compliance with US Pharmacopoeia guidelines.

PCR inhibitor - Products are tested via PCR amplification and gel electrophoresis analysis. Samples must show normal amplification to be considered free of PCR inhibitors.

Quality Control Testing - This product has been 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



Quality Manager

