COVIDIEN

CERTIFICATE OF ANALYSIS/CONFORMANCE

This is to certify that the product(s) listed below were manufactured and inspected in accordance with FDA and ISO 13485 Quality System Requirements and Kendall specifications, and that the subject product(s) comply with all requirements. Further, the devices are listed with the US FDA (Food and Drug Administration), and are manufactured at a facility which is registered with the US FDA. All original records are maintained at the manufacturing facility

Product: *TT-BCS GRA 16 X 100 10ML P.O.-F*

Item Code: 8881352796

Lot Number: 423226

Manufacture Date: 8/13/14-8/14/14

Expiration Date: *2016-07*

Tested For	Acceptance Range	Results	Reference
Draw Gauge Height	Min 69mm/Max 73mm	*Min 70mm/Max 72mm*	*FS10015185*
Powder Weight Potassium Oxalate	Min 0.0150 g/tube Max 0.0260 g/tube	Min 0.0150 g/tube Max 0.0242 g/tube	*FS10015185*
Powder Weight Sodium Fluoride	Min 0.0880 g/tube Max 0.1120 g/tube	Min 0.0888 g/tube Max 0.1074 g/tube	*FS10015185*
Stopper Removal	Min 4.0 lbs.	Min 6.78 lbs.	GS10001670
Assay Pot Ox	Spec. 15.0-26.0 mg/tube	21.58 – 22.18 mg/tube	*FS10015185*
Assay Sod Fl	Spec. 88.0-112.0mg/tube	93.5-100.4 mg/tube	*FS10015185*

Sterilization:

☐ **Non-Sterile** *Method of sterilization (Please say "Non-Sterile" if applicable)*

☒ **Sterile** - This certifies that sterilization records for the product(s) listed below have been reviewed and found to be in compliance with the current Kendall requirements for sterility. These products have been processed in a validated sterilization cycle which meets the current standards and recommended practices published by the Association for the Advancement of Medical Instrumentation (ANSI/AAMI/ISO). Further, these products meet the AAMI/ANSI/ISO standards for ETO residuals.

Lesley Hanson — 10/3/16

Lesley Hanson
Senior Quality Engineer
Quality Assurance

Date