CardinalHealth™

Certificate of Analysis & Sterility

This is to certify that the Cardinal Health products listed below are designed, manufactured and inspected in accordance with the applicable US Code of Federal Regulations Title 21 Part 820 "Quality System Regulation"; International Standard EN ISO 13485 "Medical Devices – Quality Management Systems"; and Cardinal Health specifications. Further, the products are manufactured in facilities that are registered with and have undergone applicable Agency and Notified Body audits against these requirements. All required manufacturing records are maintained in the Device History Record and are stored within a controlled documentation system.

Product Description: TT-BCS GRA 16X100 10 P.O.F.
Product Catalog Number: 8881352796
Lot/Serial Number: 302362
Date of Manufacture: 12/7/2022
Expiration Date: 11/30/2024

Product Quality Assurance

Each lot (representative production samples) or serialized product is inspected and/or tested to assure compliance to manufacturing specifications. Results of the testing are included in the table below:

Lot/Serial Number	Test Type	Acceptance Criteria	Results
302362	Functional Testing	Product must meet applicable functional testing requirements	Meets Specifications
	Visual Inspection	Product must meet applicable visual testing requirements, including labeling review	Meets Specifications

Sterility Assurance

Method of Sterilization: Sterile

This certifies that products labeled as sterile have been processed in a validated sterilization cycle which meets the current standards and recommended published practices (ANSI/AAMI/ISO); sterilization records have been reviewed to ensure compliance with sterility specifications.

Cardinal Health
Mia Proli, Director Global QMS, Medical Segment
Date of Issuance: 5/9/2023

Note: On July 29, 2017 Cardinal Health completed its acquisition of the Covidien Patient Recovery business previously held within Medtronic's Minimally Invasive Therapies Group (MITG).

TRITECHFORENSICS
identify. collect. preserve.

TUG10 OEM Statement

The Tri-Tech Forensics, Inc. (TTF) gray stoppered 10ml blood tubes, product number TUG10 are made under TTF FDA 510(K) number K922342. These tubes are privately labeled and manufactured by Cardinal Health solely for Tri-Tech Forensics and are Cardinal Health product number 8881352796.

Tube Specifications
10ml – 16x100 mm
Potassium Oxalate = 15.0 - 26.0 mg/tube
Sodium Fluoride = 88.0 – 112.0 mg/tube

Sincerely

Eric A. Barton

Eric Barton
Vice President

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