

Certificate of Quality

REF

455040P

LOT

B16113MH

Product description: VACUETTE® TUBE 8 ml K2E K2EDTA Separator
16x100 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"



2018-05-09

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: 2017-04-11

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