



FACSIMILE COVER SHEET

TO: Kim Cole Tritsch

FAX NUMBER: 1-910-457-0094

FROM: Covidien

DATE: 9-17-15

TOTAL PAGES: 3

MESSAGE: Cert of Compliance + Cert of Sterility



CERTIFICATE OF COMPLIANCE

TO: *Tri-Tech Forensics Inc*

P.O. NO. *50365*

LOT NO. *524533*

ITEM *8881352796*

QUANTITY *50,000*

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 TYCO/HEALTHCARE/KENDALL. INDIVIDUAL INSPECTION RECORDS ARE AVAILABLE UPON REQUEST FOR SPECIFIC LOTS.

9/17/15

DATE

BY: *Pegley Hanson Sr. OE*

QUALITY ASSURANCE MANAGER

226-08-394

NFZ 52-52-308 REV 03

COVIDIEN

P. O. Box 1169

Norfolk, Nebraska 68702-1169

Tel: (402) 371-9010

Certificate of SterilityTo: *TRI-TECH FORENSICS INC*

This is to certify that the following product meets all the sterility requirements as specified by **COVIDIEN** with a sterility assurance level of 10^{-3} . The lot was gamma radiation sterilized and dosimetric released in accordance with **COVIDIEN** procedures, the AAMI recommended practice, and 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

HRI No. 8881-352796

Lot No. 524533

Sterilization Date 09/09/2015

The Sterilization Process at Covidien 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 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 Covidien.

Sterilization Manager:

William Murphy

Date:

09/09/2015

Quality Assurance:

Debbie Harmon Sr. QE

Date:

9/17/15