

## Certificate of Compliance

Product description: Greiner VACUETTE® Urine Collection Products  
Greiner Product No. : 453080  
Lot No.: F1510374  
Expiry date: March 2017

We hereby certify that our products have been manufactured under controlled conditions, according to:

- ISO 9001:2000 "Quality Management Systems – Requirements"
- ISO 13485:2003 "Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes"
- 21 CFR part 820 GMP – Good Manufacturing Practice

Sterile products have been subjected to electronic beam irradiation or gamma irradiation according to:

- ANSI, ISO 11137 "Sterilization of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilization".

The testing procedures are:

- 1) Incoming inspection of raw materials,
- 2) In process control of semi-finished products,
- 3) Finished goods control,
- 4) Microbiological and sterility tests,
- 5) Visual inspection of finished products (labeling, packaging).

The test results are kept for at least 5 years.

March 8, 2016  
Date



John Dewly  
On behalf of Carolyn Guthrie  
Quality Manager