

Certificate of Quality

REF

456002

LOT

B16063FP

Product description: VACUETTE® TUBE 6 ml K2E K2EDTA

13x100 lavender cap-black ring, non-ridged, USA

Following inspections were carried out and passed:

 $\begin{array}{c|cccc} \text{visual} & & & \text{passed} \\ \text{physical} & & & & \text{passed} \\ \text{chemical} & & & & \text{passed} \\ \end{array}$

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"

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2017-12-13

STERILE

SAL 10⁻⁶

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



Certificate creation date: 2016-09-16

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