



Cardinal Health
1222 Sherwood Road
Norfolk, NE 68701
402.371.9010 main

cardinalhealth.com

CERTIFICATE OF COMPLIANCE

TO: *Tk Tech Forensics
Inc*

P.O. NO. *85645*

LOT NO. *131977*

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.

10 DEC 2021

DATE

BY: *Amanda Erickson Sr Quality Engineer*
QUALITY ASSURANCE MANAGER

FM20013768 Rev 1

Cardinal Health
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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: DRY ADD

LOT NO: 131977

HRI No. 8881352796

Sterilization Date: 11/23/2021

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: Curt D. Hauler
Sterilization

DATE: 11-24-21

By: Amanda E. Wilson
Quality Assurance Manager

DATE: 10 DEC 2021