



Cardinal Health
1222 Sherwood Road
Norfolk, NE 68701
402.371.9010 main

cardinalhealth.com

CERTIFICATE OF STERILITY
Blood Collection

To: _____

This is to certify that the product meets all the sterility requirements as specified by Cardinal Health with a sterility assurance level of 10^{-3} . The lot was Gamma radiation sterilized and dosimetric released in accordance with Cardinal Health procedures, the AAMI recommended practice and the Quality System Regulation (QSR). All dosimetry requirements were satisfied, and the dosimetry is traceable to a recognized standard.

Item TT-BCS GRA 16X100 10ML P.O.-F

LOT NO. 135471

HRI No. 8881352796

Sterilization Date: 1/05/2022

The Sterilization Process at Cardinal Health has been established and validated in accordance with ISO 11137, Sterilization of Healthcare Products. All established dosage requirements are traceable to this nationally recognized standard.

Products to be sterilized are separated into product families based on product characteristics. Validation is conducted for each product family. Periodic monitoring is conducted via dose audits and bio-burden testing. The frequency of testing is based on the requirements of ISO 11137.

The Sterility Assurance Level (SAL) for the sterilized products is established in accordance with ANSI/AAMI ST67:2011, Sterilization of health care products-Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled "sterile"

All validation data and individual protocols are maintained at Cardinal Health.

By: Curtis Handler
Sterilization

DATE: 3-3-22

By: Deann M. DeHuling
Quality Assurance

DATE: 21 MAR 2022



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CERTIFICATE OF COMPLIANCE

TO: Tri Tech Forensics

P.O. NO. 90155

LOT NO. 135471

ITEM: 8881352796

QUANTITY: 100,000

DRAWING NO. NA

CUSTOMER PART NO. NA

THIS IS TO CERTIFY THAT THE MATERIAL SHIPPED ON THE NOTED PURCHASE ORDER WAS MADE IN ACCORDANCE TO BLUEPRINTS, SPECIFICATIONS AND PERTINENT REQUIREMENTS AS SPECIFIED BY CARDINALHEALTH. INDIVIDUAL INSPECTION RECORDS ARE AVAILABLE UPON REQUEST FOR SPECIFIC LOTS.

21 MAR 2022

DATE

BY: [Signature]

QUALITY ASSURANCE