

Quality Assurance Department

November 18, 2022

Dear Sir or Madam,

SKU	LOT#	Manufacture Date	Expiration Date
BX07-5025	15123065	05/31/2021	05/30/2026

Quality Management System - Complies with the current version of the ISO 9001 Standard and the FDA CFR 21 Part 820, current Good Manufacturing Practices (cGMP).

Non-Pyrogenic - Tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing" and USP, "Bacterial Endotoxins Test". The acceptance level for product is ≤ 0.10 EU/ml or ≤ 4 EU/device.

BSE-TSE - This product is deemed animal free by virtue of not containing materials of animal origin and/or complies with the latest revision of EMA/410/01 section 6.4.

USP Class VI Testing - All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter, "Biological reactivity Tests, in Vitro" and Chapter, "Biological Reactivity Tests, in vivo".

DNase/RNase Free - Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-7} Kunitz units/uL for DNase and 10^{-9} Kunitz units/uL for RNase.

Sterility - Product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137, "Sterilization of health care products- Radiation". Products meet a minimum Sterility Assurance Level (SAL) of 10^{-3} .

Volumetric Accuracy - Serological pipets are accurate to $\pm 2\%$ at full volume in compliance with ASTM E934, "Standard Specification for Serological Pipet, Disposable Plastic" and ISO 12771, "Plastics laboratory ware - Disposable serological pipettes".

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:

Visual Inspection - Pass

Packaging Inspection - Pass

Integrity Test - Pass

Best Regards,

Tyler Gittens
Operations Manager