

## Certificate of Quality

**REF**

456024P

**LOT**

B16103AN

Product description: VACUETTE® TUBE 4.5 ml K2E K2EDTA Separator  
13x100 lavender cap-yellow ring, non-ridged, USA

Following inspections were carried out and passed:

|          |                                     |        |
|----------|-------------------------------------|--------|
| visual   | <input checked="" type="checkbox"/> | passed |
| physical | <input checked="" type="checkbox"/> | passed |
| chemical | <input checked="" type="checkbox"/> | passed |

We hereby certify that our products were manufactured and tested in accordance with the following international standards and meet the required specifications:

98/79/EC "Directive 98/79/EC of the European Parliament and of the Council of 27th Oct 1998 on in vitro diagnostic medical devices"

ISO 6710 "Single-use containers for venous blood specimen collection"

ISO 11137 "Sterilization of health care products - Radiation"

EN 14820 "Single-use containers for human venous blood specimen collection"

ISO 9001 "Quality management systems - Requirements"

ISO 13485 "Medical devices - Quality management systems - Requirements for regulatory purposes"



2018-04-05

**STERILE**

SAL 10<sup>-6</sup>

This certificate is valid for the above mentioned lot and has no validity if no lot number is provided.



Certificate creation date: 2017-01-12

[www.gbo.com](http://www.gbo.com)